

AWARD NUMBER: W81XWH-18-1-0083

TITLE: Addressing Neuromuscular Deficits for Improved Outcomes in Ankle
Rehabilitation

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REPORT DATE: 14 MAR 20

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 13-04-2019		2. REPORT TYPE Annual		3. DATES COVERED 15 MAR 19- 14 MAR 20	
4. TITLE AND SUBTITLE Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation				5a. CONTRACT NUMBER W81XWH-18-1-0083	
				5b. GRANT NUMBER DM170430	
				5c. PROGRAM ELEMENT NUMBER Blank	
6. AUTHOR(S) Gribble, Phillip; Golden, Andrew; Wikstrom, Erik; Heebner Nick; Hoch, Matt; Johnson, Nathan; Powell, David E-Mail: phillip.gribble@uky.edu				5d. PROJECT NUMBER Blank	
				5e. TASK NUMBER Blank	
				5f. WORK UNIT NUMBER Blank	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Kentucky 900 South Limestone Lexington, KY 40506				8. PERFORMING ORGANIZATION REPORT NUMBER Blank	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S) Blank	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S) Blank	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES Blank					
14. ABSTRACT The primary purpose of this study will seek to identify lateral ankle sprain (LAS) patients that do not respond to physical rehabilitation under a traditional medical model and who subsequently develop chronic ankle instability (CAI). The proposed study will evaluate established clinical outcomes along with innovative measures of brain and spinal cord function and ankle joint stability during a one-year follow-up after injury. Our hypothesis is that patients who develop CAI within one-year after injury will demonstrate poorer clinical outcomes, larger alterations in innovative measures of brain and spinal cord function, and early ankle joint cartilage turnover compared to the LAS patients that develop into Copers. The secondary purpose of this study will be to transition the results to methods that can be applied in multiple rehabilitation settings across civilian and military treatment facilities. We will determine which clinical measures are most related to the advanced brain and spinal cord measures.					
15. SUBJECT TERMS Lateral ankle sprain; sensorimotor; musculoskeletal treatment; physical readiness					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified		19b. TELEPHONE NUMBER (include area code) Blank

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1. INTRODUCTION

Lateral ankle sprains (LAS) are the most commonly reported injury in military and civilian populations. Up to 70% of those who sustain a LAS will develop chronic ankle instability (CAI), with re-injury and persistent functional disability. In the military, those who suffer from CAI typically have less service time prior to discharge as a function of the physical limitations imposed by the ankle injury. Many with LAS history will develop ankle joint degeneration, marked by changes in its cartilage and has been shown even in young adults. This suggests the need to determine why some individuals follow the cascade of events of sustaining a LAS, to developing CAI, to developing osteoarthritis. A strong contribution to CAI appears to be related to lingering changes in the structure of the brain, which impacts efficient cortical regulation of overall body control. Standard of care (SOC) for LAS typically consists of symptom management or activity modification and a recovery protocol to improve motion and strength of the ankle but does not typically address central nervous system (CNS) deficiencies. However, the high rate of CAI suggests the SOC may not be sufficient. The purpose of this study is to compare the success of an innovative sensorimotor ankle rehabilitation training (SMART) protocol to mitigate the CNS deficiencies that likely lead to CAI and ankle joint degeneration. Ultimately, this study will utilize an integrative medicine approach (brain/spinal cord influence on neuromusculoskeletal injury rehabilitation) to address a common issue (why some people respond to treatment and are able to return to normal activities, while others do not) associated with LAS. This will improve the ability to disrupt the cascading transition from LAS to potential joint degeneration. This innovative and integrative approach to rehabilitation will significantly impact the short and long-term health and well-being of those affected by LAS.

2. KEYWORDS

Lateral ankle sprain; sensorimotor; musculoskeletal treatment; physical readiness

3. ACCOMPLISHMENTS

Major Goals and Accomplishments

SOW Goals	Timeline	Achieved
Major Task 1: Administrative Objectives	Months	Y/N
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	Y
Finalize consent form & human subjects protocol	1-3	Y
Coordinate with Sites for IRB protocol submission	1-3	Y
Coordinate with Sites for University of Kentucky IRB review	1-6	Y
Coordinate with Sites for University of North Carolina IRB review	1-6	Y
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	Y
<i>Milestone Achieved: Local IRB approval at UK, UNC and BAMC</i>	3	Y
<i>Milestone Achieved: HRPO approval for all protocols and local IRB approval through University of Kentucky.</i>	18	Y
Coordinate with Sites for job descriptions design	1-4	Y
Advertise and interview for project related staff	1-5	Y
Coordinate for space allocation for new staff	1-6	Y
Coordinate with Sites for Independent Evaluators hiring and trainings	5-11	Y
Coordinate with Sites for training Independent Evaluators until 100% concordance	8-11	Y
<i>Milestone Achieved: Research staff trained</i>	8-11	Y
Quarterly Reports to USAMRMC	Quarterly	Y
Annual Reports to USAMRMC	Annually	Y
Major Task 2: Technical Objectives		
Finalize assessment measurements	1-4	Y
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-6	Y
<i>Milestone Achieved: 1st participant consented, screened and enrolled at each site</i>	7-8	Y
Subject recruitment. Participants complete follow-up assessments upon completion of physical therapy for acute LAS	7-32	Y
Complete follow-up assessments 6 months after completion of physical therapy	13-38	N
Complete follow-up assessments 12 months after completion of physical therapy	19-44	N
Milestone Achieved: All participants enrolled and follow-up assessments completed	44	N
Data Analysis: Clinical, CNS, and MRI outcomes	7-48	N
Data interpretation and dissemination	36-48	N
<i>Milestone Achieved: Report findings from completed assessments</i>	36-48	N
Coordinate with Sites for annual IRB report for continuing review	Annually	Y
Submit amendments, adverse events and protocol deviations as needed	As Needed	N

Summary

Human Subject Protections

Summary from Year 1: Approval of human subject protections was initiated in MAY 18 between the IRB offices of UK, UNC and WBAMC. Reliance agreements were discussed to recognize UK as the primary site for the study for all IRB offices. Initial approval of the study was obtained by the UK IRB on 10 MAY 18. Initial HRPO documents were submitted 4 JUN 18. Notification of receipt and initiation of review was received from Brittane Foy at MPMC on 11 JUN 18. Initial HRPO Administrative Review was received 2 AUG 18. Responses and supporting documents were returned to Brittane Foy 10 AUG 18. Second HRPO Administrative Review was received 5 AUG 18. Much of the 2nd Administrative Review required coordination and revisions to documents relative to WBAMC. From NOV 18 to JAN 19, Dr. Gribble coordinated with Larissa Schmearsal, WBAMC Human Protections Administrator, to address requested revisions, as well as begin preparing CLAR materials to be submitted from WBAMC after HRPO review. By the end of Year 1 period (15 MAR 19), HRPO approval was not yet received.

During Year 2, efforts continued to obtain HRPO approval. On 4 APR 19, the 3rd HRPO Administrative Review was received and a response was submitted on 16 APR 19. After follow-ups were sent, a response was received 14 MAY 19 from Dr. Natalie Klein that Ms. Brittane Foy had left HRPO and the study review was re-assigned to Ms. Karen Eaton. A 4th HRPO Administrative Review was received 17 MAY 19, and a response was submitted 23 MAY 19. Initial approval from HRPO was received 5 JUL 19.

Per suggestions from IRB officers at UK, WBAMC and HRPO during the Administrative Review process, it was suggested that we delay making any known addendums to the initially submitted protocol until initial approval was obtained. During JUL and AUG 19, Dr. Gribble worked with these personnel, particularly Dr. Schmearsal at WBAMC, to prepare substantive changes to the protocol, including a site-PI change at WBAMC (CPT Golden) and modifications to the shared consent form. The Amendment Approval was received 6 SEP 19.

Enrollment commenced in OCT 19. In JAN 20 during the UK IRB annual review, an oversight was discovered in the previously approved consent form related to HIPAA language that was not allowable by UK. Dr. Gribble worked with UK IRB, Dr. Schmearsal and HRPO personnel during JAN 20 to modify the consent form to remove the HIPAA language and an Amendment Request was submitted 1 FEB 20, and approval of this amendment was received 11 MAR 20. Previously enrolled participants at all sites were re-consented with the new consent form.

The HRPO Continuation Review was submitted in conjunction with the Amendment approval described above and was approved 11 MAR 20.

Personnel

Ms. Meaghan Beck left her position at the University of Kentucky effective 3 JUN 19. Dr. John Abt left his position at the University of Kentucky effective 1 JAN 20. Duties of these two personnel were assumed by Dr. Gribble and tasks as needed were distributed to other study personnel.

Dr. Kyle Kosik was added to the funded personnel of the study as a post-doctoral research fellow in the fall 19.

On 29 JUL 19, MAJ Helton began transitioning out of WBAMC for a transfer effective 26 AUG 19 and was replaced at WBAMC by CPT Andrew Golden. Subsequently, CPT Golden assumed the role of Site-PI for WBAMC for the project on 29 JUL 19. Dr. Gribble worked with MAJ Helton and CPT Golden JUL-AUG 19 for the transfer of this position within the study.

Equipment Acquisition

No equipment acquisitions took place in Year 2 of the project.

SOP Procedures and Site Visit

Dr. Johnson and Dr. Powell (UK) communicated with MRI technicians and personnel at UNC and WBAMC to coordinate and verify data collection procedures for the imaging outcomes of the study. This has been facilitated by Dr. Wikstrom (UNC) and Ms. Roberts, MAJ Helton and CPT Golden (WBAMC).

Site visits by Dr. Gribble to WBAMC and UNC were discussed with site personnel as the initial subject enrollment commenced, and tentative plans were made for spring 20. Plans were suspended when COVID-19 related restrictions emerged.

Opportunities for Training and Professional Development

Nothing to Report

Dissemination of Results to Communities of Interest

Nothing to Report

Plan for Next Reporting Period

As of this report, 8 participants have been enrolled across the three sites (UK: 4, UNC: 2; WBAMC: 2). Due to an 18-month delay in HRPO approval, our goal of 50% enrollment and completion of interventions by the end of CY 19 had to be modified. We will continue to aggressively recruit in an effort to keep on track for study completion of enrollment and 1year follow-ups by the end of CY 21.

4. IMPACT

Impact on Principal Disciplines of the Project

Nothing to Report

Impact on Other Disciplines

Nothing to Report

Impact on Technology Transfer

Nothing to Report

Impact on Society Beyond Science and Technology

Nothing to Report

5. CHANGES/PROBLEMS

Changes in Approach and Rationale

Nothing to Report

Actual or Anticipated Problems or Delays

We had a delay in the start of our enrollment while waiting for initial HRPO approval and amendments of our study protocols. A detailed summary of the timeline seeking HRPO approval is provided in section 3 and copies of communications and document submissions are found in the Appendices.

We anticipate that in Year 3, there will be delays in additional enrollment due to the COVID-19 outbreak that began to affect the United States in FEB 20. We have continued with the project and enrolled participants through the reporting period in MAR 20. We have begun to explore methods to attempt to maintain new enrollments and grant activities as likely restrictions due to the COVID-19 outbreak are enforced.

Changes in Expenditures

Nothing to Report

Changes in Use or Care of Human Subjects

Nothing to Report

6. PRODUCTS, INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES**Publications, Conference Papers, and Presentations**

Nothing to Report

Websites or Other Internet Sites

Nothing to Report

Manuscripts

Nothing to Report

Technologies or Techniques

Nothing to Report

Inventions, Patent Applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Individuals Working on Project	Source of Compensation
Phillip Gribble	No Change
Nicholas Heebner	No Change
Matthew Hoch	No Change
Nathan Johnson	No Change
David Powell	No Change
Katherine Bain	No Change
Kyle Kosik	No Change
Erik Wikstrom	No Change
Katie Roberts	No Change

Changes in Active Support of PD/PI or Senior/Key Personnel

Nothing to Report

Other Involved Partner Organizations

Dr. Gribble, MAJ Helton, CPT Helton and Ms. Roberts at WBAMC have been working together extensively with Ms. Larissa Schmersal, WBAMC Human Protections Administrator, throughout the process of obtaining HRPO approvals from MRMC.

8. SPECIAL REPORTING REQUIREMENTS

Collaborative Awards

Nothing to Report

Quad Chart

Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation

Program: Joint Program Committee 8/Clinical & Rehabilitative Medicine Research Program

Funding Opportunity Number: W81XWH-17-DMRDP-CRMRP-NMSIRRA



PI: Gribble, Phillip A

Org: University of Kentucky

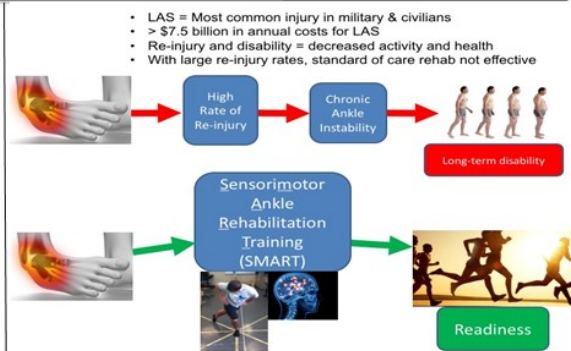
Award Amount: \$2.5 million

Study/Product Aim(s)

- **Aim #1:** Determine if a novel sensorimotor ankle rehabilitation training (SMART) protocol improves clinical outcomes (patient-reported function and quality of life, lateral ankle sprain (LAS) re-injury rates, postural control, ankle ROM) and ankle joint integrity (articular cartilage turnover) in LAS patients.
- **Aim #2:** Determine if SMART improves innovative measures of central nervous system (CNS) function (corticospinal excitability and brain white matter integrity) in LAS patients.
- **Aim #3:** Delineate the association between explanatory mechanistic measures (corticospinal excitability and brain white matter integrity) and the hypothesized improvements in clinical and ankle joint integrity in LAS patients receiving SMART.

Approach

We will compare SMART protocol against a standard of care protocol to demonstrate successful 1-year outcomes and lower rates of re-injury and disability. We expect improvement in clinical outcomes, CNS function and joint health, improving health in LAS patients, bringing translational application to military personnel.



Timeline and Cost

Activities	CY	18	19	20	21
Regulatory/human subjects					
Participant enrollment, intervention implementation, post-testing					
1- year follow up testing					
Analysis of clinical, sensorimotor and MRI outcomes					
Estimated Budget (\$K)		\$745	\$565	\$580	\$610

Goals/Milestones

CY19 Goal – 25% enrollment

☐ Post-testing complete on 25% of sample

☐ Analysis of outcomes begins

CY20 Goals – 100% enrollment

☐ Post-testing complete on 100% of sample

☐ 1 year follow up complete on 50% of sample

☐ Analysis of outcomes continues

CY21 Goal – Completion of follow-up and outcomes analysis

☐ 1 year follow up complete on 100% of sample

☐ Analysis of outcomes at all time points of 100% of sample

CY22 Goal

☐ Dissemination of data

APPENDICES

- A. Email – 16 APR 19 from Dr. Gribble to Ms. Brittane Foy Re: Response to 3rd HRPO Administrative Review (page 14)
- B. Document – Response to 3rd HRPO Administrative review submission packet (page 16)
- C. Email - 14 May 19 from Dr. Natalie Klein to Dr. Gribble Re: change in HRPO review personnel (page 274)
- D. Email - 23 MAY 19 from Dr. Gribble to Ms. Karen Eaton Re: Response to 4th HRPO Administrative Review (page 276)
- E. Document: Response to 4th HRPO Administrative review submission packet (page 278)
- F. Email: 6 SEP 19 from Ms. Nancy Englar to Dr. Gribble Re: HRPO approval of submitted Amendment (page 351)
- G. Email: 1 FEB 20 from Dr. Gribble to Ms. Nancy Englar Re: UK IRB continuation review approval and substantive change for HRPO approval request (page 354)
- H. Document: UK IRB continuation review approval packet submitted to HRPO for request of substantive change approval (page 356)
- I. Email: 11 MAR 20 from Ms. Kimberly Odam to Dr. Gribble Re: HRPO approval of substantive change request (page 372)

Subject: RE: A-20657.1a, A-20657.1b, and A-20657.1c, Third Administrative Review (Proposal Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Tuesday, April 16, 2019 at 1:43:07 PM Eastern Daylight Time

From: Gribble, Phillip A.

To: Foy, Brittane S CTR USARMY MEDCOM USAMRMC (USA), Wikstrom, Erik A.

CC: Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US), Office of Sponsored Projects Administration, Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (US), Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (US), Brown, Joe R., Schmursal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (US), Klein, Natalie M CIV USARMY MEDCOM USAMRMC (US), Roberson, Tykisha L CTR USARMY MEDCOM USAMRMC (USA), Carter, Kim

Attachments: W81XWH-18-1-0083_Responses to 3rd Admin Review Recommendations.pdf, image001.png, W81XWH-18-1-0083 HRPO Protocol Submission Form v 4.0.pdf

Good afternoon Brittane,

Please find attached the responses to the 3rd Administrative Review of our awarded grant. Additionally, I have attached the updated and revised HRPO protocol submission form packet, which reflects updates and revisions to the Protocol and Consent form as well as requested supporting documentation. Many of the requested items for clarification, documents and changes pertained to site specific items at William Beaumont Army Medical Center (WBAMC). Subsequently, we have been working with Larissa Schmursal, Human Protections Administrator, at WBAMC to revise and update the documents to address these current revisions, but also to work to coordinate the work needed to prepare the CLAR submission following HRPO approval.

I hope that we have addressed the requests thoroughly, but please let me know if more attention is needed. I will continue to work with Ms. Schmursal at WBAMC as needed to address any item that is still unsatisfactory.

Thank you,
Phillip



Phillip Gribble, PhD, ATC, FNATA
Professor, Director Division of Athletic Training
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206C Charles T. Wethington Building
Lexington, KY 40536-0200
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phillip.gribble@uky.edu

-----Original Message-----

From: Foy, Brittane S CTR USARMY MEDCOM USAMRMC (USA) <brittane.s.foy.ctr@mail.mil>
Sent: Friday, April 5, 2019 7:55 AM
To: Gribble, Phillip A. <phillip.gribble@uky.edu>; Wikstrom, Erik A. <ewikstro@email.unc.edu>
Cc: Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US) <jodi.h.bennett.civ@mail.mil>;
kcarter.1@uky.edu; Office of Sponsored Projects Administration <OSPA@uky.edu>; Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (US) <christopher.l.meinberg.civ@mail.mil>; Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (US) <darius.j.ghannadian.civ@mail.mil>; Brown, Joe R. <joe.brown@uky.edu>; Schmursal, Larissa A CIV USARMY MEDCOM WBAMC (USA) <larissa.a.schmursal.civ@mail.mil>; Odam,

Kimberly L CIV USARMY MEDCOM USAMRMC (US) <kimberly.l.odam.civ@mail.mil>; Klein, Natalie M CIV USARMY MEDCOM USAMRMC (US) <natalie.m.klein.civ@mail.mil>; Roberson, Tykisha L CTR USARMY MEDCOM USAMRMC (USA) <tykisha.l.roberson.ctr@mail.mil>; Foy, Brittane S CTR USARMY MEDCOM USAMRMC (USA) <brittane.s.foy.ctr@mail.mil>

Subject: A-20657.1a, A-20657.1b, and A-20657.1c, Third Administrative Review (Proposal Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Third Administrative Review of Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by Phillip Gribble, PhD, University of Kentucky, Lexington, Kentucky, Proposal Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Numbers A-20657.1a (UK site), A-20657.1b (UNC site), and A-20657.1c (WBAMC site)

Dear Dr. Phillip Gribble,

The research protocol and supportive documents for your research project at the University of Kentucky (UK) was received by the US Army Medical Research and Materiel Command on 4 June 2018, have been reviewed for compliance with human subjects' protection requirements. Below you will find a list of requests for clarification, documents and changes to protocol that need to be addressed to continue the review process in our office.

Modifications to the protocol will require review by the UK Institutional Review Board (IRB), however, I would suggest that you wait until further along in our review process before submitting any amendments to your local IRB so as to limit your visits to same.

Recommendations.

A. Required Information/Documents.

1. Provide the site specific documents for each site or complete and return the attached site-specific addendum document.
2. Provide the human subjects training for Dr. Erik Wikstrom and CPT Gary Helton.
3. Provide the University College Dublin review for Dr. Delahunt's analysis of de-identified data. If not available I strongly recommend adding his role and responsibilities to the protocol for HRPO review.
4. Provide the Institutional Agreement for IRB Review (IAIR) with the University of Kentucky (UK) and William Beaumont Army Medical Center (WBAMC).
5. Clarify whether or not the research performed at the UK and/or UNC sites are under a HIPAA covered entity.
6. Provide the HIPAA authorization or documentation for a waiver of HIPAA authorization for WBAMC is a covered entity as well as UK and UNC to the extent these institutions are covered entities.
7. Provide the contact information for CPT Gary Helton.

B. Revisions to be made to the protocol (Version/Date ____).

1. Provide the WBAMC specific protocols or update the current protocol to cover additional requirements for the informed consent form at DoD sites, such as military personnel may receive compensation if they are off duty or on leave during the time they are participating in the protocol.

C. Revisions to be made to the consent form (IRB Approved 8/9/2018).

1. Clarify whether or not subjects may withdraw at all the research sites. Currently, the informed consent form (ICF) mentions withdrawal specific to WBAMC.

2. Provide the site specific ICFs.

- a. Ensure the WBAMC ICF includes language appropriate for research related injury.

- b. Ensure the ICFs list the local Principal Investigator (PI) and their contact information.

3. Work with Larissa to ensure local requirements for compensation of military personnel are met

4. Consider adding language regarding randomization to the informed consent.

Please ensure CPT Gary Helton coordinates the WBAMC local review with the input of Dr. Schmersal.

It is requested that you respond to the above clarifications, and submit your responses back to the USAMRMC ORP HRPO for additional review. If all documents are in order and all clarifications have been provided, you will be asked to submit the revised documents back to the UK IRB.

You are reminded not to initiate the study until you receive approval from this office.

As you consider the revisions, modify the documents, and prepare for further review of the research protocol, please do not hesitate to contact me at any time.

Regards,

Brittanë Foy

Human Subjects Protection Scientist

General Dynamics Health Solutions (GDHS) Human Research Protection Office (HRPO) Office of Research Protections (ORP) U.S. Army Medical Research & Material Command (USAMRMC) Fort Detrick, Maryland

Email: Brittane.S.Foy.CTR@MAIL.MIL

Phone: 301-619-2286 or DSN 343-2286

Fax: 301-619-7803 or DSN 343-7803

Mailing Address:

Commanding General

U.S. Army Medical Research and Material Command

ATTN: MCMR-RPH/Brittane Foy

810 Schreider Street

Frederick, Maryland 21702-5012

CLASSIFICATION: UNCLASSIFIED

Recommendations.

A. Required Information/Documents.

1. Provide the site specific documents for each site or complete and return the attached site-specific addendum document.

We have been working together with Larissa Schmiersal, Human Protections Administrator, at WBAMC to complete these documents, including the updated consent forms and Protocol, to ensure that documents are in compliance for utilization at all sites. Copies of these are included in the attached document.

2. Provide the human subjects training for Dr. Erik Wikstrom and CPT Gary Helton.

These are found in the attached packet on page 125 (Helton) and page 132 (Wikstrom).

2. Provide the University College Dublin review for Dr. Delahunt's analysis of de-identified data. If not available I strongly recommend adding his role and responsibilities to the protocol for HRPO review.

As a consultant, Dr. Delahunt will only come in contact with de-identified data for assistance in interpretation of analyzed data. As suggested, Dr. Delahunt's roles and responsibilities described in the attached protocol on page 3.

4. Provide the Institutional Agreement for IRB Review (IAIR) with the University of Kentucky (UK) and William Beaumont Army Medical Center (WBAMC).

This is provided in the document package on page 57-64

5. Clarify whether or not the research performed at the UK and/or UNC sites are under a HIPAA covered entity.

We have consulted with Larissa Schmiersal at WBAMC regarding HIPPA covered entity distinction. This has been revised under her advisement and review is reflected in the included documents.

6. Provide the HIPAA authorization or documentation for a waiver of HIPAA authorization for WBAMC is a covered entity as well as UK and UNC to the extent these institutions are covered entities.

We have consulted with Larissa Schmiersal at WBAMC regarding HIPPA covered entity distinction. This has been revised under her advisement and review and is reflected in the included protocol documents.

7. Provide the contact information for CPT Gary Helton.

MAJ Gary Helton, PT, DSc, OCS, CSCS

Director, Army-Baylor University Doctoral Physical Therapy Internship Mendoza Soldier Family Care Clinic

11335 SSG Sims Street

Fort Bliss, TX 79918

915-742-1511

gary.l.helton8.mil@mail.mil

B. Revisions to be made to the protocol (Version/Date ____).

1. Provide the WBAMC specific protocols or update the current protocol to cover additional requirements for the informed consent form at DoD sites, such as military personnel may receive compensation if they are off duty or on leave during the time they are participating in the protocol. **We have consulted with Larissa Schmiersal and the document now reflects the correct information relative to compensation for military personnel.**

C. Revisions to be made to the consent form (IRB Approved 8/9/2018).

1. Clarify whether or not subjects may withdraw at all the research sites. Currently, the informed consent form (ICF) mentions withdrawal specific to WBAMC.

We have clarified that subjects may withdraw at all research sites.

2. Provide the site specific ICFs.

a. Ensure the WBAMC ICF includes language appropriate for research related injury.

We have consulted with Larissa Schmiersal and this language is reflected in the consent form.

b. Ensure the ICFs list the local Principal Investigator (PI) and their contact information.

We have consulted with Larissa Schmiersal and this information is reflected in the consent form.

3. Work with Larissa to ensure local requirements for compensation of military personnel are met **We have consulted with Larissa Schmiersal and the document now reflects the correct information relative to compensation for military personnel.**

4. Consider adding language regarding randomization to the informed consent. **We discussed this with Larissa Schmiersal at WBAMC and also presented this as a potential modification request to the University of Kentucky IRB. The UK IRB determined that it was acceptable to withhold a description of random allocation to the two intervention groups in the study. This preserves blinding in the study, while still informing participants that they will be enrolled into a supervised rehabilitation protocol. Documentation of this review and approval is provided in the packet on page 66-69.**

**US Army Medical Research and Materiel Command
Office of Research Protections**

**Human Research Protocol Submission Form for Headquarters Level
Administrative Review of Extramural* Research**

PURPOSE: All United States Army Medical Research and Materiel Command (USAMRMC) supported research involving humans, human data, human specimens, or cadavers must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the Office of Research Protections (ORP).

INSTRUCTIONS: Enter protocol information in the spaces provided to complete all appropriate sections of the form. Submit this completed form and the protocol documents to the electronic mailbox at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil. An incomplete submission will result in delay in review. This form is divided into three sections: Section A requests protocol information; Section B is a checklist of documents to be submitted to the ORP, and Section C lists the reporting requirements and responsibilities of the Principal Investigator to the ORP Human Research Protection Office (HRPO).

NOTE: Complete a Protocol Submission Form for each human subjects research protocol performed under the DoD/USAMRMC proposal. For example, if your research proposal includes three separate research protocols, submit one completed Protocol Submission Form for each protocol.

For multi-site studies, please complete this form for the Master Protocol only at this time. Identify all participating sites in the protocol. Additional site-specific documents will be requested at a later date.

For questions regarding ORP HRPO human research protocol review requirements or assistance in completing this form, leave a message at 301-619-2165 or usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil and a staff member will contact you.

NOTE: You are reminded not to initiate the study until you receive approval from the ORP HRPO.

** The ORP HRPO defines intramural research as research conducted by USAMRMC laboratories. All other USAMRMC managed research is considered extramural*

Protocol Submission Form

Section A: Protocol Information. The purpose of this section is to obtain administrative details for each protocol submitted to ORP HRPO. The information is required for the ORP to review and approve each research protocol and performance and collaborative site(s) associated with the study.

1. Protocol Title: Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation

2. Associated DoD/USAMRMC Proposal:

Proposal Log # DM170430 Award # W81XWH-17-DMRDP-CRMRP-NMSIRRA

3. HRPO Log Number (If known): A-20657

4. Funded Activities. Which activities in the protocol are funded by the DoD/USAMRMC?

- a. ☒ All Protocol Activities
OR
b. ☐ Select activities (Describe in detail):

5. Key Study Personnel. (If more space is needed, attach additional page(s) to the end of this form)

a. List all key study personnel below, including the Principal Investigator (PI) and other study team members, along with a brief statement of their study role(s) and responsibilities. Note: Key study personnel are persons who have direct contact with subjects or their identifiable data or specimens.

Key Study Personnel (Include Degrees and Credentials)	Study Roles and Responsibilities	Primary Point of Contact (Select one)
Name: Phillip Gribble, PhD, ATC, FNATA Affiliated Institution: University of Kentucky	Study Role(s): PI Responsibilities: overall project management; oversee enrollment at UK, data collection, interventions, and data analysis, interpretation and dissemination of data	☒
Name: Erik Wikstrom, PhD, ATC Affiliated Institution: University of North Carolina	Study Role(s): Site PI Responsibilities: oversee enrollment, data collection, interventions at UNC, and data analysis, interpretation and dissemination of data	☐
Name: Gary Helton, CPT, PT Affiliated Institution: Beaumont Army Medical Center	Study Role(s): Site PI Responsibilities: oversee enrollment, data collection, and interventions, at Beaumont Army Medical Center, dissemination of data	☐

Protocol Submission Form

Name: John Abt, PhD, ATC, FACSM Affiliated Institution: University of Kentucky	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	☐
Name: Nicholas Heebner, PhD, ATC Affiliated Institution: University of Kentucky	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	☐
Name: Nathan Johnson, PhD, PT Affiliated Institution: University of Kentucky	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	☐
Name: David Powell, PhD Affiliated Institution: University of Kentucky	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	☐
Name: Matthew Hoch, PhD, ATC Affiliated Institution: University of Kentucky	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	☐
Name: Katherine Bain, PT, DPT, ATC, MSAT Affiliated Institution: University of Kentucky	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	
Name: Katherine Roberts, MSAT Affiliated Institution: Beaumont Army Medical Center	Study Role(s): Co-I Responsibilities: collection, analysis, interpretation and dissemination of data	

b. List all other personnel involved in the research. (e.g., statistician, consultants, collaborators)

Other Involved Personnel	Study Roles and Responsibilities
Name: Eamonn Delahunt, PhD, BSc, SMISCP Affiliated Institution: University College Dublin	Study Role(s): Consultant Responsibilities: analysis, interpretation and dissemination of non-identifiable data
Name: Meaghan Beck, MPA Affiliated Institution: University of Kentucky	Study Role(s): Study Coordinator Responsibilities: coordinate research activities associated with the project, including activities related to human subject protection, budgets, and reporting
Name: Affiliated Institution:	Study Role(s): Responsibilities:
Name: Affiliated Institution:	Study Role(s): Responsibilities:
Name: Affiliated Institution:	Study Role(s): Responsibilities:

Protocol Submission Form

c. Conflict of Interest. Do any study personnel have a conflict of interest to declare?

☒

No

☐

Yes. If yes, please explain here.

Protocol Submission Form

6. Involved Institutions and Institutional Review Board (IRB) Reviews.

List all institution(s) involved in this protocol and the study activities occurring at each institution (Columns A and B). If employees of the institution are interacting with subjects or have access to identifiable data, complete the rest of the columns (C-J) for each institution. Identify all reviewing IRBs and the IRB actions taken regarding this protocol. If more rows are needed, attach additional page(s) to the end of the submission form. If you need assistance, please contact your local IRB office or the ORP at 301-619-2165 or usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

A	B	C	D	E	F	G	H	I	J
Institution (If multi-site, include each site and site PI)	Study Activities (e.g. recruitment, enrollment, data/specimen collection, analysis, data storage)	DHHS Federal Wide Assurance # (Click here to search)	Name of Reviewing IRB	IRB Approval* (Indicate: Yes, No, Pending)	IRB Approval Date	IRB Approval Expiration Date	Type of IRB Review (Full Board or Expedited)	IRB Determina tion	IRB Approved Waivers** (Indicate: A, B, C, D)
University of Kentucky	Recruitment, enrollment, data collection, intervention, analysis, data storage	00005295	University of Kentucky IRB	Yes	5/9/2018	5/8/2019	Expedited	No Greater Than Minimal Risk to Subjects	No
University of North Carolina – Chapel Hill	Recruitment, enrollment, data collection, intervention, analysis, data storage	00004801	University of Kentucky IRB	Yes	5/9/2018	5/8/2019	Expedited	No Greater Than Minimal Risk to Subjects	No
Beaumont Army Medical Center	Recruitment, enrollment, data collection, intervention, data storage	00005646	University of Kentucky IRB	Yes	5/9/2018	5/8/2019	Expedited	No Greater Than Minimal Risk to Subjects	No

IRB Approval*: Indicate whether IRB approval has taken place or is pending. If there are any Institutional Agreements for IRB review planned, describe in the space provided.

IRB Determination: Indicate the determination made by the IRB during the initial review of the protocol. Please contact your IRB office for assistance.

IRB Approved Waivers:** In the space provided, type the letter(s) representing the waivers granted by the IRB: **A.** Waiver of the requirement to obtain informed consent from subjects; **B.** Waiver of the requirement to obtain a signed consent form from subjects; **C.** Waiver of HIPAA Authorization requirements for this protocol; **D.** Waiver of HIPAA Authorization requirements for recruitment purposes only.

Protocol Submission Form

Multi-Site Studies: Identify all proposed sites, site Principal Investigators, and IRBs in the above table. Additional site documents will be requested at a later date.

Protocol Submission Form

7. Research Monitor Requirements. If the protocol is considered greater than minimal risk to subjects, a research monitor must be identified. Please check one of the following:

- a. ☒ Not applicable
- b. ☐ Protocol is greater than minimal risk (Complete the table below)

Research Monitor	Role and Responsibilities*
Name:	Study Role(s):
Affiliated Institution:	Responsibilities:
Note: Please provide a current CV/Biosketch and documentation of human subjects' protection training for the Research Monitor. A Research Monitor must not be a member of the study team and is not a Clinical Research Associate (CRA). A Data Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) member may serve as the DoD required Research Monitor.	

* Additional information about the Research Monitor's duties and responsibilities can be found in the document **"Information for Investigators: Headquarters, U. S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protections Regulatory Requirements"** found on ORP HRPO website:
https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

8. Use of Medical Products.

a. **Drugs, Biologics or Dietary Supplements.** Does the protocol assess the use a drug, biologic or dietary supplement?

- ☐ Yes (If Yes, continue to question i.)
- ☒ No (If No, skip to question b)

i. Is the purpose of your protocol to determine the safety or effectiveness of the drug, biologic, or dietary supplement?

- ☐ Yes (If Yes, complete the table below.)
- ☐ No (If No, skip to question b)

ii. Does the protocol assess the use of a drug, biologic or dietary supplement that is FDA approved AND will be used in accordance with the labeling and indications as reviewed by the FDA?

- ☐ Yes (If Yes, protocol may be exempt from an Investigational New Drug (IND) application, continue to the table below)
- ☐ No (If No, continue to the table below)

Product Name(s)	Has the IRB/Institution or FDA evaluated whether an IND is required? (Yes/No)	IND Application Status (Indicate IND#, IND pending, or IND exempt)	Who holds the IND?
			☐ Sponsor* ☐ Investigator** ☐ Other:

Protocol Submission Form

			☐ Sponsor* ☐ Investigator** ☐ Other:
			☐ Sponsor* ☐ Investigator** ☐ Other:

*Include documentation from the sponsor or FDA identifying the IND number for this study.

b. Investigational Devices. Does the protocol assess the use of a medical device?

- ☐ Yes (If Yes, proceed to question i)
☒ No (If No, skip to Section B (Checklist of Documents to be Submitted to ORP))

i. Is the purpose of your protocol to evaluate the safety or effectiveness of a medical device as defined at 21 CFR 812?

- ☐ Yes (If Yes, continue to question ii)
☒ No (If No, skip to Section B, (Checklist of Documents to be Submitted to ORP))

ii. Does the protocol use a medical device that is FDA cleared AND will the device be used in accordance with the labeling and indications as reviewed by the FDA?

- ☐ Yes (If Yes, the protocol may be exempt from IDE requirements. Skip to Section B, (Checklist of Documents to be submitted to ORP))
☐ No (If No, complete the table below)

Device Name(s)/Manufacturer	Has the IRB/Institution or FDA evaluated whether an IDE is required? (Yes/No)	IDE status* (Indicate not applicable, pending, IDE#, or IDE exempt)	Who holds the IDE?
			☐ Sponsor ☐ Investigator ☐ Other:
			☐ Sponsor ☐ Investigator ☐ Other:
			☐ Sponsor ☐ Investigator ☐ Other:

*Sponsor/PI's Device Risk Determination for Device(s) as Used in this Study

- ☐ **Non-Significant Risk** Note: Study is subject to abbreviated IDE requirements, Provide documentation of a Non-Significant Risk determination reviewed by the convened IRB.
☐ **Significant Risk Device** Note: Study must have an FDA-approved IDE.
☐ **Study is Exempt from IDE requirements.**

NOTE: An Investigational device is a device that is the object of an investigation. When a protocol is research involving one or more subjects to determine the safety or effectiveness of a device, it is subject to the requirements of FDA's Investigational Device Exemption (IDE) regulations unless determined exempt from the requirements. If available, include documentation from the sponsor or FDA identifying the IDE status, IDE number.

Protocol Submission Form

Section B. Checklist of Documents to be Submitted to the ORP

PI Name: Phillip Gribble

Protocol Title: Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation

The ORP reviews and approves the same documents reviewed and approved by the local Institutional Review Board (IRB). To promote a timely review, submit all IRB-approved study documents, additional applicable documents, and this Protocol Submission Form.

If your protocol meets the criteria for Secondary Research Involving the Use of Data/Specimens please complete the HRPO Submission Form – Secondary Research Involving the Use of Data/Specimens found on the ORP HRPO website http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo and submit your institution's exemption determination letter. Contact the ORP HRPO for protocol submission instructions at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil or 301-619-2165.

1. Institutional Review Board (IRB)-Approved Documents. Please provide all documents that were submitted to the IRB for review. These are required documents for acceptance of the protocol submission for ORP review. Please check the box beside each document included with this Protocol Submission Form.

- ☒ Research Protocol. (Please note the version(s) and date(s) of the approved protocol: Medical IRB Protocol #44172. **Initial Approved 05/09/2018. Updated Approved 5/30/2018. Updated Approved 9/7/2018. Modifications made 11/7/2018**
- ☒ IRB Application. (*If required by your institution.* Indicate the version(s) and date(s) of the IRB Application: **Electronic application submitted 04/26/2018. Approved 05/09/2018 as Protocol #44172. Not available in PDF format.**
- ☒ Informed Consent Document(s), HIPAA Authorization Forms, and Assent Forms. (Please note the version(s) and date(s) of the approved informed consent document(s) here: **Informed Consent document under Medical IRB Protocol #44172 approved 05/09/2018. Updated 8/9/2018.**
- ☒ IRB Approval Letter(s) (Original and current approval letter and amendment approval letter (if any))
- ☒ Subject recruitment material (e.g., telephone recruitment script, online or print advertising)

2. Other applicable and available study documents. If applicable and when available, submit the following research-related documents for ORP review. Please check the box beside each document included with this Protocol Submission Form.

- ☒ Scientific/Peer Review of Protocol
- ☒ Current Curriculum vitae or Biosketch for PI and Research Monitor (If protocol is greater than minimal risk)
- ☒ Documentation of human subjects training for the Principal Investigator, Co-Investigator, Associate Investigator(s), Research Monitor
- ☒ Study instruments and data collection forms
- ☒ Conflict of Interest forms (per your institutional requirements)

Protocol Submission Form

- ☐ Additional committee and regulatory committee approvals (e.g., radiation control committee, institutional biosafety committee, etc): **NA**
- ☒ Letter of Support from collaborating institutions
- ☒ Unit Commander Letter of Support (if military sites involved)
- ☐ Other documents signed by the subject (e.g., procedural consent, consent for sample donation, consent for testing for communicable diseases, audio/video release form): **NA**
- ☒ FDA Determination related to IND/IDE
- ☐ Medical Product Package Insert/ Investigational Brochure
- ☐ Device Manual: **NA**
- ☐ Form FDA 1572: **NA**
- ☐ Case Report Forms: **NA**

3. International Sites. If your study involves international research sites, please contact the ORP HRPO for guidance on completing an international protocol submission form and requirements for international research sites. This form is found on the HRPO website: [Click Here](#)

4. Multi Site Protocols. If this is a multi-site protocol, you will be asked to provide each site's IRB approved documents (including the IRB Application) as a separate submission for ORP HRPO review. If the IRB application is unavailable for a site, complete the Site-Specific Protocol Addendum found on the HRPO website: [Click Here](#). **Reliance Agreement in progress.**

5. Cadaver Research. Activities involving human cadavers supported by the USAMRMC must be reviewed for compliance with the US Army policy and approved by the ORP HRPO. Contact the ORP HRPO for cadaver protocol submission instructions at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil or 301-619-2165.

Protocol Submission Form

Section C. Reporting Requirements and Responsibilities of the Principal Investigator to the USAMRMC ORP Human Research Protections Office (HRPO).

The Principal Investigator must comply with the following minimum reporting requirements. Specific reporting requirements for the protocol will be included in the HRPO Approval Memorandum. Failure to comply could result in suspension of funding.

The protocol will not be initiated until written notification of approval of the research project is issued by the USAMRMC ORP HRPO.

1. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRMC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc), significant change in study design (i.e. would prompt additional scientific review) or a change that could potentially increase risks to subjects.
2. Any changes of the IRB used to review and approve the research will be promptly reported to the USAMRMC ORP HRPO.
3. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the US Army Medical Research and Materiel Command, ATTN: MCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.
4. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the Sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.
5. A copy of the continuing review approval notification by the IRB of Record must be submitted to the HRPO as soon as possible after receipt. Please note that the HRPO also conducts random audits at the time of continuing review. Additional information and documentation may be requested at that time.
6. The final study report, including any acknowledgement documentation and supporting documents, must be submitted to the HRPO when available.
7. The knowledge of any pending compliance inspection/visit by the FDA, DHHS Office of Human Research Protections (OHRP), or other government agency concerning this research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any regulatory agencies including legal or medical actions and any instances of serious or continuing noncompliance with the regulations or requirements, must be promptly reported to the HRPO.

Protocol Submission Form

Principal Investigator Signature Page. Please sign and scan this signature page.

I have read the above reporting requirements and responsibilities of the Principal Investigator to the USAMRMC ORP HRPO.

Protocol Principal Investigator Signature

Date: Click here to enter a date.

Printed Name: Phillip Gribble

Point of Contact Regarding this Protocol Submission: Phillip Gribble

Study Role: PI Contact Information: phillip.gribble@uky.edu 859-218-0885

PROTOCOL TYPE

Which IRB

☒ Medical ☐ NonMedical

Protocol Process Type

- ☐ Exemption
☒ Expedited (Must be risk level 1)
☐ Full

IMPORTANT NOTE: Once you have saved your choices under "Which IRB" and "Protocol Process Type", you will not be able to change your selections. If your application is deemed eligible for a different Protocol Process Type, it may be necessary to create a new application.

Please see below for guidance on which selections to make, and/or download the IRB Introduction Packet for more details [\[PDF\]](#). If you still have questions about which IRB or Protocol Process Type to choose, please contact the Office of Research Integrity (ORI) at 859-257-9428 prior to saving your selections.

Which IRB

The Medical IRB reviews research emanating from the Colleges of Dentistry; Health Sciences; Medicine; Nursing; Pharmacy and Health Sciences; and Public Health.

The Nonmedical IRBs review research originating from the Colleges of Agriculture; Arts & Sciences; Business & Economics; Communications & Information; Design; Education; Engineering; Fine Arts; Law; and Social Work. The Nonmedical IRB does not review studies that involve administration of drugs or studies that involves invasive medical procedures, regardless of from what college the application originates.

Which Protocol Process Type

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review;
- by exemption certification [\[see categories\]](#);
- by expedited review [\[see categories\]](#);

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. For assistance in determining which review process type your IRB application is eligible for, please see the IRB Introduction Packet [\[PDF\]](#).

EXPEDITED CERTIFICATION

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

- A. Research activities that (1) present no more than [*minimal risk](#) to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and [21 CFR 56.110](#). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. [45 CFR 46.102\(i\)](#)*

Check the appropriate categories that apply to your research project: _____

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- A. Research on drugs for which an investigational new drug application ([21 CFR Part 312](#)) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- B. Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](#)) is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

*A determination on whether an IDE application is required may be made by the FDA or based on a Non-Significant Risk (NSR) determination by the convened IRB. Unless the study has documentation from FDA indicating that an IDE application is not required, it may not be approved under expedited mechanisms.

** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements- [21 CFR 812.2\(c\)](#)

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP [\[PDF\]](#) for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#) If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- A. Hair and nail clippings in a nondisfiguring manner;
- B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- C. Permanent teeth if routine patient care indicates a need for extraction;
- D. Excreta and external secretions (including sweat);
- E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- F. placenta removed at delivery;
- G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- J. Sputum collected after saline mist nebulization.

☒ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

- A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- B. Weighing or testing sensory acuity;
- C. Magnetic resonance imaging;
- D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☒ 5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101\(b\)\(2\) and \(b\)\(3\)](#). This listing refers only to research that is not exempt.)

PROJECT INFORMATION

Title of Project: (If applicable, use the exact title listed in the grant/contract application). ⓘ

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

Short Title Description

Note: "Short Title" should consist of a couple key words to easily identify your study - these key words (rather than the whole title) will be displayed on the Dashboard in the listing for your study.



Neuromuscular Ankle Rehabilitation

Anticipated Ending Date of Research Project: 12/31/2022

Number of human subjects ⓘ

150

Study is/will be open to new subject enrollment (or data/specimen collection): ⓘ ☒ Yes ☐ No

PICONTACT INFORMATION

The Principal Investigator's (PI) contact information is filled in automatically based on who was logged in when the application was created (with LinkBlue ID). If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be the same person listed below.

If you are not the Principal Investigator, do NOT add yourself as study personnel. You may change the PI contact information on an application that is in Researcher edit mode by:

- clicking the "Change Principal Investigator" link below;
- searching for the PI's name using the search feature;
- clicking "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with edit authorization so you can continue editing the application.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to [myUK](#) and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a '[Name Change Form](#)' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the [HR Benefits Office](#) for additional information.

Note: Principal Investigator (PI) role for E-IRB access

The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*). 

[Change Principal Investigator:](#)

First Name:	Phillip	Room# &	
Last Name:	Gribble	Bldg:	900 South Limestone
Department:	Health Sciences - Rehabilitati ...	Speed	
PI's		Sort#:	405360200
Employee/Student ID#:	12060036	Degree:	PhD, ATC
PI's Telephone #:	859- 218-0885	Rank: 	Associate Professor
PI's e-mail address:	phillip.gribble@uky.edu	Dept Code:	7N600
PI is R.N. ☐ Yes ☒ No		PI's FAX Number:	
		Trained:	Yes
		Date Trained	4/6/2017

Do you, the PI, have a [significant financial interest](#) related to your responsibilities at the University of Kentucky (that requires disclosure per the [UK administrative regulation 7:2](#))?

☐ Yes ☒ No

RISK LEVEL

Indicate which of the categories listed below accurately describes this protocol

- ☐ (Risk Level 1) Not greater than minimal risk
- ☐ (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individuals subjects
- ☐ (Risk Level 3) Greater then minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ☐ (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests [\[45 CFR 46.102\(i\)\]](#)

Download UK's guidance document on assessing the research risk for additional information on risk [\[PDF\]](#) 

SUBJECT DEMOGRAPHICS

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) to

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations

(Please note: The IRB will expect this information to be reported at Continuation Review time):

Enter Numbers Only!		
Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:	0	0
Asian:	4	4
Black African American:	10	8
Hispanic/Latino:	8	6
Native Hawaiian/Pacific Islander:	0	0
White/Caucasian:	59	51
Other or Unknown:	0	0

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☒ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal

ADDITIONAL INFORMATION:

Please visit the [IRB Survival Handbook](#) under the named topic:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults: Link to required [Form](#)

And/OR:

- UKMC Residents or House Officers [see [requirement of GME](#)]

Material

- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☒ Normal Volunteers
- ☒ Military Personnel and/or DoD Civilian Employees
- ☒ Patients
- ☐ Appalachian Population

- Non-English Speaking [see [instructions for recruitment](#) and E-IRB Research Description section on same topic]
- International Citizens [[HTML](#)] (DoD SOP may apply [[PDF](#)])
- Military Personnel and/or DoD Civilian Employees (DoD SOP may apply [[PDF](#)])

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

- ☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

☐ Yes ☐ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: <https://ris.uky.edu/ori/oriforms/formt/Scale.asp>

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

Additional Resources:

- Sample Repository/Registry/Bank Consent ([PDF](#)) ([Word](#))
- [Instructions for Proposed Informed Consent Document](#)
- [Instructions for Proposed Assent Form](#)

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
 - Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
 - It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
 - Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
- Document Types that do NOT get an IRB approval stamp are:

- "Highlighted Changes",
- "Phone Script", and
- "Sponsor's Sample Consent Form".

You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) as a PDF (if open to enrollment).

After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!



Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☒ Phone Script (and/or Assent Script)
- ☒ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol

Attachments

Attach Type	File Name
Informed Consent/Parental Permission	Form_C_Med_and_HIPAA_v3 SMART.pdf
Informed Consent_Highlighted Changes	Form_C_Med_and_HIPAA_v3 SMART_highlighted changes.pdf
Informed Consent_Highlighted Changes	Telephone Screening Script_highlighted changes.pdf
Phone Script	Telephone Screening Script_11.7.2018.pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), your research activities must fit into one of two regulatory options:

- 1) The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).
- 2) The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English-* [\[WORD\]](#), *Spanish-* [\[WORD\]](#) The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

Option 1

- a) The only record linking the participant and the research would be the consent document:

- b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant must be asked whether (s)he wants to sign a consent form; if the participant agrees to sign a consent form, only an IRB approved version should be used.

Option 2

- a) The research presents no more than minimal risk to the participant:

- b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

STUDY PERSONNEL

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must save by hitting the 'Save Study Personnel Information' button.

Yes No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is being completed to meet the requirements of a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed as such below.
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR, MR) or 'Other Review', and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature, search for applicable personnel first, then click "select" by the listing for the person you want to add as study personnel to your protocol. For each individual selected, be sure to specify responsibility in the project, whether authorized by the principal investigator to obtain informed consent, AND denote who should regularly receive E-IRB notifications.

NOTE: Study personnel are required to receive human research protection (HSP) training before implementing any research procedures (e.g., CITI). For information about mandatory training requirements for study personnel, visit UK's [FAQ's on Mandatory Training web page](#), or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (Jen.Hill@uky.edu) for credit.

Study personnel assisting in research project:

Add Personnel

My Study Personnel	Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	Removed?	Last Updated	Recorded Training	SFI
			Co-Investigator											
			Co-Investigator				PT, DPT, ATC, MSAT							
			Study Coordinator											
			Co-Investigator				PhD, ATC							
			Co-Investigator											
							PhD, DPT							
			Co-Investigator				PhD, ATC							
			Co-Investigator											

RESEARCH DESCRIPTION

****!!!!PLEASE READ!!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.

Workaround(s):

- Save your work often to avoid losing data.
- Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

Given the sevenfold increased rate of musculoskeletal injuries in the military and the current rates of Service Members who are medically discharged due to neuromusculoskeletal injuries, there is a clear need to optimize clinical care for these injuries. Clinical prediction rules have long demonstrated the phenomenon that some individuals respond to physical therapy successfully (Responders), while others do not (Non-Responders). For certain injuries, clinicians have abstract characteristics that appear to identify successful Responders to rehabilitation, but a significant gap exists as to what is the underlying mechanism for success in some and failure in others. Patients undergo physical rehabilitation that addresses clinical goals, but given the unacceptable rates of Non-Responders, there is a need to evaluate the standard of care given to determine additions and amplifications needed to create desired long-term success. Lateral ankle sprains (LASs), the most prevalent neuromusculoskeletal injury in general and physically active populations,¹⁻⁵ are associated with long-term pain, disability and a substantial financial burden.^{6,7} Between 628,000 and 1.01 million LASs are treated annually in US emergency departments, equating to over \$7.5 billion in estimated yearly costs.^{1,4,8} Among military populations, ankle injuries are the most commonly reported injury, representing 13% of the nearly 750,000 musculoskeletal injuries incurred annually, mimicking the prevalence seen in civilian populations.⁹ Neuromusculoskeletal injuries create a substantial manpower time loss in military populations, equating to a \$5.5 billion annual financial burden attributable to treating and returning its warfighters to active duty.¹⁰ Between 50-70% of the people who sustain a LAS, will develop chronic ankle instability (CAI), a condition characterized by ongoing pain, ankle joint instability, injury recurrence, and persistent functional disability.¹¹ Chronicity of symptoms and re-injury has been shown to occur rapidly, with recent work demonstrating the onset of CAI as early as 6-12 months after the initial acute LAS.¹²⁻¹⁶ Further, over 70% of CAI cases have developed early onset post-traumatic ankle joint osteoarthritis (PTOA),¹⁷⁻²⁰ with consequent deteriorations in physical activity and health-related quality of life.²¹⁻²⁴ A smaller percentage of LAS patients, referred to as LAS Copers, breaks the cycle of recurrent injuries and disabilities seen in CAI, exhibiting neuromuscular control and functional levels similar to a population with no history of LAS.^{12,15,25} In the military, there is a shorter service time among those that develop CAI compared to LAS Copers.²⁶ Usual care for ankle instability patients consists of symptom management or activity modification;^{27,28} but given the persistence of CAI and its negative impact on joint and general health, it is clear that the standard of care is inadequate for many.²⁹ Recent systematic reviews^{30,31} suggest that the typical standard of care for LAS may not be comprehensive and robust enough, given the high rate of CAI development and long-term disability seen in the population. Some researchers have speculated that the root cause for continued pain and disability and loss of function for many individuals who fail to improve is due to central nervous system (CNS) alterations. Recent work by our group has demonstrated deficits in brain white matter structural integrity³², as well as motor excitability outputs^{33,34} in patients with CAI. Additionally, we have observed altered strength³⁵ and movement patterns in the proximal joints of the lower extremity³⁵⁻⁴⁰. We have seen these alterations in structural integrity and motor excitability correlate with functional deficits in CAI patients^{32,33}, which is likely helping to explain the aberrant movement patterns that contribute to instability, altered loading, and potential for long-term consequences seen as decreased physical activity, quality of life and joint health.^{6,7} One of the more significant consequences of the aberrant patterns associated with CNS alterations is the deterioration of ankle joint cartilage integrity, an early marker of PTOA. Recent work has demonstrated that ankle PTOA is present in young adults with a history of LAS,¹⁸ disputing the notion that ankle PTOA is an age-dependent disorder. The aberrant movement patterns that are present in young CAI patients are likely contributing to this phenomenon by introducing excessive loading to the ankle joint. While the assumption is that LAS patients will recover without long-term consequence following the rehabilitative standard of care, the high rate of CAI observed in the military and general populations suggests the current standard of care is inadequate. Further, we know that similar aberrant movement patterns and balance deficits are likely to develop 6-12 months following an acute LAS, giving an indication that the CNS changes may be developing rapidly after the initial injury. However, to date, no previous studies have introduced interventions to address the deficits from the time of acute LAS through a one-year follow-up, representing a time period when CAI and the subsequent disability develops. The long-term negative outcomes associated with LAS patients are emerging,^{6,7} and we know that even with standard of care treatments, LAS patients can develop symptoms of CAI 6-12 months after acute injury.^{12,14-16,41} Recent work by our group demonstrates successful outcomes in CAI patients when sensorimotor techniques are utilized.^{42,43} However, there has yet to be a comprehensive study that employs sensorimotor focused rehabilitation for LAS patients in a prospective study design to diminish the suspected CNS deficits that develop, resulting in better clinical outcomes and ankle joint health and reductions in CAI development. Our preliminary data suggest lingering CNS alterations in CAI patients, which an innovative sensorimotor ankle rehabilitation protocol can address. This rehabilitative approach would optimize the short- and long-term physical performance and resiliency for LAS patients, leading to more LAS Copers and fewer CAI patients.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section.

Therefore, the purpose of this study is to demonstrate the effectiveness of an innovative sensorimotor rehabilitation protocol compared to a standard of care protocol at improving clinical and novel outcomes, which will associate with lower rates of LAS re-injury and development of CAI during a 12-month follow-up period. The proposed project will focus on three specific aims and is aligned with FY17-18 JPC-8/CRM RP NMSIRRA Focus Areas: • Lack of short- and long-term evidence for existing support and reintegration strategies, and a need for new evidence-based support and reintegration strategies • Limited ability to predict, prevent, and mitigate development of secondary health deficits following neuromusculoskeletal injury • Limited understanding of the management of patient rehabilitation strategies throughout the rehabilitation process following neuromusculoskeletal injury • Lack of validated metrics that effectively assess initial presentation, rehabilitation, and reintegration following neuromusculoskeletal injury and Identified Areas of Emphasis: • Validate optimal dose, timing, frequency, duration, and setting of rehabilitation techniques for Service members with neuromusculoskeletal injuries • Develop and evaluate metrics to assess initial presentation, rehabilitation, and reintegration of Service members with neuromusculoskeletal injuries • Identify biomechanical markers of the development and/or progression of secondary musculoskeletal deficits (e.g., osteoarthritis, low back pain, etc.) in Service members with neuromusculoskeletal injuries • Develop and evaluate innovative rehabilitation techniques for Service members with neuromusculoskeletal injuries • Develop and evaluate new short- and long-term evidence-based support and reintegration interventions relevant to Service members with neuromusculoskeletal injuries The purpose of this project is to compare a novel sensorimotor ankle rehabilitation training (SMART) protocol for LAS against a standard of care (SOC) protocol to determine if it is more successful at producing successful one-year outcomes and lower rates of re-injury and improved health. This will address the identified needs for evidence-support and reintegration strategies to improve understanding of the management of patient rehabilitation strategies throughout the rehabilitation process following neuromusculoskeletal injury. The project will validate an innovative rehabilitation approach while providing metrics of success using a variety of clinical and innovative markers. Specifically, in Aims 1 and 2, we will use common clinical outcomes and innovative metrics of central nervous system function to validate the short-term success of the rehabilitation. We will replicate these measures along with measures of re-injury and disability along with MRI of the ankle to indicate ankle joint health at a 12-month follow-up to provide evidence for long-term success. Finally, in our third aim, we will use our outcomes to develop mechanistic models to explain our anticipated successes from the novel sensorimotor rehabilitation outcomes. Specific Aim #1: Determine if SMART improves clinical outcomes (patient-reported function and quality of life, LAS re-injury rates, postural control, ankle ROM) and ankle joint integrity (articular cartilage turnover) in LAS patients. Hypothesis 1.1: Compared to the SOC, LAS patients participating in the SMART program will have improved patient-reported function and quality of life, postural control, and ankle ROM at the time of return to full activity. Hypothesis 1.2: Compared to the SOC, LAS patients participating in the SMART program will have improved patient-reported function and quality of life, postural control, ankle ROM, and lower LAS re-injury rates at the 6-month follow-up. Hypothesis 1.3: Compared to the SOC, LAS patients participating in the SMART program will have improved patient-reported function and quality of life, postural control, ankle ROM, lower LAS re-injury rates, and less ankle joint cartilage turnover at the 12-month follow-up. Specific Aim #2: Determine if SMART improves innovative measures of central nervous system function (corticospinal excitability and brain white matter integrity) in LAS patients. Hypothesis 2.1: Compared to the SOC, LAS patients participating in the SMART program will have improved central nervous system function at the time of return to activity, and at the 6-month and 12-month follow-ups. Specific Aim #3: Delineate the association between explanatory mechanistic measures (corticospinal excitability and brain white matter integrity) and the hypothesized improvements in clinical and ankle joint integrity in LAS patients receiving SMART. Hypothesis 3.1: Improved mechanistic measures in these innovative outcomes will help explain the success from SMART on the clinical outcomes and ankle joint integrity at the 12-month follow-up.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting [community-based participatory research \(CBPR\)](#), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a research repository describe the repository design and operating procedures. For relevant information to include, see question 22 of the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [\[PDF\]](#).

Using a double-blinded, randomized control trial design, we will compare clinical and innovative outcome measures at three time points between cohorts of acute LAS patients that receive a standard of care (SOC) rehabilitation compared to an innovative sensorimotor ankle rehabilitation training (SMART) program to determine if the SMART can reduce the rate of re-injury and the development of CAI during the 12 months following the acute LAS (Figure 7). Using a 2 (Intervention) x 2 (Group) by 3 (Time) mixed model statistical design, we will make comparisons of clinical and innovative outcomes between intervention groups (SMART vs SOC) and those LAS patients that develop CAI and those that do not (LAS Coper) during a 12-month follow-up period after completing the assigned intervention for their acute LAS. Within one week of completing the designated rehabilitation program and returning to unrestricted physical activity, patients will complete assessments of clinical outcomes (patient-reported outcomes, balance and ROM). Additionally, measures of CNS structural integrity and function and ankle joint cartilage turnover will be assessed. These measures will be repeated at approximately 6 and 12 months after the initial assessment. At the 12-month follow-up, patients will be dichotomized into either a CAI or LAS Coper category based on if there was successful return to physical activity without lingering pain and disability or re-injury. Interested subjects will contact a member of the research team to complete a telephone screening to determine eligibility to avoid any unneeded screening visits. Subjects eligible will then complete informed consent.

Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners or others who are likely to be vulnerable. If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of these groups requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button.

Patients will be between the ages of 18-44 and are initiating rehabilitation for a first time acute grade I, II, or III LAS that they have sustained within 72 hours of study enrollment. Patients will be enrolled from orthopaedic departments, emergency departments, and outpatient rehabilitation clinics at UK and UNC, as well as Fort Bliss/William Beaumont Army Medical Center. Participants will be diagnosed by a physician, medic, athletic trainer, physical therapist, or other providing medical coverage in operational environments as having sustained a LAS and referred to the study personnel at each site to initiate rehabilitation. After confirming the diagnosis of LAS by study personnel and obtaining voluntary written consent, the study site Clinical Research Coordinator (Katie Roberts) will randomly assign the participant into one of two intervention groups described below to begin supervised rehabilitation with a member of the study personnel (physical therapist or athletic trainer). The Site PI (MAJ Helton) will be blinded to group membership and will carry out the outcomes testing at this site. Patients will consent to receiving the assigned treatment as well as participation in assessment of the outcomes at the time they are released from supervised rehabilitation back to full physical activity, and 6 months and 12 months after this return to activity. Severity of LAS (Grade I, II, or III)⁸⁹ and length of rehabilitation will be noted and used as a covariate in the statistical analysis. The study investigators have previously completed separate RCTs at their home institutions involving participants with ankle instability (see preliminary data). Collectively, our research team has amassed data on more than 700 ankle instability participants. This demonstrates adequate access to the targeted patient population for this proposed project and extensive experience in key areas of clinical trial management, including multi-site recruitment, retention, blinded assessment and analysis

techniques that have positioned these new investigators with the requisite essential skills to conduct this multi-site RCT. The university settings represent flagship state institutions with large medical centers and >30,000 individuals in each of these university community. Along with Fort Bliss/William Beaumont Army Medical Center as military clinics and military treatment facilities with a large military population available, the recruitment needed for this study will be easily attained. Sample size To the authors' knowledge, no published literature exists combining our proposed dependent variables and interventions for our targeted population. Therefore, we have estimated our sample size based on previously published work related to the study design and selected outcomes.^{12-15,18,32-34,49-52,59,68,76,90} In order to observe group differences between the CAI and LAS Coper groups we would have first utilized minimally clinically important difference (MCID) in the outcomes. However, as MCID have not been established for our selected outcomes, we will utilize sample sizes that mimic that of the largest of the sample sizes from the previously published literature in this area, which was 82 LAS patients.¹⁴ Allowing for an average attrition rate across the sites of up to 45%, we will enroll 150 LAS patients, recruited equally (50 per site) at each site. Consented LAS patients will be assigned randomly to one of two intervention groups, a standard of care (SOC) or a sensorimotor ankle rehabilitation training (SMART) protocol. Balanced group membership with random assignment will be achieved by counter-balancing. Upon consenting, group membership will be revealed by opening a sealed envelope with group assignment enclosed.

Attachments

Subject Recruitment Methods & Privacy: Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.

Please note: Based upon both legal and ethical concerns, the UK Medical Institutional Review Board (IRB) will not approve finder's fees for research studies.

For UK and UNC Men and women between the ages of 18 and 44 years, representative of the racial and ethnic makeup of greater Lexington or Chapel Hill areas will be recruited through general advertisements and word of mouth. Health care facilities on both campuses will be given approved research flyers to distribute to patients with identified acute lateral ankle sprains. Additionally, the University of Kentucky Center for Clinical and Translational Science and the University of North Carolina Clinical and Translational Research Center have extensive marketing and recruitment programs. Recruitment support includes volunteer databases (allowing investigators to contact eligible subjects), recruitment specialists, online resources, and strategic placement of flyer and other recruitment material around campus. Interested patients will contact a member of the research team to schedule a telephone

screening to determine eligibility. No identifiable information will be collected during this contact. Eligible patients will then be scheduled for testing. For William Beaumont Army Medical Center (WBAMC) Men and women between the ages of 18 and 44 years, representative of the racial and ethnic makeup of El Paso, TX. The study will recruit any patients eligible for care at WBAMC, including active duty personnel and beneficiaries. Flyers will be posted through the main WBAMC hospital and outlying physical therapy clinics to advertise the study. Additionally, word of mouth announcements of the study opportunity will be provided by the brigade physical therapists on post at Fort Bliss. Brigade physical therapists will be able to provide approved informational flyers to patients. Interested subjects will contact a member of the research team, by email or phone, to schedule a telephone screening to determine eligibility. No identifiable information will be collected during the telephone screening eligible patients will then be scheduled for in person testing. At all sites, interested respondents will contact the study site's research coordinator who then holds a no obligation conversation about the study details and risks. The research coordinator will clearly explain the research design, procedures, and goals. If interested, the potential participant will be screened over the telephone to avoid any unneeded screening visits. Each participant must meet inclusion/exclusion criteria based on medical health history, medications, and lifestyle and exercise habits. Qualifying participants will then come in for a face-to-face interview. The research coordinator will review and have each participant sign the consent form. Established procedures allow us to develop relationships with each participant, while guaranteeing a fully informed willingness to volunteer. The investigators collectively have conducted similar studies with civilians and Conventional and Special Operations Forces for the last decade and have a record of recruiting over 4000 participants for laboratory- based clinical trials and clinical studies. Using similar recruitment strategies, the investigators do not anticipate recruitment difficulties and are cognizant to the special consideration required of recruiting military personnel. The principal investigator will monitor confidentiality and data monthly to ensure accuracy and recruitment of subjects. Weekly meetings, with the co-investigators, will be held to verify compliance and testing procedures. These meetings will monitor recruitment, retention, data, adverse events, and breaches in confidentiality.

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Advertising: Specify if any advertising will be performed. If yes, please see [“IRB Application Instructions - Advertisements”](#) for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment" on ORI's [IRB Survival Handbook](#) web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [\[PDF\]](#). If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities. 

Participation in this study will be announced to patients via flyers posted throughout WBAMC and UK and UNC HealthCare facilities.

Attachments

Attach Type	File Name
Advertising	Research Flyer_Approved.pdf
Advertising	Recruitment Slide_DOD_UNC.pdf
Advertising	Research Flyer Template_WBAMC.pdf

Informed Consent Process: Describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent (Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application), steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent (i.e., research involving adult subjects with impaired consent capacity) and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page. For additional information, see the [Informed Consent Standard Operating Procedures \(SOPs\)](#) (PDF).

Informed Consent for Research Involving Emancipated Individuals

If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the [Informed Consent SOP](#) (PDF).

Informed Consent for Research Involving Non-English Speaking Subjects

If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see [IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture](#).

Research Repositories

If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the "[University of Kentucky Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use](#)" (PDF).

Interested subjects will contact a member of the research team to complete a telephone screening to determine eligibility to avoid any unneeded screening visits. All subjects will first consent to participation and then verify no change in eligibility status since the telephone screening process. The informed consent interview will be administered by a member of the research team. The subject will be provided the opportunity to ask any questions related to the research study and procedures prior to signing the informed consent form. The informed consent process will be completed outside the Chain of Command (Officers, Enlisted, Non-Commissioned Officers). At WBAMC, all recruitment and consent activities will be conducted individually (not in a group).

The research coordinator will be responsible to conduct the consent process with interested patients. The WBAMC PI will be available to answer questions, as needed. The PI, who is active duty, will wear civilian attire during any recruitment or consenting activities to avoid any perceptions of undue influence. No individuals in the Chain of Command for any potential subject will be present during the recruitment or consenting activities."

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Interventions: SMART vs SOC Enrolled participants will be randomly assigned to either a standard of care (SOC) or a novel rehabilitation protocol, Sensorimotor Ankle Rehabilitation Training (SMART). The SMART protocol will be used to improve clinical and central nervous system (CNS) outcomes in LAS patients beyond what is achieved in the typical SOC interventions. SMART will incorporate novel sensorimotor tasks with elements of SOC to achieve more robust improvement goals, which we believe will associate with a lower incidence of repeated ankle instability and subsequent re-injury rate during a 12-month follow-up period. The SOC protocol will include restoration of ankle joint range of motion, strength and functional movement. This has been developed in part from the protocols currently utilized at Fort Bliss/William Beaumont Army Medical Center, under the direction of LTC Scott Carrow. The SMART protocol will utilize the elements of the SOC, and will also include "Sensorimotor Improvements" and other specific additions that will focus on sensory inputs, motor outputs, and integration of the sensory and motor pathways. The SMART protocol additions were created from the expertise of our research team, which includes members of the Executive Committee of the International Ankle Consortium, along with contemporary theory and recent published evidence and recommendations.^{30,31,42,43,61,62} This includes techniques such as plantar cutaneous massage to stimulate sensory inputs^{42,43}, ankle joint mobilizations to stimulate sensory inputs and improve ankle range of motion^{42,43}, gluteal muscle strengthening to target under-utilized motor pathways that have been shown to have deficits in ankle instability patients³⁵, and finally an advanced progression protocol based on an individual's movement proficiency which was designed to and does improve integration of sensory and motor pathways^{42,43,61}. The advanced progression protocol will also be used because not all patients progress at the same pace in clinical practice. This protocol is based on milestone achievements (e.g. completing a given level of difficulty without movement errors) rather than a standardized timeline of progression (e.g. complete 10 repetitions and advance).³¹ The intervention is divided into three phases: 1) Initial Management, 2) Post-acute, and 3) Return to Function/Activity. In the pages that follow, we provide an overview of the clinical goals and interventions that will be used to meet those goals specific to the SOC and SMART protocols in each of these phases. These will include a mixture of supervised intervention sessions in our designated facilities at each site, as well as prescribed intervention tasks to be performed at home.⁶² Participants will be given exercise logs to record their home progressions. Patients must complete at least 80% of supervised and unsupervised sessions to remain in the study. Members of our research personnel will be conducting the SMART and SOC protocols at our testing facilities. These personnel will be either licensed physical therapists and/or athletic trainers.

Subjects may request information about the results and the interventions used in the study after the study is complete. The site PI at each site, blinded to intervention group membership, will determine completion and readiness to return to activity/terminate rehabilitation. Therefore, this will be a double-blinded, randomized controlled trial. The protocols are presented below in Tables 1-3 (see attachment) with major differences/additions in the SMART protocol relative to the SOC highlighted in gray in the tables. Measures and Outcomes Within this mixed model with prospective cohort creation, we will be able to demonstrate that our SMART protocol reduces the prevalence of clinical and innovative outcomes associated with CAI and long-term disability following LAS. The measurement tools are as follows: Patient Reported Outcomes Self-reported Ankle Function and Disability Self-reported ankle region function and disability of the ankle will be assessed using three validated instruments, as recommended by the International Ankle Consortium.^{11,44,63} the Ankle Instability Instrument⁶⁴, the Identification of Functional Ankle Instability (IdFAI)⁶⁵ and Foot and Ankle Ability Measure (FAAM)⁶⁶ Quality of Life, Physical Activity and Pain We will assess quality of life using the Short Form 8 physical (SF8P) and mental (SF8M) component instruments, and physical activity using the Tegner scale. Self-reported pain in the ankle will be assessed from questions embedded within the Cumberland Ankle Instability Tool (CAIT) and overall self-reported body pain will be assessed through a visual analog scale. Ankle Re-injury Rates At the 6 and 12-month follow-ups, participants will be asked to report any new LAS incidents to the same previously injured ankle. LAS injury will be defined as an acute traumatic injury to the lateral ligament complex of the ankle joint as a result of excessive inversion of the rear foot or a combined plantar flexion and adduction of the foot, resulting in some initial deficits of function and disability.⁶ Any LAS and/or episodes of giving way to the opposite limb during these time periods will also be recorded for future analysis. Dynamic Balance Dynamic balance will be assessed using the Star Excursion Balance Test (SEBT).⁶⁷ The SEBT requires the patient to remain balanced on a testing limb at the end of a measuring tape secured to the floor while reaching in different directions with the opposite limb in an effort to make a maximum reach, tap on the ground with the toes, and return back to the start position without compromising the base of support. The reach distances are normalized to the participant's leg length, measured from the anterior superior iliac spine to the base of the medial malleolus of the tibia, and reported as a percentage score.⁶⁷ Our research team has extensive experience with this measurement applied to CAI populations, and it has strong interrater reliability with utility for multi-site application.^{12,37,48,67-71} Based on work by the research team, we will utilize three of the reaching directions (Anterior, Posteromedial, and Posterolateral), using the normalized reach distances.⁶⁷ Dr. Gribble's work has established guidelines, which are now internationally adopted for administering the SEBT⁶⁷ and which have established strong multi-site interrater reliability⁷⁰, giving us confidence that this outcome may be used reliably to collect dynamic postural control data across all sites. Range of Motion The weight-bearing lunge test (WBLT) is a valid and reliable clinical test of ankle dorsiflexion ROM.^{72,73} The test will be conducted bilaterally in accordance with previously utilized procedures.^{72,73} A tape measure will be fixed to the floor, perpendicular to a wall. The participant will be asked to face the wall, placing the hallux and heel of test limb in line on the tape measure. The participant will be asked to lunge forward, keeping the foot flat against the ground, and touch the anterior aspect of the knee to the wall. The participant may place their hands on the wall and non-test limb on the floor for support. If the participant successfully touches their knee to the wall, the distance from the hallux to the wall is recorded in centimeters. The goal of the test is to contact the anterior knee to the wall with the hallux at the furthest distance possible, indicating a greater degree of dorsiflexion ROM. Up to five trials can be utilized to determine maximum performance. Differences in WBLT scores between injured and uninjured limb will indicate the magnitude of dorsiflexion ROM deficit. Central Nervous System Activation Central nervous system activation will be assessed at the corticospinal level using transcranial magnetic stimulation and spinal reflex pathway levels using H-reflex testing. Transcranial Magnetic Stimulation (TMS) Patients that meet the inclusion for TMS as outlined in Protection of Human Subjects (section 1) will participate in TMS testing of the fibularis longus muscle. Methods will be consistent with those previously implemented by the PI in participants with CAI.⁴⁸⁻⁵¹ A Magstim 200 (Magstim Company, Wales, UK) will be used to produce a magnetic stimulus (max 2.0 Tesla) over the motor cortex contralateral to the test limb. Testing will be performed over the area generating the greatest motor evoked potential (MEP) while participants perform 20% ankle eversion contractions in an isokinetic dynamometer. Active motor threshold (AMT) will be determined as the lowest stimulator intensity required to elicit an MEP peak-to-peak amplitude 100 μ V or greater in at least four of 8 trials. A higher AMT indicates decreased excitability, as a greater stimulus intensity is required to elicit an MEP of at least 100 μ V in at least 4 of 8 trials. Eight stimuli will be delivered at 120%, 130%, and 140% of AMT, and peak-to-peak MEP amplitudes will be recorded for each trial. The cortical silent period (CSP) will be measured as the distance from the end of the MEP to a return of the mean EMG signal plus two times the standard deviation of the baseline (pre-stimulus) EMG signal.⁷⁴ A longer CSP indicates a greater corticospinal inhibition within the fibularis longus. Spinal reflex testing Patients that meet the inclusion for spinal reflex testing as outlined in Protection of Human Subjects (section 1) will participate in spinal reflex testing of the fibularis longus muscle. Methods will be consistent with those used previously by the PI in CAI participants.^{48,49,51} While lying supine, a stimulating electrode will be positioned over the sciatic nerve in the popliteal space. Peak-to-peak Hoffmann reflexes (H-reflex) will be measured and the stimulus intensity increased by increments of two volts until a maximal H-reflex is observed. Three H-reflexes will be recorded, averaged, and normalized to the maximal M-response, representing the ratio of the motor neuron pool reflexively activated to the amount of the motor neuron pool available (H:M ratio). Maximal M-responses will be determined following identification of the H-reflex by continuing to increase the stimulus intensity until a maximal M-wave amplitude is elicited. Higher H-reflex values and H:M ratios indicate greater spinal reflexive excitability. White Matter (WM) Microstructure WM microstructure will be assessed in the superior cerebellar peduncle and corticospinal tracts (Figure 8). DTI data will be collected on 3-Tesla Siemens TIM scanners with a 32-channel head coil at each testing site using previously reported methods by Dr. Johnson.^{52,54} Pre-processing and analysis of the FA data will follow a series of steps previously described in his work.^{52,54} Briefly, DTI data will be preprocessed and analyzed using the Functional MRI of the Brain (FMRIB) software library (FSL v5.0.9). Each diffusion-weighted volume will be corrected for motion and residual eddy current distortion using a 12-parameter affine alignment to the corresponding b0 image, via FMRIB's Linear Image Registration Tool. Brain masks will then be generated from each b0 image using FMRIB's brain extraction tool (BET v2.1) to exclude non-brain voxels from all subsequent processing. Next, FMRIB's Diffusion Toolbox (FDT v2.0) will be used to fit the diffusion tensor and calculate eigenvalues for fractional anisotropy (FA). Registration of FA images into MNI152 space will follow a series of procedures described in detail in our previous work.^{52,54} All MNI-transformed FA images will be averaged to create a mean FA image used to generate a common WM tract skeleton. An FA value of 0.2 will be used to threshold the skeleton in order to minimize partial voluming effects after warping across subjects. Next, each participant's spatially normalized FA image will be projected onto the FA skeleton in order to account for residual misalignments between participants after the initial nonlinear registration. A region of interest approach will be implemented to extract FA values from the superior cerebellar peduncle and corticospinal tract systems. The Johns Hopkins University ICBM-DTI 81 WM labels and WM tractography atlases will be used to isolate each tract. The FA values range from 0.0-1.0, indicating if the structures of the tract are

more isotropic or anisotropic. Values closer to 0 indicate reduced density, and therefore more diffusion of water in the neural tracts, which associates with a loss of structural integrity (Figure 9). Ankle Joint Cartilage Turnover T1rho MRI Relaxation Time Analysis The early progression to osteoarthritis following injury is marked by depletion of proteoglycans within the cartilage, an increase in cartilage water content, and disruption of collagen fibril network.^{75,76} Cartilage T1rho MRI relaxation times are sensitive to early changes in proteoglycan content of the cartilage.^{77,78} There is a strong association between longer T1rho relaxation times and altered physical properties of cartilage tissue,⁷⁹ as well as proteoglycan loss.⁸⁰⁻⁸³ T1rho will be collected on Siemens TIM Trio 3T scanners at each site using a 4-channel Siemens large flex coil to quantify changes in the proteoglycan density of the cartilage matrix.^{84,85} We will use a T1rho prepared 3D FLASH sequence to estimate T1rho. In this sequence, a 500 Hz spin lock power is used. Five different spin lock durations (TSL) will be used: TSL=40, 30, 20, 10, 0 ms. T1rho can then be obtained via the following equation: $S(TSL) = S0 \exp(-TSL/T1rho)$. For the above equation S(TSL) is signal, TSL is the length of the spin-lock time, S0exp is a constant, and T1rho is the T1 relaxation time in the rotating frame. Estimation of T1rho relaxation times is performed using a modified version of the T1rho MATLAB-based analysis. Cartilage Segmentation for Post-Processing Talar cartilage will be manually segmented using anatomical images from a Proton Density Space (PD space) scanning sequence (ITK-Snap Software, GNU General Public License). All T1rho images of the same structures will be converted from the time dimension into three-dimensional images using ImageJ Software (National Institutes of Health). All three-dimensional T1rho data will be processed using custom-made Matlab code (Mathworks, Inc., Natick, MA, USA) to determine voxel-by-voxel relaxation times. T1rho data will be overlaid onto the anatomical PD space image to determine volumetric and T1rho outcomes for specific areas of the talus. T1rho relaxation time data from the talus will be divided into anterior, middle and posterior sections for analysis (Figure 5). Statistical Analysis Specific Aim #1: Determine if SMART improves clinical outcomes (patient-reported function and quality of life, LAS re-injury rates, postural control, ankle ROM) and ankle joint integrity (articular cartilage turnover) in LAS patients. Specific Aim #2: Determine if SMART improves innovative measures of central nervous system function (corticospinal excitability and brain white matter integrity) in LAS patients. The primary comparison we will make in these two aims is how does the SMART improve short-term and long-term clinical outcomes, ankle joint integrity CNS function relative to the SOC. This means we will compare those Intervention groups at each Time point. Additionally, using a prospective cohort design will be able to dichotomize all participants into either the CAI or LAS Coper Group at the end of the 12-month follow-up, based on the re-injury rates and ankle-specific disability questionnaires. This will allow us to track these subgroups during all three time points to examine how the assigned intervention influenced their development of long-term disability from the beginning to the end of the study. Therefore, for each dependent variable in these specific aims, we will employ a three-way, mixed model ANOVA model (Intervention by Time by Group). In the event of statistically significant interactions, we will employ Tukey's post hoc testing. Statistical significance will be set at $P < 0.05$. Multiple covariates such as age, gender, body mass, physical activity and severity of ankle injury will be considered in these models. Statistical significance will be set at $P < 0.05$ for all analyses. Specific Aim #3: Delineate the association between explanatory mechanistic measures (corticospinal excitability and brain white matter integrity) and the hypothesized improvements in clinical and ankle joint integrity in LAS patients receiving SMART. To determine the strength of associations between the clinical and innovative measures, we will employ Pearson Product Moment correlations. The following criteria will be used to interpret correlation coefficients (r): 0.00-0.29 = negligible correlation, 0.30-0.49 = low correlation, 0.50-0.69 = moderate correlation, 0.70-0.89 = high correlation, 0.90-1.00 = very high correlation.⁸⁶ To determine differences in correlation coefficients between the CAI and LAS Coper groups, Fisher's r-to-z transformations will be employed.

Attachments

Attach Type	File Name
ResearchProcedures	Pages from ProjectNarrative and Attachment 12.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

All data and questionnaires will be stored and managed in the University of Kentucky's Research Electronic Data Capture (REDCap), the secure, web-based application designed exclusively to support data capture for research studies. Data will be collected in the native programs, as appropriate, and exported to REDCap.

Attachments

Attach Type	File Name
DataCollection	Data Collection Forms.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see [FDA Guidance](#)). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are

geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see [IRB Application Instructions - Off-Site Research](#) web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

Facilities and Resources Sports Medicine Research Institute The Sports Medicine Research Institute (SMRI) is a 9000 square foot state-of-the-art facility located in the University of Kentucky's Nutter Training Facility and comprised of a research laboratory, academic/administrative offices, and conferencing space. It is a multidisciplinary research facility dedicated to injury prevention, performance, treatment, and rehabilitation, specializing in musculoskeletal, neurobehavioral, and physiological/metabolic health. The SMRI is supported by a team consisting of thirteen core faculty, staff, and graduate students, and 44 affiliated faculty across the University. **Laboratory Facility** The SMRI is outfitted with biomechanical, physiological, musculoskeletal, and neurocognitive equipment. The biomechanics laboratory includes a 14 camera 3D motion analysis system, dual force plate system, multi-axial and virtual reality stability device, accelerometers, and inertial measurement unit system. The exercise physiology laboratory includes desktop and portable metabolic units, electromagnetic cycle ergometer, multiple treadmills, and wearable technology. The neurobehavioral laboratory includes visual acuity hardware/software, visual motor and neurocognitive rehabilitation and sports training device, and neurocognitive software. The musculoskeletal laboratory includes isokinetic dynamometry, handheld dynamometer, therapeutic exercise equipment, and diagnostic ultrasound. SMRI's dedicated lab space is connected to the UK Athletic Training Facility. The SMRI is located within the athletics facilities portion of campus. Within the same building as the SMRI are the coaches and team meeting rooms, athletic training room, nutrition room, and sports performance training facility for track and field, baseball, swimming and diving, golf, and tennis. The SMRI is within five to fifteen-minutes walking distance from all UK Athletic facilities on campus including, football, basketball, soccer, and softball. The SMRI's proximity and integration into athletics provides easy access to the student athletes, coaches and administrators on campus. The SMRI currently assists on an as-needed basis for rehabilitation, injury, and performance consultations for our athletic teams and student athletes on campus. This relationship with the individual teams and their coaching and medical staff will be a significant aid in facilitating recruitment and retention of research subjects for this proposed project. **Clinical** The SMRI is outfitted with two clinical examination rooms for physicians to evaluate patients as part of their regular clinical practice and research enrollment. The SMRI also has sufficient space and therapeutic exercise equipment for physical therapy or other rehabilitation services. **Computer** Multiple computers are available for data collection, processing and analysis, with data redundancy completed by peripherals and the internal server/network for the SMRI. The computers are latest generation Intel quad core i7 processor, with a minimum of 8GB RAM and 256GB SSD. Systems are configured with Windows Pro OS (7 or 10) and various Office, statistics, and programming software. All graduate students are provided workstations within the laboratory. All personnel are provided with full support of computers and information technology to enhance productivity. **Offices** Dr. Gribble has a 100-square foot office in the College of Health Sciences, within close proximity to SMRI. His office is equipped with a dedicated telephone line, personal computer, printer and filing cabinets to ensure confidentiality of records. Dr. Gribble also has a dedicated workspace in SMRI. Drs. Abt and Heebner have 150-square foot offices at SMRI that are fully equipped and conducive to team meetings. The research coordinator's office is adjacent to Dr. Abt's office. SMRI is staffed with an administrative staff support person who provides phone coverage and administrative support during regular business hours. When not on-site together, the investigative team can meet via Zoom teleconferencing in any UK investigator office or in the SMRI state-of-the-art conference room. **Video-Teleconferencing** Each faculty has access to Zoom video conferencing and web conferencing service. This technology is widely used by UK investigators and allows for immediate and scheduled communication with unlimited participants across multiple platforms. Zoom unifies cloud video conferencing, simple online meetings, group messaging, and a software-defined conference room solution into one easy-to-use platform. Security features include work email single sign-on, Secure Socket Layer encryption, AES 128-bits encryption, HTTPS access, role-based access control, and admin feature controls. Zoom will be used by the investigators for all video teleconference/teleconference meetings between existing investigators and development of new collaborations. **Other Resources: Institutional Faculty Resources.** As a University of Kentucky faculty member, the PI and his co-investigators have access to robust research-support services, including multiple core facilities, shared resources, and outstanding clinical research expertise. The services most integral to this project include: REDCap Project and REDCap Survey. UK is a member of the Research Electronic Data Capture (REDCap) Consortium, a coalition of institutions that supports a secure web application designed to support data capture for research studies. The application allows users to build and manage online surveys and databases quickly and securely. The core supports REDCap Project and REDCap Survey by providing training and design support to CCTS investigators. REDCap Project allows researchers to easily collect data for research studies ranging from simple laboratory-based studies with limited data collection and participants to complex multi-site clinical trials with multiple encounters per participant. Data collection forms and surveys are easy to create and modify and are available through a simple web-based interface that provides strong security and audit trails. Authorized users can download data collection forms and surveys into several formats for further analysis. The UK REDCap instance, launched in 2009, has over 2,000 production projects and over 2,000 users. **Participant Recruitment Services.** To support studies involving human subjects, the UK Center for Clinical and Translational Science (CCTS) provides wide-ranging participant recruitment services (PSR) such as consultation and strategic support for development of advertising campaigns; planning and creation of flyers, brochures, educational materials, posters, and postcards; and development of web, social media, video, and camera-ready resources. Services also include assistance with recruitment language for IRB submission, tools to capture enrollment metrics, and representation at community outreach events. PSR assistance is supported by various digital and software tools including the i2b2 tool to access the CCTS clinical data warehouse in order to estimate a specific patient population, the ResearchMatch registry funded by the CTSA as a recruitment tool, and the Kentucky Women's Health Registry. **Office of Research Integrity.** The UK Office of Research Integrity (ORI), a unit reporting to the Office of the Vice President for Research, plays a central role in the institution's fully accredited Human Research Protection Program (HRPP). The ORI promotes research within the current ethical, regulatory, and legal framework by supporting investigators, staff, and students with human research protections, regulatory oversight, privacy requirements, and data retention and ownership. The UK Human Research

Protection Program (HRPP) achieved full accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in June 2007 after a three-year evaluation process. The UK HRPP was re-accredited and awarded five-year cycles for accreditation in 2010 and 2015. Achieving accreditation demonstrates UK's commitment to the highest ethical standards in the conduct of human research. The professional team of over 20 staff members collectively provide key administrative support to six federally mandated review boards: four Medical Institutional Review Boards (IRBs), one Nonmedical IRB, and the Radioactive Drug Research Committee. Specific areas of administrative responsibility include protocol review, ethics/regulatory training and advising, quality improvement and efficiency initiatives, allegation and compliance reporting, and research compliance policy development. In addition, designated ORI staff facilitate IRB review of off-site and collaborative research and coordinate IRB reliance agreements for select multi-site research. ORI administrators serve as liaisons with other institutional administrative units with responsibilities for human research protection and research compliance. A designated Research Compliance Officer within the ORI, who is unaffiliated with any specific research protocol, provides a confidential channel for all research participants to discuss problems, concerns, and questions; obtain information; or offer input. This team will play an integral role in this multi-site study. The University of Kentucky Research Foundation (UKRF). UKRF serves as the university's agent in the receipt of all external grants and contracts, intellectual property income and other designated income; oversees the protection, development, and commercialization of intellectual properties; and manages special cooperative agreements. The Office of Sponsored Projects Administration (OSPA), a unit within the Office of the Vice President for Research, serves UKRF in the procurement, review, approval, and submission of proposals. OSPA ensures compliance with the terms and conditions of grants and contracts, including the submission of progress, final, and other appropriate reports, excluding financial reports. OSPA also provides general grant, contract, and agreement administration with project sponsors. University Financial Services (UFS) provides post-award grant accounting, including financial reporting, invoicing, and collection of receipts in accordance with federal, state, and sponsor guidelines. UFS also oversees time and effort reporting functions. College of Health Sciences Resources: The UK College of Health Sciences, the administrative home of the SMRI, offers investigators robust administrative and research support services. Administrative/financial oversight. The College of Health Sciences works closely with OSPA and UFS to establish, administer, and close sponsored awards. A College Grants Officer (CGO) is employed by OSPA and assigned to the College. The CGO serves as the liaison between OSPA and the College. The CGO provides financial grant reports and meets monthly with the project director to review expenditures and plan budget adjustments. The CGO serves as the liaison between the project and OSPA to ensure the program remains in compliance with university and federal policy. CHS's Office of Finance and Administration supports the College's academic, research, and service efforts in managing financial resources. This professional staff of six full-time employees is responsible for personnel and financial management for the College, including financial reporting, facilities management, purchasing, payroll, and grant management. As a public, land grant university, UK's business processes are governed by a comprehensive set of Administrative regulations (uky.edu/regs/ar.htm) and a detailed Business Procedures Manual (uky.edu/ufs/business-procedures-manual). Office of Research. The college has a dedicated Office of Research wholly dedicated to support faculty investigators as they seek and secure intramural and extramural funding. The Office of Research is staffed with the Associate Dean for Research, the Director of Extramural Support, The College Grants Office and an administrative support specialist. This office identifies appropriate funding opportunities, offers proposal development support, and serves as a liaison between the faculty investigator and various university departments and colleges. The Office of Research works closely with individual faculty on all pre-award and post-award issues. The Office of Research offers competitive pilot grants annually to assist with the collection of preliminary data to better position faculty for extramural support. Additionally, the Office of Research hosts a monthly (academic year) grantsmanship seminar. This seminar provides faculty and doctoral students the opportunity to share their proposed research ideas and receive critical input from other investigators. Financial Resources. The College of Health Sciences invests in and rewards faculty research efforts. The university's Facilities and Administrative (F & A) rate is 53% for on-campus research. A portion of the F & A funds generated by extramural research is returned directly to the faculty investigator to support his or her laboratory (graduate research assistants, supplies, equipment maintenance, etc.). The University is supported with state budget dollars with salary lines dedicated to faculty positions. When a regular-title series faculty investigator is able to off-set their salary costs through sponsored research, a portion of the salary savings is returned directly to the faculty for investment in research and other scholarly supports. If a faculty member offsets 25% of their salary costs in a fiscal year, a portion of those funds are returned to the faculty in the form of a personal bonus. Professional Development. The College of Health Sciences is committed to growing young faculty into independent faculty investigators. Faculty development and mentoring are important responsibilities jointly shared by College faculty and administration. The College provides a structure for formal faculty mentoring with oversight by the CHS Associate Dean for Academic and Faculty Affairs. To facilitate 1:1 mentoring, the Department Chair, in consultation with the Division Director, identify appropriate mentoring faculty for each new faculty member. With the agreement of the CHS senior faculty member and new faculty member, the mentor-mentee relationship is established for one year. The mentor and mentee may choose to continue the relationship beyond the expected one-year commitment. The content and structure of the mentorship is individualized based on the needs and preferences of the pair. Meetings with the Department Chair about Distribution of Effort allocation, Faculty Performance Review, and 2- and 4- year reviews provide faculty members with additional opportunities to assess skills and progress and to discuss faculty development strategies. Department Chairs and faculty provide suggestions to the Associate Dean regarding faculty development needs, and these form the basis for periodic workshops and activities available to all CHS faculty. In addition to these activities, periodic Grantsmanship sessions are also available. Faculty are encouraged to attend university-sponsored faculty development opportunities throughout the year. They also are provided with funding and release time to attend and participate in professional meetings and faculty development activities. Equipment Sports Medicine Research Institute Major Equipment The SMRI is outfitted with a variety of biomechanical, musculoskeletal, and neurocognitive equipment. The neurobehavioral laboratory includes an iPad (Model A1822, Apple Inc, Cupertino, CA) use for neurocognitive assessments including the NIH Toolbox for assessment of Neurological and Behavior Function application and a dedicated network-wired desktop computer (Lenovo THINK Station, IBM Corp, Armonk, NY) and the REDCap electronic data capture tool application (supported by NIH/NCATS UL1 TR000445) used for demographic surveys and standardized questionnaires. The biomechanics laboratory space includes a motion analysis system (Vicon, Centennial, CO) with integrated force plate system (model 6090, Bertec Corp, Columbus OH) and portable 16 channel wireless inertial measurement unit system (IM Trigno sensors, Delsys Inc, Natick, MA). Integrated data collection utilizes Vicon Nexus software (Vicon, Centennial, CO) running in Microsoft Windows 10 operating system (Windows Corp, Redmond, WA) on a Dell Precision Tower 5810 (Dell Inc, Round Rock, TX). In addition to data collection instrumentation the SMRI is equipped with 11 networked desktop computer systems (Lenovo THINK stations and HP Z1 stations) at researcher workstations with access to Matlab (Mathworks, Natick, MA) data processing

software, SPSS (IBM Corp, Armonk, NY) statistical software, and an entire suite of Microsoft software packages through Office 365 (Windows Corp, Redmond, WA). The computers are latest generation Intel quad core i7 processor, with a minimum of 8GB RAM and 256GB SSD. Other University of Kentucky Resources Each faculty has access to Zoom video conferencing and web conferencing service. This technology has been used by investigators for the several years and allows for immediate and scheduled communication with unlimited participants across multiple platforms. Zoom unifies cloud video conferencing, simple online meetings, group messaging, and a software-defined conference room solution into one easy-to-use platform. Security features include work email single sign-on, Secure Socket Layer encryption, AES 128-bits encryption, HTTPS access, role-based access control, and admin feature controls. Zoom will be used by the investigators for all video teleconference/teleconference meetings between existing investigators and development of new collaborations. Zoom allows for true remote access and relies only on internet connectivity through cellular or wireless networks. Multi-Site Communication Weekly video-teleconference/teleconference meetings will be held with key personnel at the University of Kentucky, University of North Carolina, and WBAMC. These meetings will discuss subject recruitment, data quality, adverse events, confidentiality, subject complaints, and compliance relative to IRB procedures and test protocols. These meetings will also monitor project specific timelines and progress while addressing logistical implementation and impediments to successful completion of the identified aims. The study will also undergo a yearly review by the institutional review board. We do not anticipate any problems, but should anything occur it will immediately be reported to the Institutional Review Board, and the appropriate steps will be taken as per Institutional Review Board policies. The principal investigator will continually monitor the project for confidentiality and safety and consider the benefit relative to the risks. As needed during the quarterly meetings with the research team safety and data monitoring procedures will be reviewed. The principal investigator will review confidentiality, safety, and efficacy and in consultation with its Institutional Review Board, make decisions concerning stoppage of the study if needed. Data collection, transmission, storage, processing, analysis, and sharing procedures will be embedded within the IRB protocols of participating consortium institutions. This regular communication will be crucial in facilitating optimal oversight of clinical sites at UK, UNC, and WBAMC and translations of studies' progress and outcomes to be put into clinical practice or developed further in future research projects. Quarterly site visits will occur with the investigators to ensure data quality control and data collection procedures. The University of Kentucky will maintain a reliance agreement with the other institutions and will be the master IRB of record for any human subjects approvals. At WBAMC: All other regulatory requirements will be maintained through communication with WBAMC Human Research Protections Office (HRPO), as outlined below.

Adverse Events, Unanticipated problems, and deviations: The PI shall report all serious adverse events (SAE) to the WBAMC Human Protections Administrator, HRPO, and University of Kentucky IRB:

- Death due to *any cause*
- A permanent or substantial disability
- Hospitalization (inpatient admission or overnight stay) or prolongation of hospitalization
- An immediately life-threatening event
- Report of overdose (intentional or not)
- Report of congenital anomaly

A deviation is considered to be any change or departure from the research activities outlined in the approved protocol, that is *under a researcher's control* and that has not been reviewed by the WBAMC IRB and approved by its Institutional Official prior to its initiation or implementation. A protocol deviation may include accidental or intentional changes, including changes made to eliminate an immediate hazard to subjects or others. Note that unapproved departures from the study design or procedures that *are not under the control of the research team* are considered unanticipated problems.

A change to research without prior IRB approval constitutes a "deviation" If an investigator makes an unapproved protocol change to eliminate an apparent hazard to subjects, the Principal Investigator (PI) must immediately report the change by phone or email to the WBAMC Human Protections Administrator, HRPO, and University of Kentucky IRB. The PI then completes a Report, which must be submitted to the IRB within one (1) week of the deviation.

Modification of Protocol

Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to WBAMC Human Protections Administrator and University of Kentucky IRB for approval prior to implementation. - All other amendments will be submitted with the continuing review report to the USAMRMC HRPO for acceptance.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Foreseeable Risks The procedures outlined for measuring rehabilitation outcomes proposed are considered safe. The PI and the Co-PI each have over 10 years of experience with performing the proposed measures without incidence of injury. There are no serious risks to participants that are associated with participating in this research. The potential risks for participants in the current study are minimal, and include the following:

- Participants could develop minor, local, transient skin irritations from electrodes used for the corticospinal and spinal reflex excitability measures.
- Participants could develop minor, transient muscle soreness from the SOC or the SMART protocols and the proposed outcome measures.
- Participants may experience mild discomfort at the site of magnetic stimulation and transient headaches.
- While seizures are the major risk for transcranial magnetic stimulation (TMS), the risk of seizures is less than 1 in 10,000.
- Participants may feel restless or uncomfortable when lying in the MRI scanner.
- Participants could experience claustrophobia due to their presence in the MRI scanner.
- The MRI scanner produces loud noise, and all participants are required to wear ear protection provided by the experimenter.
- There are always possibilities that unknown side effects may occur during or following testing. As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and we will follow thorough procedures to maintain confidentiality.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

All participants will be recruited from the university and local communities in the cities of each study site through partnerships, referrals, flyers, and advertisements. All recruitment efforts will be in compliance with HIPAA regulations. The Co-PI's will oversee recruitment procedures at their study site. Participants may contact the PI's on their own volition after seeing flyers and recruitment materials. Clinicians (physicians, physical therapists, athletic trainers, physiotherapists, etc) may alert patients with ankle sprain history of the study. They will screen the patients for the presence of any conditions that would make the patient ineligible for the study (see exclusion criteria above). The clinicians will only refer patients that they believe are qualified for the study and express an interest in participating. Interested patients will be provided with additional detailed information regarding the study by the Investigative Team. Oral and written information will be provided that explains to the patient in simple terms: 1) the criteria for participation, 2) the purpose of the research and the procedures involved, 3) the patient's right to withdraw at any time without penalty, 4) potential risks and benefits to the patient, 5) assurance of anonymity, and 6) terms of remuneration. If the potential patient meets the acceptance criteria and is interested in participating, the information just described will be reviewed, questions will be answered, and the patient will be requested to sign the consent form. All protocols and techniques to be used will be approved by the Institution Review Board and the Scientific Advisory Committees as applicable to each study site prior to initiation of the study. Informed written consent will be obtained from a member of the study team who has been trained according to institutional guidelines. Volunteers will meet with a study representative in a private and quiet room and will be permitted ample time to read the document in an unhurried setting. The study representative will be present to answer questions regarding the study or procedures, should they arise. Once the volunteer has read over the document, the study representative will review the entire document with the patient to be sure that the procedures

and time commitments are understood. The volunteer's comprehension and autonomy will be assessed by asking patients to explain in their own words what the study is about. The patient will initial the bottom of each page once this has been done. The patient will receive a copy of the signed and dated consent document. The study representative will then review the HIPAA Authorization form and explain what protected information will be collected, who will have access to it, and what steps will be taken to protect this information. The volunteers will initial the bottom of each page once this has been done, and will receive a copy of the signed and dated HIPAA Authorization form. Confidentiality of all medical records is strictly maintained by established procedures. Volunteers will be identified in computer files only by a coded patient ID that is unique to the study and distinct from any medical record numbers. Only the research staff (at each local site) will have access to these codes. Codes will not be shared across sites. All hard copies of data and backup disks of computer files related to this study will be stored in a locked cabinet located in the study coordinator's office. The office is locked when the coordinator is not present. The study personnel have extensive experience in the conduct of all aspects of the proposed investigation. The following special precautions will be taken. Study personnel are all trained in CPR and Emergency Response techniques and hold certifications for this skills (i.e. American Red Cross). Certifications will be kept in IRB study binder along with human subjects research training credentials. Appropriately maintained emergency equipment (i.e. AED's) is accessible in all facilities. To minimize the risk for muscle strains or ligament sprains during testing, patients will be given adequate warm-ups and practice attempts. To minimize the risks with treatment, specific guidelines for advancing exercise have been developed as described in the Research Design and Methods. In order to minimize the risk associated with the TMS testing (transient headache, scalp soreness, or seizure), all patients will be carefully screened for eligibility using the following TMS exclusion criteria from the National Institute of Neurological Disorders will minimize any risks: 1) personal or familial history of epilepsy or seizures; 2) history of migraine headaches; 3) ocular foreign body, increased intracranial pressure, open head injury or significant closed head injury; 4) cochlear implants; 5) implanted brain stimulators, aneurysm clips or other metal in the head (except mouth); 6) implanted medication pumps, pacemakers or intracardiac lines; 7) current medication with tricyclic anti-depressants, neuroleptic agents or other drugs that lower seizure threshold; 8) history of diagnosed major psychiatric disorder; 9) history of illicit drug use; 10) current alcohol abuse or currently withdrawing from alcohol abuse; and 11) history of heart disease. All patient information will be kept confidential, and patients

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc...), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for [Protection of Vulnerable Subjects \[C3.0100\]](#) (PDF).

The patients benefit immediately from the educational experience surrounding frequent interaction with the investigators who are highly interested in addressing functional limitations following LAS. In addition, there are possible long-term benefits for improvements in function and general health for patients receiving progressive rehabilitation. Finally, all LAS patients enrolled will receive free rehabilitation during the study enrollment. The LAS patients enrolled in the SOC group will be offered access to the SMART intervention program after completion of the study enrollment at the 12 month follow up. As the risks associated with the proposed measures in this study are low, this study has a high benefit to risk ratio.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

NA. The standard of care treatment as part of this study is consistent with what the patient would receive had they chosen not to participate in this study.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):

If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "[Frequently Asked Questions \(FAQs\) on the Return of Research Results or Incidental Research Findings](#)" (PDF).

All information collected will be de-identified. Tracking will be limited to contact information obtained during initial enrollment.

Confidentiality: Specify where the data/specimens will be stored and how the researcher will protect both the data and/or specimens with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality); and procedures employed when sharing material or data, (e.g., honest broker (if applicable), written agreement with recipient not to re-identify). If you plan to procure, store, and/or share material (tissue/specimens/data) expressly for use in current or future research, describe measures that you will take to secure and safeguard confidentiality and privacy.

Provide a time table for destroying the data/specimens and identify how they will be destroyed, or provide rationale for perpetual maintenance [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the [Study Closure SOP](#) (PDF). If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if

longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK.

NIH-funded genomic research: The National Institutes of Health (NIH) [Genomic Data Sharing \(GDS\) Policy](#) sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Please note: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "[Confidentiality and Data Security Guidelines for Electronic Data](#)" (PDF).

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriate protected.

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There is an extremely small risk of loss of confidentiality. The investigators will make every effort to maintain each and every participant's confidentiality. While the information gained during this study is not typically considered sensitive, injury information from an athletic population may be considered sensitive. The investigators will record all information in the database, but it will not be linked to your name in a database. To reduce the risk of loss of confidentiality, all collected data will be kept in a locked cabinet in the principal investigator's office, or on a password protected computer. Only the investigators in this study will have access to the data that is collected. In addition to the risks listed above, subjects may experience a previously unknown risk or side effect. As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and we will follow thorough procedures to maintain confidentiality. Confidentiality of all medical records is strictly maintained by established procedures. Volunteers will be identified in computer files only by a coded patient ID that is unique to the study and distinct from any medical record numbers. All hard copies of data and backup disks of computer files related to this study will be stored in a locked cabinet located in the study coordinator's office. The office is locked when the coordinator is not present. Any information about the subjects obtained from this research will be kept as confidential (private) as possible. The identity of the subjects enrolled under this project will be coded rather than listed by name. A unique identifier (UK001..., UNC001..., and WBAMC001...) will be created for each aim with hierarchical delineation of aim for which the specific research subject is enrolled. The subject identifiers will allow for the data to be queried and to address specific research questions that are dependent on aim or subject specificity. Only the site PI and coordinator (at each site) will have access to these codes. The study PI (Gribble) will have access to all codes per regulatory guidelines. These codes will be maintained separately from the research records on a secured HIPAA compliant University of Kentucky network server. Access to the linking file will be limited to the Principal Investigator. Hard-copy paper forms that contain identifiable information, such as consent forms, will be kept locally at UK, UNC, and WBAMC, in a separate locked filing cabinet from all other study material. The only people with key access to the filing cabinet will be the site PI and coordinator (at all sites). When the results of the research are published or discussed in conferences, no information will be included that would reveal individual subject identity. Individual study investigators will only be provided de-identified data. Access to the data will be limited to the site PI and coordinator (at all sites) and exported from the database as requested. The restricted mechanism will be established to prevent improper handling, accidental deletion or corruption of data, or inadvertent release of identifiable data. Data will be maintained for a period of seven years after the completion of the study and then destroyed using software designed to sanitize electronic storage devices. Also at this time any paper records that include identifiable information, such as consent forms, will be destroyed.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Non-military personnel will be compensated \$100 for completing all aspects of the study. Federal personnel will not be compensated for participation in this study.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a

consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There will be no costs involved for participating in this study.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). [Click here for additional guidance on developing a Data and Safety Monitoring Plan.](#)

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, [click here for additional guidance](#) for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review. ⓘ

The primary investigator will monitor confidentiality and data bi-monthly to ensure accuracy and recruitment of subjects. Weekly meetings, with the co-investigators, will be held to verify compliance and testing procedures. These meetings will monitor recruitment, retention, data, adverse events, and breaches in confidentiality. All hard copy records related to involvement in this research study will be stored in a locked file cabinet at UK, UNC, and WBAMC. An electronic repository is used to store data and is maintained on a secured network server. This data will be house on a University of Kentucky HIPAA-compliant server. Data access will be limited to those investigators listed on the project. Data will be maintained for a period of seven years and then destroyed using software designed to sanitize electronic storage devices.

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Complaints about the study, a subject can contact the investigators, Phillip Gribble at 859-218-0885 or phillip.gribble@uky.edu. (UK), Eric Wikstrom at 919-962-2260 or ewikstro@email.unc.edu (UNC), MAJ Gary Helton at 915-742-1511 or gary.l.helton8.mil@mail.mil. The subjects will be encouraged to ask questions at any time during the consenting process to determine if he would like to participate and throughout the study to determine continued participation. Subjects having any questions or concerns about this study or rights as a research subject may contact the principal investigator or the University of Kentucky's Office of Research Integrity at 859-257-9428 or toll free at 1-866-400-9428.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture?**

☒ Yes ☐ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the IRB Application Instructions on [Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture](#).

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first.**)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the [International Compilation of Human Research Standards](#)

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc....)?**

☐ Yes ☒ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "[Reporting Requirements for Diseases and Conditions in Kentucky](#)" (PDF).

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online [IRB Survival Handbook](#) to download a copy of the Medical IRB's requirements for [Protection of Human Subjects in Research Involving HIV Testing \[D65.0000\]](#) (PDF), and visit the [Office for Human Research Protections web site](#) for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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- 1) involves testing a Nonsignificant Risk (NSR) Device, or
- 2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

☐ Yes ☒ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the PI assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor [IND regulatory requirements for drug trials](#) (PDF), [IDE regulatory requirements for SR device trials](#) (PDF), and [abbreviated regulatory requirements for NSR device trials](#). For detailed descriptions see [FDA Responsibilities for Device Study Sponsors](#) or [FDA Responsibilities for IND Drug Study Sponsor-Investigators](#).

- Describe your (the PI's) experience/knowledge/training (if any) in serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if you have transferred any sponsor obligations to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see [Sponsor-Investigator FAQs](#)). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the PI completed the mandatory PI-sponsor training prior to this submission?

☐ Yes ☒ No

If you (the PI) have completed equivalent sponsor-investigator training, you may submit documentation of the content for the IRB's consideration.

[Attachments](#)

HIPAA

Is HIPAA applicable? ☐ Yes ☐ No

(Visit ORI's [Health Insurance Portability and Accountability Act \(HIPAA\) web page](#) to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s): 

☐ HIPAA De-identification Certification Form

☐ HIPAA Waiver of Authorization

Attachments



Consent to Participate in a Research Study

ADDRESSING NEUROMUSCULAR DEFICITS FOR IMPROVED OUTCOMES IN ANKLE REHABILITATION

IRB Approval
8/9/2018
IRB # 44172
ID # 58854

You are being invited to take part in a research study about successful outcomes following lateral ankle sprain rehabilitation. You are being invited to take part in this research study because you have sustained a lateral ankle sprain as diagnosed by a health care provider. This is a joint study between the University of Kentucky, the University of North Carolina at Chapel Hill, and William Beaumont Army Medical Center (WBAMC).

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to examine the effects of rehabilitation on short and long-term outcomes following lateral ankle sprain.

By doing this study, we hope to learn how the initial treatment of lateral ankle sprain affects future return to full activity, function, and pain.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this research study you will have the opportunity to engage in unique opportunity to engage in unique performance measures that will be tracked as you progress through a prescribed ankle rehabilitation program under the guidance of a health care professional, and during a follow-up period of 12 months after you have completed rehabilitation for your ankle sprain. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not participate in this study if you have had a lower extremity fracture or surgery, previous history of ankle sprain to either limb, and acute lower extremity or head trauma in the 3 months prior to testing.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You may choose not to participate in this study, and your care will not be affected in any way. There is no alternative research study to participating in this study. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study at each site. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Phillip Gribble at 859-218-0885 or phillip.gribble@uky.edu. (UK), Eric Wikstrom at 919-962-2260 or ewikstro@email.unc.edu (UNC), MAJ Gary Helton at 915-742-1511 or gary.i.helton8.mil@mail.mil (WBAMC).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify for this study if you have had a lower extremity fracture or surgery, previous history of ankle sprain to either limb, and acute lower extremity or head trauma in the 3 months prior to testing.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

If you are enrolling at the University of Kentucky, the research procedures will be conducted at the University of Kentucky Sports Medicine Research Institute (UK-SMRI), Musculoskeletal Laboratory (MSL), Magnetic Resonance Imaging and Spectroscopy Center (MRISC) and in your home.

If you are enrolling at the University of North Carolina, the research procedures will be conducted at the Sports Medicine Research Laboratory and UNC Health Care.

If you are enrolling at WBAMC, the research procedures will be conducted at the Department of Physical Therapy and the Department of Radiology for testing procedures.

For all sites: The initial in-person visit will take approximately 20 minutes to be consented and complete some surveys. You will be required to report for supervised rehabilitation sessions (about 3-4 times week) for up to eight weeks. Each of these rehabilitation sessions will last approximately 45 minutes. Additionally, you will be given some rehabilitation exercises to perform at home. You will be required to come to your campus sites for three testing sessions: at the completion of your rehab, six months after rehab, and 12 months after rehab. Each of these testing sessions will last approximately 120 minutes.

WHAT WILL YOU BE ASKED TO DO?

Rehabilitation Intervention

You will be asked to complete a supervised rehabilitation program that will focus on improving your strength, range of motion, balance, and physical function. You will report to a designated facility for sessions 3-4 times per week under the supervision of a licensed physical therapist and/or athletic trainer. He or she will guide through sessions lasting approximately 20-30 minutes. Additionally, you will be given hard copy printouts of some additional rehabilitation exercises you will be asked to complete in your home on the days that you do not come to our facilities for supervised sessions. You will be asked to keep records of your completed home rehabilitation sessions. These rehabilitation sessions will commence begin within 48 hours after you agree to participate in this study, and will continue for up to 8 weeks, depending on the severity of your ankle sprain.

Laboratory Measurements

We will take several measurements in our facilities on our campus to track your progress of your recovery from your ankle sprain. This battery of measurements will be repeated at multiple time points. The first visit will take place within a few days after you agree to enroll in this study, and will serve as your baseline. A second scheduled session will take place within a few days after your final rehabilitation session and will indicate your status when you are ready to return to full activity. A third session will be scheduled approximately 6 months after you return to activity to serve as a follow-up. A fourth and final session will be scheduled approximately 12 months after you return to activity to serve as a final follow-up.

The tasks and tests that will be used in these testing sessions include:

Self-Reported Questionnaires:

You will be asked to complete multiple self-report surveys. These surveys will ask you about how you feel about your overall health and physical activity, as well as the health of your ankles. This survey will be assessed at the initial encounter, as well as when you return to full activity, six months, and 12 months following the initial injury. The survey will be emailed to you for the follow up periods.

Dynamic Balance:

By balancing on one leg we will be able to assess your dynamic postural control. You will be positioned in the center of a grid resembling a “Y” that is outlined by three standard metric tape measures secured to the ground. You will be instructed to place your hands on your hips and stand on one leg. Next, you will reach as far as you can with your opposite leg while maintaining your balance and keeping your heel flat on the ground. Four practice trials for each direction will be provided and then three test trials for each direction will be recorded. Failed trials will be repeated until three successful trials are recorded for data analysis.

Ankle Range of Motion:

We will test how far you are able to comfortably move your ankle in a standing and in a seated position. During the standing position you will face a wall and place your hands on the wall to help maintain balance. Your feet will be placed in a tandem position (one foot in front of the other) over a secured tape measure. You will be asked to lunge as far as you feel comfortable until the front of your knee touches the wall and keeping your heel on the ground. During the seated position, you will sit on the edge of a treatment table and you will be asked to pull your toes up towards your head as far as you feel comfortable.

Maximal Ankle Muscle Response:

This test provides an estimate of how well nerves in the lower legs function. This test is conducted while you are lying down. You will be asked to relax your musculature. Two electromyography (EMG) electrodes (stickers) will be placed over your lower leg muscle (the soleus) on the testing leg and the medial malleolus on the non-testing leg. These electrodes do not do anything to you; they simply record your normal muscle electrical activity. The areas of the EMG electrodes will be shaved, gently scraped with fine sandpaper, and cleaned with isopropyl alcohol wipes. This is done to help the electrodes get the best reading possible of the muscles under that skin area. An electrode that provides a stimulus will be taped on the backside of your knee. Several reflex measurements will be taken while you are lying down.

These measurements include several brief (1-millisecond) electrical stimuli in order to make the nerve respond reflexively. The intensity of each stimulus will vary depending on the reflex being elicited. You will feel the stimuli similar to static electricity felt as you touch a doorknob after walking across carpet.

Neural Excitability:

This testing provides us important information regarding how your brain is sending messages to muscles controlling your ankle. You will be asked to sit in a chair that resembles a car seat. You will have a seat belt applied so that you do not move your body as you attempt to contract your lower leg muscles as hard as you can. Specifically, you will be asked to move your ankle like you are pushing down on a gas pedal as hard as you can and hold it for five seconds. You will then be asked to pull your ankle towards you as hard as you can. We will position a coil over your head and adjust the position of the coil until it is in the ideal spot to deliver a stimulus to the muscles we are studying. We will ask you to wear a swim cap and ear plugs. A brief magnetic stimulus will then be produced which will sound like a “click.” You may feel a brief muscle contraction in the muscles of your ankle. You will be asked to flex certain lower leg muscles at a small to moderate intensity while we provide a series of brief magnetic stimuli to your head. Sets of 8 stimuli will be delivered. The intensity of the stimuli will be varied up and down with each set until the researchers find the lowest intensity possible that makes your muscle contract 4 out of 8 times during a set. Stickers (electrodes) will be placed on the skin overlying the muscles of your legs (the soleus and tibialis anterior muscles). These electrodes record the activity of your muscles. This process will take approximately 20 minutes.

You will be taken to the MRI scanner in the Magnetic Resonance Imaging and Spectroscopy Center by the experimenter. In the interest of your individual safety, the safety of others, and to prevent damage to the equipment itself, you will be asked to remove all jewelry, body piercings, hair accessories, belts, wallets, credit cards, and loose change and leave these items with the experimenter. You will also fill out a short questionnaire asking about the presence of metal in your body. You will then be instructed about specific MRI procedures, which include the need to remain still while in the scanner, the need to remain attentive and awake during the study, and how we will communicate with you while you are in the MRI scanner. The experimenter will then place you on the bed of the MRI scanner and will take a few minutes to make sure you are positioned correctly and are comfortable. You are then placed into the MRI scanner, the experimenter goes to the control room and communicates with you via an intercom system.

We will take scans of your brain and of your ankle. The MRI scans will start with a scan of your brain. You will be asked to lay flat on your back on a table that will slide into the scanner. We will place a coil around your head neck that resembles a neck brace. Once you indicate you are comfortable, the table will slide into the scanner and the procedures will begin. After the brain scan is complete, the table will slide you out of the scanner and the neck coil will be removed. You will be asked to reposition yourself on the table so that your feet are now facing the scanner. A flexible coil will be wrapped around your foot and lower leg comfortably, and then the table will slide into the scanner again to complete the scan of your ankle.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

When participating in any research study, you may encounter some risks. Although the risk for taking part in this study is very low, you may experience one or more of the following:

1. Because you are performing balance tests, there is a slight chance of falling and or losing your balance during the testing. However, you will be given instruction on how to perform the task and as much practice as you need to become comfortable with the task. Finally, an investigator will be standing nearby in the unlikely event that you need assistance.
2. You may experience minor muscle soreness or tiredness for one to three days following the study as you would after exercising strenuously or doing a new activity for the first time. You will be given the rest periods between test trials in order to minimize this risk.
3. You might experience minor discomfort from noise associated with the magnetic stimulation pulse (less likely risk). To minimize this risk, you will be offered ear plugs to wear during testing. Hearing loss has also been reported, but only in patients given multiple repetitive magnetic stimulation to treat disorders such as depression. You will not be receiving repetitive magnetic stimulation.
4. You may experience mild, temporary skin irritation from the electrodes and markers, although this is a very unlikely risk.
5. You may experience a mild headache following magnetic stimulation and lasting a few hours after testing although these risks are very unlikely risks.
6. In individuals with a history of seizures, there is a slight possibility of causing a seizure with the magnetic stimulation; therefore, you must tell us prior to testing if you have ever had a seizure so we can exclude you from the study.
7. Magnetic stimulation of the brain is safe; however, it may have short or long-term risks associated with it that are not presently known or suspected. If you become pregnant, the particular procedures involved in the study may involve risks to the embryo or fetus that are currently unknown.
8. If during the MRI an incidental finding is seen, we will provide you a recommendation for possible follow-up with your physician.

The risks of participating in the MRI study are outlined in the table below.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Claustrophobia	It occasionally occurs	Can be treated	Yes, participant is removed from the magnet
Loud noise	It is expected to occur	Not serious	Yes, participants wear ear protection

There is a slight chance of falling and or losing balance of participants during a balance assessment, or feeling tired while walking. In addition to the risks listed below, you may experience a previously unknown risk or side effect.

There is an extremely small risk of loss of confidentiality. The investigators will make every effort to maintain each and every participant's confidentiality. While the information gained during this study is not typically considered sensitive, injury information from an athletic population may be considered sensitive. The investigators will record all information in the database, but it will not be linked to your name in a database. To reduce the risk of loss of confidentiality, all collected data will be kept in a locked cabinet in the principal investigator's office, or on a password protected computer. Only the investigators in this study will have access to the data that is collected. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help certified athletic trainers, physical therapists, and sports medicine physicians to better treat ankle injuries across the population.

WHAT WILL IT COST YOU TO PARTICIPATE?

There will be no cost involved in participating in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

Officials of the Department of Defense, the University of Kentucky, and U.S. Army Medical Research and Materiel Command may look at or copy pertinent portions of records that identify you.

REDCap, a secure, web-based program, will be used to capture and store data at the University of Kentucky. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to the server.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition*;
- authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.
- For WBAMC: Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep all names and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

First, we will give everyone a code number and remove their names from all data collection documents. All information that is collected will be kept in a locked cabinet in an investigator's office. All electronic data will be password protected.

Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky, University of North Carolina, WBAMC, and the Department of Defense.

The information that we obtain from you may be included in future studies for other types of comparisons. However, the information used will have no identifiable link to your personal identification.

Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still in route to us.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

For patients enrolled at WBAMC, you may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. Whether or not you withdrawal your participation in this research study will have no effect on your current or future relationship with the US Army, Department of Defense, or military status. Whether or not you withdraw, your participation in this research study will have no effect on your current or future medical care within the military.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Phillip Gribble at 859-218-0885 immediately.

Dr. Phillip Gribble and the local principal investigator will work together to determine what type of treatment, if any, is best for you at that time.

For patients enrolled at UK or UNC: It is important for you to understand that the University of Kentucky, University of North Carolina, or WBAMC do not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, neither the University of Kentucky nor the University of North Carolina will pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be

- your responsibility
- or**
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or**
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be costly.

For patients enrolled at WBAMC:

If you think that you have a research-related injury, notify your Principal Investigator immediately: MAJ Gary Helton at 915-742-1511.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

For all participants: You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

The Department of Defense is providing funding in support of this study.

For non-military personnel, you will receive \$100 payment for completing all aspects of the study. For military personnel, per DOD guidelines you will not be paid for your participation in this study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. Because the investigators will not have access to information that identifies you, the research findings will generally not be provided to you.

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Dr. Phillip Gribble; 900 South Limestone, 206C Wethington Building, University of Kentucky, Lexington, KY 40536-0200.

WHAT ELSE DO YOU NEED TO KNOW?

A description of this clinical trial will be available on [ClinicalTrials.gov](https://clinicaltrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION OR SPECIMEN(S):

Identifiable information such as your name, medical record number, or date of birth may be removed from the information or samples collected in this study. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information (Date of birth, age, gender, race, ethnicity, occupation)
- Last four digits of social security number
- Military identification number
- Contact information

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- WBAMC Human Research Protection Office Representatives
- Officials at the Department of Defense and U.S. Army Medical Research and Materiel Command

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky, the University of North Carolina, or WBAMC;
- Current or future payments to the University of Kentucky, the University of North Carolina, or WBAMC;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Phillip Gribble, phillip.gribble@uky.edu, Room 206C Wethington Building, 900 South Limestone Street, Lexington, Kentucky 40536-0200 to inform him of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information. The use and sharing of your information has no time limit.
- Your health information is being used for this study only and is not requested for future research studies.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent
- Authorization to Use or Disclose Your Identifiable Health Information

You will receive a copy of this consent form after it has been signed.

Signature of research subject or, if applicable, *research subject's legal representative	Date
Printed name of research subject	
Printed name of [authorized] person obtaining informed consent and HIPAA authorization (if HIPAA applies)	
Signature of Principal Investigator or Sub/Co-Investigator	



Purpose of form: If not using the SMART IRB Online Reliance System to coordinate and document study-specific reliance arrangements, institutions may use this template to document the Reviewing IRB and Relying Institutions for a study.

ACKNOWLEDGEMENT OF SITE AGREEMENT TO CEDE IRB REVIEW AND REVIEWING IRB TO PROVIDE OVERSIGHT

This form documents that:

- 1) University of Kentucky will serve as the Reviewing IRB for **The University of North Carolina at Chapel Hill** for the study noted below;

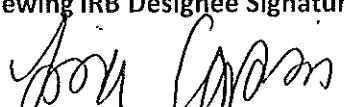
and

- 2) **The University of North Carolina at Chapel Hill** has agreed to cede IRB review to University of Kentucky for the study noted below.

Study Title:	Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation
Overall PI, IRB Study #:	Phillip Gribble, # 44172
UNC/Relying Site Investigator, IRB Study #:	Erik Wikstrom, # 18-1538

IRB review will be ceded under the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

Acknowledged by (sign/date):

Reviewing IRB Designee Signature:  Print Name: Lisa A. Cassis Title: Vice President for Research	Date: 7/11/18
Relying IRB Designee Signature:  Print Name: Elizabeth Kipp Campbell, Ph.D., CIP Title: Director, Office of Human Research Ethics	Date: 6/29/18

Questions about the IRB review process or study status should be directed to the UNC IRB point of contact (POC): John Roberts, Reliance Manager UNC-CH, jtr@unc.edu, 919-966-2748

**Department of Defense
Human Research Protection Program**

**DOD INSTITUTIONAL AGREEMENT
FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW (IAIR)**

General Instructions to Institutions and IRBs

- This form is should be used when an institution will be engaged in human subject research and will use an Institutional Review Board (IRB) that is not organizationally or legally part of the institution. This Agreement will help ensure that the engaged institution with the federal assurance and the IRB providing the review and approval of the research (in accordance with 32 CFR 219 and DoD Directive 3216.02) know the responsibilities of each party to this agreement. Contact your DoD Component Headquarters office (or DoD sponsor) for guidance if you want to submit an equivalent agreement or want to alter this form.
- This agreement will become an amendment to your DoD Assurance.
- Contact your DoD Component Headquarters office (or DoD sponsor) for guidance if you have questions.
- Follow your DoD Component Headquarters office (or DoD sponsor) instructions for paper or electronic submission.
- The "Institution Relying on the IRB Services" is the institution engaged in the research. The "Institution supplying the IRB Services" is the IRB or organization with the IRB.
- For DoD-sponsored extramural research: This agreement is needed for only for the external IRBs that will review DoD-sponsored research. It is not needed for any IRBs that review research not supported by DoD.

**Department of Defense
Human Research Protection Program**

**DOD INSTITUTIONAL AGREEMENT
FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW**

BETWEEN

**INSTITUTION RELYING ON THE IRB SERVICES: William Beaumont Army Medical
Center**

AND

**INSTITUTION SUPPLYING IRB SERVICES: University of Kentucky Research
Foundation**

**PART 1
INSTITUTION INFORMATION**

This DoD Institutional Agreement for IRB Review describes the responsibilities of the engaged institution and the institution with the IRB. This Agreement, when signed, becomes part of the engaged institution's Federal Assurance for the Protection of Human Research Subjects approved by DoD (and may become part of the Federalwide Assurance (FWA) approved by the Department of Health and Human Services (DHHS)).

A. Engaged Institution Relying on the IRB

Name: William Beaumont Army Medical Center
DoD Assurance Number (if applicable): DoDA10028
DHHS FWA Number (if applicable): 00005646
DoD Addendum to the DHHS FWA Number (if applicable):

B. Institution Supplying the IRB Services

Name: University of Kentucky
DoD Assurance Number:
DoD IRB Number* (if applicable):
DHHS FWA Number (if applicable): 00005295
DHHS IRB Number* (if applicable): 00000423, 00000424, 00000977, 00005975,
00004367
DoD Addendum to the DHHS FWA Number (if applicable): DoD N-A3381

*Provide for each IRB that is part of this agreement.

C. Scope

This Agreement applies to the following research conducted by the engaged institution:

☒ A single research protocol only (list title and other identifying information):

Title: Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

Funding: U.S. Army Medical Research and Materiel Command
Congressionally Directed Medical Research Programs (CDMRP)
Year 2017-18 Defense Medical Research and Development Program
(DMRDP), Neuromusculoskeletal Injuries Rehabilitation Research
Award – Funding Level 2

Grant: DM170430 (CDMRP Log Number)
GRANT 12288695 (Grants.gov ID number)

☐ A group of research protocols (describe here or attach list):

☐ All research performed by this institution.

D. Effective Dates

This Agreement is effective as of the date approved and signed by the DoD Component Designated Official and expires on the date listed in the DoD approval document.

PART 2 INSTITUTIONAL RESPONSIBILITIES

All institutions are responsible for ensuring that their personnel (i.e., the Institutional Official, the IRB, IRB office staff, investigators and research staff, and any other personnel supporting research covered under this Agreement) act in accordance with all applicable federal, state and local laws and regulations (e.g., Title 32 Code of Federal Regulations Part 219 (32 CFR 219); Title 10 United States Code Section 980 (10 USC 980); DoD Directives and Instructions (e.g., DoDD 3216.02); 45 CFR Part 46 (Subparts B, C, and D as made applicable by DoDD 3216.02); DoD Component policies; and the Food and Drug Administration regulations and guidance (e.g., 21 CFR Parts 50, 56, 312, and 812) where applicable in addition to the terms and conditions of the organizations' DoD Assurance and/or their DHHS FWA.

Specific DoD Component requirements are stated in Part 3 of this document.

All institutions will permit, upon request, the inspection of any facilities used in support of the activities described in the "Scope" and other research areas by federal agencies responsible for oversight of human research protection and proper management of the research within the scope of this agreement.

A. The Institutional Official of the Engaged Institution Relying on the IRB will:

1. Ensure that all institutional personnel involved in the research (covered within the scope of this agreement) have completed education and training requirements.
2. Verify that scientific review of the research protocol has been conducted and that the IRB considered the feedback from the scientific review.
3. Verify that the IRB has reviewed the research protocol in accordance with DoD requirements, including those identified in the research contract or agreement.
4. Ensure institutional personnel comply with requirements and oversight established by the IRB.
5. Ensure institutional personnel follow the approved research protocol.
6. Ensure institutional personnel report to the IRB and DoD: (a) unanticipated problems involving risks to subjects or others; (b) serious or continuing non-compliance; (c) suspension or termination of IRB approval; and (d) any other events or circumstances requiring notification.
7. Ensure institutional personnel maintain current copies of the IRB approved research protocol (initial review, continuing review, amendments, adverse event reports, and final report), all communications with the IRB, this Agreement, and other relevant information in accordance with DoD record keeping requirements.
8. Verify the IRB has the expertise and policies and procedures needed to review and oversee the research submitted by the institution (in accordance with 32 CFR 219.107, §.103(b)(3), and §.115).

B. The Institution Supplying the Reviewing IRB will:

1. Verify that personnel involved in the research have completed required education and training for the protection of human research subjects.
2. Verify that the IRB is properly constituted for reviewing the study.

3. Fulfill the IRB responsibilities identified in the engaged institution's assurance.
4. Provide the Institutional Official of the engaged institution with information about the IRB, such as a list of IRB members or expertise and the written procedures for executing IRB responsibilities in accordance with paragraph A.8 above.
5. Provide to the engaged institution conducting the research and the Principal Investigator(s) a copy of the IRB review and determinations concerning the research (e.g., IRB minutes or other appropriate documents).
6. Maintain current copies of the IRB approved research protocol (initial review, continuing review, amendments, adverse events reports, and final report), all communications with the institution, this Agreement, and other relevant information in accordance with DoD Component record-keeping requirements.

C. Amendments and Termination

1. This Agreement may be modified, cancelled, or renegotiated upon mutual consent, at any time through an amendment signed by authorized representatives of the organizations. A decision to amend or terminate will be submitted to the DoD Component Designated Oversight Official.
2. The DoD Component Designated Official is not obligated to approve this Agreement.

PART 3 DOD COMPONENT REQUIREMENTS

A. This institution will comply with the requirements of the DoD Component issuing this Agreement. These requirements are identified in Part 3, paragraph B. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Agreement (32 CFR 219.101(d)).

B. When this institution conducts research supported by or in collaboration with an organization of another DoD Component, this institution must comply with the policies and procedures of that organization. The requirements of selected DoD Components are identified below:

Department of the Army

- AR 70-25 Use of Volunteers as Subjects of Research, 25 January 1990
- AR 40-38, Clinical Investigation Program, 1 September 1989

- AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 4 January 1991

Department of the Navy

- SECNAVINST 3900.39D of 6 November 2006

Department of the Air Force

- Air Force Instruction 40-402, Protection of Human Subjects in Research

Office of the Secretary of Defense for Personnel and Readiness

- HA Policy 05-003

National Geospatial Intelligence Agency

-

National Security Agency

-

Defense Intelligence Agency

-

Defense Threat Reduction Agency

-

Defense Advanced Research Projects Agency

-

United States Joint Forces Command

-

United States Special Operations Command

-

**PART 4
INSTITUTIONAL AGREEMENT**

A. Engaged Institution Relying on the External IRB

1. Institutional Signatory Official at the Engaged Institution

Acting in an authorized capacity on behalf of this institution and with an understanding of the institution's responsibilities under its assurance, I assure protections for human subjects as specified above.

Signature:  Date: 16 MAR 2018

Name: Erik G. Rude
Rank/Grade: COL, MS
Institutional Title: Commander
Telephone Number: 915-742-2201
Email Address: erik.g.rude.mil@mail.mil
Mailing Address: William Beaumont Army Medical Center
5005 N. Piedras Street
El Paso, TX 79920-5001

2. Primary Contact for Human Research Protection at the Engaged Institution

Name: Larissa A. Schmiersal, Ph.D.
Institutional Title: WBAMC Human Protections Administrator
Rank/Grade: DAC/GS-13
Telephone Number: 915-742-9502
Email Address: larissa.a.schmiersal.civ@mail.mil
Mailing Address: William Beaumont Army Medical Center
5005 N. Piedras Street
El Paso, TX, 79920-5001

B. Institution with the Reviewing IRB

1. Reviewing IRB Chair Agreement

Acting in an authorized capacity on behalf of the IRB and with an understanding of the institution's responsibilities under this assurance, I assure protections for human subjects as specified above.

Signature:  Date: 3/12/18

Name: Terry R. Malone, Ed.D./P.T.

Rank/Grade: Professor

Institutional Title: Executive Chairperson of the UK Medical IRB

Email Address: trmalo1@uky.edu

Telephone Number: (859) 218-0600

Mailing Address: Rehabilitation Science
204N Wethington Building
900 South Limestone Street
University of Kentucky
Lexington, KY 40536-0200

2. Institutional Official of Institution with the Reviewing IRB

I am aware that my IRB is entering into this agreement.

Signature:  Date: 3/9/18

Name: Lisa A. Cassis, Ph.D.

Rank/Grade: Institutional Official

Institutional Title: Vice President for Research

Email Address: lcassis@uky.edu

Telephone Number: (859) 257-5294

Mailing Address: Vice President for Research
311 Main Building
University of Kentucky
Lexington, KY 40506-0032

3. Primary Contact for Human Research Protection at the Institution with the Reviewing IRB

Name: Amy S. Kolasa, M.S./C.I.P.
Rank/Grade: Professional Associate
Institutional Title: Office of Research Integrity Reliance Manager
Email Address: akolasa@uky.edu
Telephone Number: (859) 257-9425
Mailing Address: Office of Research Integrity
407 Kinkead Hall
University of Kentucky
Lexington, KY 40506-0057



Office of Research Integrity
IRB, RDRC

Modification Review

Approval Ends:
5/8/2019

IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Modification Request

DATE: 9/7/2018

On 9/7/2018, the Medical Institutional Review Board approved your request for modifications in your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

If your modification request necessitated a change in your approved informed consent/assent form(s), the new IRB approved consent/assent form(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]

Note that at Continuation Review, you will be asked to submit a brief summary of any modifications approved by the IRB since initial review or the last continuation review, which may impact subject safety or welfare. Please take this approved modification into consideration when preparing your summary.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

From: [Larson, Karen](#)
To: [Williams, Jessica](#); [Gribble, Phillip](#)
Cc: [Abt, John](#); [Beck, Meaghan](#)
Subject: RE: question on protocol 44172
Date: Monday, March 11, 2019 10:36:50 AM
Attachments: [image001.png](#)

Hi Dr. Gribble,

Thank you for your email. I was out of the office last week. After discussion with Jessica Williams and review of the approved IR application, please submit a Modification Request (MR) in E-IRB for this protocol. Specifically, to ask the IRB to make a determination, if alteration of the current approved Consent Form is appropriate, per DoD staff request. Please include this email trail as an attachment as part of the MR. Thank you.

Karen Larson, DC, MS, CPC, CIP
Professional Associate III
Medical IRB #3 Expedited Initial and Continuation/Final Reviews
University of Kentucky
Office of Research Integrity
305 Kinkead Hall
Lexington, KY 40506-0057
(859) 257-3038
Fax (859) 257-0588
Karen.larson@uky.edu
www.research.uky.edu/ori/

The University of Kentucky has transitioned from a paper/e-mail based IRB application submission system to a Link Blue-secure, web-based IRB application system called “E-IRB”. This transition affects how initial and continuation review IRB materials will be accepted by the Office of Research Integrity (ORI). To keep apprised of news and updates about this transition, as well as training options, please review the [E-IRB Info web page](#). To learn how to navigate in the new system review the various [E-IRB Video Tutorials](#) and online resources today.

From: Williams, Jessica
Sent: Monday, March 04, 2019 3:58 PM
To: Gribble, Phillip <phillip.gribble@uky.edu>; Larson, Karen <klars2@uky.edu>
Cc: Abt, John <john.abt@uky.edu>; Beck, Meaghan <meaghan.beck@uky.edu>
Subject: RE: question on protocol 44172

Dr. Gribble,

Unfortunately, I was not involved in the initial review of this protocol, and thus I am not familiar with the discussion points at initial review. I did look through the file within our E-IRB system and I am unable to access any information regarding the blinding of randomization groups within which subjects will be placed during research procedures. This is something that Karen will need to address when she returns. I do not want you to have to do double work, so I am recommending to wait until Karen returns so that you can discuss this with her, and she can then talk with the IRB reviewer who approved the study. This may be a simple fix, but Karen definitely needs to be involved since she manages this protocol.

Thank you,

Jessica

Jessica Roe Williams, MA, MS, CIP
Professional Associate IV
ORI Reliance Manager
Office of Research Integrity
University of Kentucky
407 Kinkead Hall
Lexington, KY 40508
(859) 218-1501

CONFIDENTIALITY STATEMENT

The contents of this E-mail message and any attachments are confidential and are intended solely for the addressee(s). The information in this transmission may also be legally privileged. This transmission is sent in trust, for the sole purpose of delivery to the intended recipient(s). If you have received this transmission in error, any use, reproduction or dissemination of the information in this message is strictly prohibited. If you are not the intended recipient, immediately notify the sender by reply E-mail, or call (859) 257-9764 and delete this message and its attachment(s).

From: Gribble, Phillip
Sent: Monday, March 04, 2019 3:41 PM
To: Larson, Karen <klars2@uky.edu>
Cc: Williams, Jessica <jessica.williams@uky.edu>; Abt, John <john.abt@uky.edu>; Beck, Meaghan <meaghan.beck@uky.edu>
Subject: question on protocol 44172

Hi Karen,
I left you a voicemail but wanted to follow up with an email.

An approved protocol (44172) is associated with a funded grant from DOD. We are working with the IRB at one of the testing sites, William Beaumont Army Medical Center (WBAMC), and a question regarding the consent form has come up. I am requesting a verification to satisfy a question that Larissa Schmearsal, Human Protections Administrator at WBAMC, has raised.

If you recall, we've established reliance agreements with WBAMC that UK will serve as the primary on the IRB. However, a clarification on the consent form was raised by Larissa.

“The consent form does not provide specific information to the potential subjects about the true purpose of the study (comparing SOC with SMART rehab protocol). I added a comment in both the consent and the protocol about that. If you do plan to move forward with a consent form that does not detail the true nature of the project, we would need documentation that the IRB approved an alteration of the elements of informed consent, given that the randomization into a study group is an important study-specific procedure. I definitely see how you can make a case that the need for a double blind study justifies an alteration of consent, but I would need to document that the IRB considered whether this request meets the regulatory requirements for an alteration of consent.”

We did discuss this previously back in the summer when the original consent form was submitted, and approved. This is a RCT and we do wish to blind participants as to which of the two rehabilitation protocols they are randomly assigned. Therefore, our language informs participants that they will be asked to complete a supervised ankle rehabilitation protocol, but we do not specify there is a standard of care (SOC) vs an experimental/innovative (SMART)rehab protocol.

Larissa has indicated that a simple email verification to this from our IRB representation is all she needs to include in her letter of endorsement of the documents moving forward to the DOD for approval.

Please let me know if you have any questions or need further clarification.

Thanks,
Phillip



Phillip Gribble, PhD, ATC, FNATA

Professor, Director Division of Athletic Training

University of Kentucky

Department of Rehabilitation Sciences, College of Health Sciences

206C Charles T. Wethington Building

Lexington, KY 40536-0200

859-218-0885

phillip.gribble@uky.edu



University of
Kentucky

Office of Research Integrity
IRB, RDRC

Modification Review

Approval Ends:
2/6/2020

IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)
SUBJECT: Approval of Modification Request
DATE: 3/12/2019

On 3/11/2019, the Medical Institutional Review Board approved your request for modifications in your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

The IRB has determined the processes being used are consistent with standard of care and that the consent form adequately describes the processes utilized.

If your modification request necessitated a change in your approved informed consent/assent form(s), the new IRB approved consent/assent form(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]

Note that at Continuation Review, you will be asked to submit a brief summary of any modifications approved by the IRB since initial review or the last continuation review, which may impact subject safety or welfare. Please take this approved modification into consideration when preparing your summary.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

RESEARCH VOLUNTEERS NEEDED FOR ANKLE SPRAIN STUDY



APPROVED

By Mallory Powell at 7:38 am, Apr 16, 2018

WHERE:

- MUSCULOSKELETAL LABORATORY
- SPORTS MEDICINE RESEARCH INSTITUTE

WHO:

- MALES AND FEMALES AGES 18-44
- SUSTAINED ANKLE SPRAIN WITHIN 72 HOURS

PURPOSE:

- TO COMPARE ANKLE REHABILITATION PROTOCOLS

You will be compensated for your participation. All queries are confidential.

For more information, please contact:



Dr. Phillip Gribble
(859) 218-0885
phillip.gribble@uky.edu



An Equal Opportunity University

RESEARCH VOLUNTEERS NEEDED FOR ANKLE SPRAIN STUDY

- Where
 - SPORTS MEDICINE RESEARCH LABORATORY
- Who
 - MALES AND FEMALES AGES 18-44
 - SUSTAINED ANKLE SPRAIN WITHIN 72 HOURS
- Purpose
 - TO COMPARE ANKLE REHABILITATION PROTOCOLS



You will be compensated for your participation. All queries are confidential
For more information please contact:

Erik Wikstrom, PhD, ATC
wikstrom@unc.edu (919) 962-2260



RESEARCH VOLUNTEERS NEEDED FOR ANKLE SPRAIN STUDY



WHERE:

- WILLIAM BEAUMONT ARMY MEDICAL CENTER

WHO:

- MALES AND FEMALES AGES 18-44
- SUSTAINED ANKLE SPRAIN WITHIN 72 HOURS

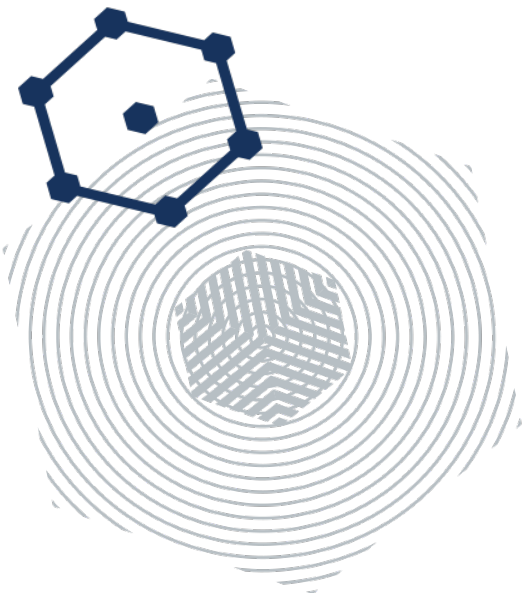
PURPOSE:

- TO COMPARE ANKLE REHABILITATION PROTOCOLS

All queries are confidential.

For more information, please contact:

MAJ Gary Helton, PT, DSc, OCS, CSCS
(662) 507-2231
gary.l.helton8.mil@mail.mil



*A Collaborative Project by:
University of Kentucky
University of North Carolina
Fort Bliss/William Beaumont Army Medical Center*

Investigator Name: Gribble	Protocol: SMART	Site Number:

Telephone Screening Script

Introduction Hello, my name is [name] and I am a researcher at [site name]. The purpose of our research study, Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation, is to learn how the initial treatment of lateral ankle sprain affects future return to full activity, function, and pain. Do you have any questions or concerns? Now that you have a basic understanding of the study, do you think you might be interested in participating? If No: Thank you for your interest. [end call] If Yes: But before enrolling people in this study, we need to determine if you may be eligible to participate. I would now like to ask you a series of questions. It will take approximately 20 minutes of your time. Is that okay? If No: Thank you for your interest. [end call]

If Yes: We will be collecting information about you during this phone call. Your taking part in this phone call is completely voluntary. Your information will only be seen by researchers at [site name]. If you do not agree to continue the phone call, it will not affect your care at [site name]. There is a possibility that some of these questions may make you uncomfortable or distressed; if so, please let me know. I will keep all the information I receive from you by phone, including your name and any other identifying information confidential. Do I have your permission to ask you these questions? <i>Inclusion:</i> 1) Are you between the ages of 18-44? 2) Are you initiating rehabilitation for a first time acute lateral ankle sprain? 3) Have you sustained an ankle sprain within 72 hours? 4) Has your ankle sprain been diagnosed by a physician, medic, athletic trainer, physical therapist, or other medical provider? <i>Exclusion:</i> 5) Do you have personal or familial history of epilepsy or seizures? 6) Do you have a history of migraine headaches?

- 7) Do you have ocular foreign body, increased intracranial pressure, open head injury or significant closed head injury?
- 8) Do you have cochlear implants?
- 9) Do you have implanted brain stimulators, aneurysm clips or other metal in the head (except mouth)?
- 10) Do you have implanted medication pumps, pacemakers or intracardiac lines
- 11) Do you current take medication with tricyclic anti-depressants, neuroleptic agents or other drugs that lower seizure threshold?
- 12) Do you have a history of diagnosed major psychiatric disorder?
- 13) Do you have a history of illicit drug use?
- 14) Are you currently experiencing alcohol abuse or currently withdrawing from alcohol abuse?
- 15) Do you have a history of heart disease?

If eligible:

Based on your answers to the questions, it appears you may eligible to participate in the research study.

During the study, you will be asked to complete a supervised rehabilitation program that will focus on improving your strength, range of motion, balance, and physical function. These sessions will begin within 48 hours after you agree to participate in this study, and will continue for up to 8 weeks, depending on the severity of your ankle sprain. You will also be asked to complete in 4 laboratory visits to track your progress of your recovery from your ankle sprain. The first visit will take place within a few days after you agree to enroll in this study. A second scheduled session will take place within a few days after your final rehabilitation session. A third session will be scheduled approximately 6 months after you return to activity. A fourth and final session will be scheduled approximately 12 months after you return to activity. During the laboratory sessions, you will be asked to complete multiple self-report surveys. These surveys will ask you about how you feel about your overall health and physical activity, as well as the health of your ankles. In addition, balance, range of motion, muscle response, and nerve response tests will be conducted.

Potential Risks include:

- A slight chance of falling and or losing your balance during the balance tests
- Minor muscle soreness or tiredness
- Minor discomfort from noise associated with the magnetic stimulation pulse
- Mild, temporary skin irritation from the electrodes and markers
- Mild headache following magnetic stimulation and lasting a few hours after testing
- In individuals with a history of seizures, there is a slight possibility of causing a seizure with the magnetic stimulation
- Magnetic stimulation of the brain is safe; however, it may have short or long-term risks associated with it that are not presently known or suspected. If you become pregnant, the particular procedures involved in the study may involve risks to the embryo or fetus that are currently unknown.
- If during the MRI an incidental finding is seen, we will provide you a recommendation for possible follow-up with your physician.

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help certified athletic trainers, physical therapists, and sports medicine physicians to better treat ankle injuries across the population.

There will be no cost involved in participating in this study.

The Department of Defense is providing funding in support of this study.

For non-military personnel, you will receive \$100 payment for completing all aspects of the study.

For military personnel, per DOD guidelines you will not be paid for your participation in this study.

Do you have any questions? Do you think you would like to take part in this research?

If Yes: May I please have your full name, phone number, and email address? I will contact you shortly to schedule your first visit *or* Are you available [date, time] to schedule your enrollment visit?

Please allow [#] hours for your first visit at [location]. I will send you a follow-up email with confirmation of your appointment, instructions, and directions.

Thank you for taking the time to talk with me today. If you have any questions or concerns, please feel free to contact me. My name is [name] and I can be reached at [phone number] and/or [email address].

If not eligible:

Unfortunately, based on your responses, you are not eligible to participate in the research study.

Thank you for taking the time to talk with me today.

FORM Z
SIGNATURE ASSURANCE SHEET

Study Title: Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

IRB Protocol #: _____

Principal Investigator's Assurance Statement:

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. to comply with all IRB policies, decisions, conditions, and requirements;
2. to accept responsibility for the scientific and ethical conduct of this research study;
3. to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. to report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. to complete, on request by the IRB, the Continuation/Final Review Forms;
6. to notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., Dunn & Chadwick, CITI);
8. each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.

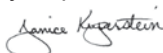
Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

SIGNATURE Phillip Gribble Digitally signed by Phillip Gribble
DN: cn=Phillip Gribble, o, ou, email=phillip.gribble@uky.edu, c=US
Date: 2018.03.13 11:17:31 -04'00' DATE 03/13/2018

If not an E-Signature (above), please print name of individual who signed: _____

***Department Chairperson's Assurance Statement:**

This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator is knowledgeable of the additional regulatory requirements of the sponsor and can comply with them.

SIGNATURE  DATE 04/20/2018

If not an E-Signature (above), please print name of individual who signed: _____

***If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should sign the Signature Assurance Sheet.**

****Faculty Advisor's Assurance Statement:**

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study; to the qualifications of the investigator(s) to conduct the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.

SIGNATURE _____ DATE _____

If not an E-Signature (above), please print name of individual who signed: _____

****If the Principal Investigator is completing this project to meet the requirements of a University of Kentucky academic program, the student's faculty advisor, in addition to the Department Chairperson, should sign the Signature Assurance Sheet. The student's faculty advisor is accepting a supervisory role in guiding the student in conducting regulatory compliant research and therefore must be certified in human research protection training throughout the life of the protocol.**

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME GRIBBLE, PHILLIP A		POSITION TITLE ASSOCIATE PROFESSOR	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of North Carolina, Chapel Hill, NC	BS	1996	Exercise Science
University of North Carolina, Chapel Hill, NC	MS	1998	Athletic Training
Pennsylvania State University, University Park, PA	PhD	2003	Kinesiology

RESEARCH AND PROFESSIONAL EXPERIENCE:

Positions and Employment

08/1998-05/2000 Lecturer, Department of Exercise Science, Appalachian State University, Boone, NC

08/2003-06/2014 Professor, Department of Kinesiology, University of Toledo, Toledo, OH

08/2003-06/2014 Director, Musculoskeletal Health and Movement Science Research Laboratory, University of Toledo, Toledo, OH

08/2003-06/2014 Director, Graduate Athletic Training Education Program, University of Toledo, Toledo, OH

08/2014 - Present Associate Professor, Department of Rehabilitation Sciences, University of Kentucky, Lexington, KY

Other Experience and Professional Memberships

1996 – Present National Athletic Trainers' Association

2003-2014 Great Lakes Athletic Trainers' Association

2015-Present Southeastern Athletic Trainers' Association

2001 – Present American College of Sports Medicine

2012 – Present Co-Director, International Ankle Consortium

Honors

2012 Fellow of the National Athletic Trainers' Association

2012 University of Toledo President's Outstanding Researcher Award

2014 University of Toledo College of Health Sciences Outstanding Researcher Award

PUBLISHED MANUSCRIPTS

1. **Gribble PA**, Terada M, Beard MQ, Kosik KB, McCann RS, Pietrosimone BG, Thomas AC. Prediction of lateral ankle sprains in football players using clinical test and BMI. *American Journal of Sports Medicine*. (In press: accepted September 2015).

2. Terada M, Thomas AC, Pietrosimone B, Hiller C, Samantha B, **Gribble PA**. The consequence of an ankle sprain on physical and self-reported functional limitations: a case study over a 5 month period. *Journal of Orthopaedic & Sports Physical Therapy*. 2015; 45(10): 756-64.
3. McLeod MM, **Gribble PA**, Pietrosimone BG. Chronic ankle instability on neural excitability in the lower extremity. *Journal of Athletic Training*. 2015; 50 (8): 847-853.
4. McCann R, Kosik K, Beard MQ, Terada M, Pietrosimone BG, **Gribble PA***. Variations in star excursion balance test performance between high school and collegiate football players. *Journal of Strength and Conditioning Research*. 2015; 29(10): 2765-70.
5. Harkey M, McLeod MM, Terada M, **Gribble P**, Pietrosimone BG. Quadratic Association Between Corticomotor and Spinal-Reflexive Excitability and Self-Reported Disability in Participants with Chronic Ankle Instability. *Journal of Sport Rehabilitation* . 2015 Mar 11. (Epub).
6. McLeod MM, **Gribble PA**, Pietrosimone BG. Chronic ankle instability on neural excitability in the lower extremity. *Journal of Athletic Training*. 2015 June 19. (Epub).
7. Terada M, **Gribble PA**. Jump landing biomechanics during a laboratory recorded recurrent ankle sprain. *Foot and Ankle International*. 2015; 36 (7): 842-848.
8. Terada M, Bowker S, Thomas AC, Pietrosimone BG, Hiller CE, Rice MS, **Gribble PA**. Alterations in stride-to-stride variability during walking in individuals with chronic ankle instability. *Human Movement Science*. 2015; 40: 154-162.
9. Terada M, Pietrosimone BG, **Gribble PA**. Individuals with chronic ankle instability exhibit altered landing knee kinematics: potential link with the mechanism of loading for the anterior cruciate ligament. *Clinical Biomechanics*. 2014; 29(10): 1125-1130.
10. Luc BA, **Gribble PA**, Pietrosimone BG. Osteoarthritis prevalence following anterior cruciate ligament reconstruction: a systematic review and numbers needed to treat analysis. *Journal of Athletic Training*. 2014; 49 (6): 806-819.
11. Terada M, Harkey MS, Wells AM, Pietrosimone BG, **Gribble PA**. The influence of ankle dorsiflexion and self-reported patient outcomes on dynamic postural control in participants with chronic ankle instability. *Gait and Posture*. 2014; 40(1): 193-197.
12. Terada M, Pietrosimone BG, **Gribble PA**. Alterations in neuromuscular control at the knee in individuals with chronic ankle instability. *Journal of Athletic Training*. 2014; 49(5): 599-607.
13. **Gribble PA**, Kelly S, Hiller CE, Refshauge KM. Inter-rater reliability of the star excursion balance test. *Journal of Athletic Training*. 2013; 48(5): 621-626.
14. **Gribble PA**, Delahunt E, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong D, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, van der Wees P, Vincenzino B, Wikstrom E. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. Concomitant publications: 1) *Journal of Orthopaedic and Sport Physical Therapy*. 2013; 43(8):585-591, 2) *British Journal of Sports Medicine*. 2014; 48(13):1014-1018, 3) *Journal of Athletic Training*. 2014; 49 (1): 121-127.
15. **Gribble PA**, Brigle J, Pfile KJ, Pietrosimone BG, Webster KA. Interrater reliability of the Functional Movement Screen. *Journal of Strength and Conditioning Research*. 2013; 27(4): 978-981.
16. Terada M, Pietrosimone BG, Pfile KR, **Gribble PA**. Effects of chronic ankle instability on energy dissipation in the lower extremity. *Medicine and Science in Sport and Exercise*. 2013; 45 (11): 2120-2128.

17. Terada M, Pietrosimone BG, **Gribble PA**. Therapeutic interventions for increasing ankle dorsiflexion after ankle sprain: a systematic review. *Journal of Athletic Training*. 2013; 48(5):696-709.
18. Webster KA, **Gribble PA**. A comparison of electromyography of gluteus medius and maximus in subjects with and without chronic ankle instability during two functional exercises. *Physical Therapy in Sport*. 2013; 14: 17-22.
19. **Gribble PA**, Hertel J, Plisky P. Using the star excursion balance test to assess dynamic postural control deficits and outcomes in lower extremity injury. *Journal of Athletic Training* 2012; 47(3): 339-357.
20. Pietrosimone BG, **Gribble PA**. Chronic ankle instability and corticomotor excitability of the fibularis longus muscle. *Journal of Athletic Training*. 2012; 47 (6): 621-626.
21. **Gribble PA**, Robinson RH. The influence of chronic ankle instability on spatiotemporal landing variables during a dynamic stability task. *Scandinavian Journal of Medicine and Science in Sports*. 2010; 20(1): e63-e71.
22. Webster KA, **Gribble PA**. Functional rehabilitation interventions for chronic ankle instability: a systematic review. *Journal of Sport Rehabilitation*. 2010; 19(2): 98-114.
23. **Gribble PA**, Robinson RH. Chronic ankle instability is associated with a reduction in knee joint torque production. *Journal of Strength and Conditioning*. 2009; 23 (2): 395-400.

PUBLISHED ABSTRACTS

1. **Gribble PA**, Terada M, Kosik KB, McCann RS, Pietrosimone BG, Beard MQ, Thomas AC. Predicting lateral ankle sprain in adolescent and collegiate athletes using functional tests. 2015 International Ankle Symposium (Dublin, Ireland). Oral presentation.
2. **Gribble PA**, Terada M, Beard MQ, Kosik K, Lepley A, McCann R, Pietrosimone BG, Thomas AC. A novel approach for prediction of lateral ankle sprains in football players using functional test performance. 2015 National Athletic Trainers' Association Annual Meeting. Oral presentation.
3. Kosik KB, Terada M, Beard MQ, Lepley AS, McCann RS, Pietrosimone BG, Thomas AC, **Gribble PA**. The influence of physical characteristics and self-reported history on functional performance tests. 2015 National Athletic Trainers' Association Annual Meeting. RapidFire presentation.
4. McCann RS, Kosik KB, Terada M, Beard MQ, Buskirk GE, **Gribble PA**. Association of the star excursion balance test and functional movement screen with isolated lower extremity strength and range of motion. 2015 National Athletic Trainers' Association Annual Meeting. RapidFire presentation.
5. Terada M, Bowker S, Thomas AC, Hiller CE, Pietrosimone BG, **Gribble PA**. Identifying the specific factors contributing to self-reported disability in individuals with chronic ankle instability. 2015 National Athletic Trainers' Association Annual Meeting. Oral presentation.
6. Bowker S, Terada M, Harkey M, Thomas AC, Hiller CE, Pietrosimone BG, **Gribble PA**. A comparison of excitability measures and ankle laxity between ankle sprain copers and participants with chronic ankle instability. 2014 National Athletic Trainers' Association Annual Meeting. Poster presentation.
7. Terada M, Bowker S, Thomas AC, Hiller CE, Pietrosimone BG, Rice MS, **Gribble PA**. Identifying the specific neural motor pathways associated with altered postural control

variability in individuals with chronic ankle instability. 2014 National Athletic Trainers' Association Annual Meeting. Poster presentation.

8. Mayes MSP, McLeod MM, Harkey MS, **Gribble PA**, Pietrosimone BG. Effect of acute lateral ankle sprain on dynamic postural control over a one-week period. 2014 National Athletic Trainers' Association Annual Meeting. Poster presentation.
9. McLeod MM, Mayes MSP, Harkey MS, **Gribble PA**, Pietrosimone BG. Changes in spinal reflexive excitability of leg musculature following acute ankle sprain over a 7-day period. 2014 National Athletic Trainers' Association Annual Meeting. Poster presentation.
10. Wilhelm SE, Terada M, Quinlevan ME, Kosik KB, McCann RS, Whitney GL, Welsch LA, Thomas AC, **Gribble PA**. Functional measures as predictors of non-contact vs. contact lower extremity injury among high school football players. 2014 National Athletic Trainers' Association Annual Meeting. Oral presentation.
11. Rullestad E, Boley H, Carey S, Quinlevan M, Terada M, **Gribble PA**. A comparison of strength, ROM, laxity, and static postural control between those at-risk and healthy. 2014 World Congress of Biomechanics. Poster presentation.
12. **Gribble PA**, Ford A, Morrell M, Pietrosimone BG. Functional measures and body mass index as predictors of lower extremity injury among collegiate football players. 2013 National Athletic Trainers' Association Annual Meeting. Thematic poster presentation.
13. Harkey MS, McLeod MM, Tevald MA, **Gribble PA**, Pietrosimone BG. Soleus corticospinal excitability predicts self-reported disability in patients with chronic ankle instability. 2013 American College of Sports Medicine Annual Meeting. Thematic poster presentation.
14. Terada M, Quinlevan ME, Carey SE, Rullestad EA, Boley HA, Pietrosimone BG, **Gribble PA**. A nonlinear dynamic measure for evaluating postural control in individuals with chronic ankle instability. 2013 American College of Sports Medicine Annual Meeting. Thematic poster presentation.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME JOHN P. ABT		POSITION TITLE ASSOCIATE PROFESSOR, DIRECTOR OF SPORTS MEDICINE RESEARCH INSTITUTE	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of Pittsburgh, Pittsburgh, PA	BS	1999	Movement Science
University of Pittsburgh, Pittsburgh, PA	MS	2001	Sports Medicine
University of Pittsburgh, Pittsburgh, PA	PhD	2004	Rehabilitation Science
University of Pittsburgh, Pittsburgh, PA	Postdoctoral	2006	Sports Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE:

POSITIONS AND EMPLOYMENT

1999 – 2002 Athletic Trainer, Carrick High School, Brashear High School, Pittsburgh, PA
 1999 – 2008 Research Associate, Neuromuscular Research Laboratory, University of Pittsburgh
 2006 – 2007 Visiting Assistant Professor, University of Pittsburgh
 2007 – 2015 Assistant Professor, Department of Sports Medicine and Nutrition, School of Health and Rehabilitation Sciences, University of Pittsburgh
 2008 – 2015 Associate Director, Neuromuscular Research Laboratory, University of Pittsburgh
 2015 - Associate Professor, College of Health Sciences, University of Kentucky
 2015 - Director, Sports Medicine Research Institute, University of Kentucky

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS

1997 - National Athletic Trainers' Association
 1999 - 2015 Eastern Athletic Trainers' Association
 2001 - American College of Sports Medicine
 2006 - 2015 Mid-Atlantic Regional Chapter- American College of Sports Medicine
 2015 - Southeast Regional Chapter- American College of Sports Medicine

HONORS

2002	National Athletic Trainers' Association Doctoral Scholarship
2012	Sir Henry Wellcome Medal and Prize Journal of Military Medicine Association of Military Surgeons of the United States (second author)
2015	American College of Sports Medicine Fellowship

PUBLICATIONS

REFEREED ARTICLES (SELECT)

1. Abt JP, Eagle SR, Sell TC, Allison KF, Nagai T, Wood DE, Lephart SM. Comparison of physiological, musculoskeletal, and biomechanical characteristics between Sea, Air and Land Operators and SEAL Qualification Students. *Journal of Strength and Conditioning Research*. In Review.
2. Heebner NH, Abt JP, Lovalekar MT, Beals K, Kane SF, Morgan JS, Lephart SM. Physical and performance characteristics related to unintentional musculoskeletal injury in United State Army Special Forces: a prospective analysis. *Journal of Athletic Training*. In Press.
3. Sell TC, Lovalekar M, Nagai T, Wirt MD, Abt JP, Lephart SM. Gender Differences in Static and Dynamic Postural Stability of Soldiers of the Army's 101st Airborne Division (Air Assault). *Journal of Sport Rehabilitation*. In Review
4. Allison KF, Abt JP, Beals K, Nagle EF, Lovalekar MT, Lephart SM, Sell TC. Aerobic Capacity and Isometric Knee Flexion Strength Fatigability are related to Knee Kinesthesia in Physically Active Women. *Isokinetics and Exercise Science*. In Press.
5. Lovalekar M, Abt JP, Sell TC, Wood DE, Lephart SM. Descriptive Epidemiology of Musculoskeletal Injuries in Naval Special Warfare Sea, Air, and Land Operators. *Military Medicine*. 2016;181(1): 64-69.
6. Nagai T, Clark NC, Abt JP, Sell TC, Heebner NR, Smalley BW, Wirt MD, Lephart SM. The Effect of Target Position on the Accuracy of Cervical-Spine Rotation Active Joint-Position Sense. 2016; 25(1): 58-63.
7. Clark NC, Akins JA, Heebner NH, Sell TC, Abt JP, Lovalekar MT, Lephart SM. Reliability and Measurement Precision of Concentric-to-Isometric and Eccentric-to-Isometric Knee Active Joint Position Sense Tests in Uninjured Physically Active Adults. *Physical Therapy in Sport*. 2016; 18:38-45.
8. Abt JP, Oliver JM, Nagai T, Sell TC, Lovalekar MT, Beals K, Wood DE, Lephart SM. Block-Periodized Training Improves Physiological and Tactically-Relevant Performance in Naval Special Warfare Operators. *Journal of Strength and Conditioning Research*. 2016; 30(1): 39-52.
9. Abt JP, Perlsweig K, Nagai T, Sell TC, Wirt MD, Lephart SM. Effects of Age and Military Service on Strength and Physiological Characteristics of U.S. Army Soldiers. *Military medicine*. 2016; 181(2):173-179.
10. Sell TC, Abt JP, Nagai T, et al. The Eagle Tactical Athlete Program Reduces Musculoskeletal Injuries in the 101st Airborne Division (Air Assault). *Military Medicine*. 2016; 181(3):250-257.

11. Allison KF, Keenan KA, Sell TC, Abt JP, Nagai T, Deluzio J, McGrail M, Lephart SM. Musculoskeletal, biomechanical, and physiological sex difference in the US military. *Army Medical Department Journal*. 2015; 22-32.
12. Parr JJ, Clark NC, Abt JP, Kresta JY, Keenan KA, Kane SF, Lephart SM. Residual impact of previous injury on musculoskeletal characteristics in Special Forces Operators. *Orthopaedic Journal of Sports Medicine*. 3(11), 2325967115616581.
13. Oliver JM, Abt JP, Sell TC, Beals K, Wood DE, Lephart SM. Salivary hormone response to 12-week block-periodized training in naval special warfare operators. *Journal of Strength and Conditioning Research*. 29(1):66-73, 2015.
14. Nagai T, Abt JP, Sell TC, Keenan KA, Clark NC, Smalley BW, Wirt MD, Lephart SM. Lumbar Spine and Hip Flexibility and Trunk Strength in Helicopter Pilots with and without Low Back Pain. *Work*. 2015; 52(3): 715-22.
15. Abt JP, Sell TC, Bozich AJ, Lovalekar MT, Kane SF, Benson PJ, Morgan JS, Lephart SM. Injury epidemiology of US Army Special Operations Forces. *Military Medicine*. 179(10): 1106-1112, 2014.
16. Sell TC, Clark NC, Wood DE, Abt JP, Lovalekar M, Lephart SM. Single-Leg Balance Impairments Persist in Fully Operational Military Special Forces Operators with a Previous History of Low Back Pain. *Orthopaedic Journal of Sports Medicine*. 2(4):1-6, 2014.
17. Stone DA, Abt JP, Keenan KA, Pederson JP, Akins JS, House AJ, Lephart SM. Local anesthetics use does not suppress muscle activity following an ankle injection. *Knee Surgery, Sports Traumatology, Arthroscopy*. DOI 10.1007/s00167-012-1984-8.
18. Abt JP, Chu Y, Sell TC, Burdett RG, Lephart SM. Running kinematics and shock absorption do not change following a brief exhaustive run. *Journal of Strength and Conditioning Research*. 25(6): 1479-1485, 2011.
19. Crawford K, Fleishman KA, Abt JP, Sell TC, Lovalekar M, Nagai T, Deluzio JB, Rowe RS, McGrail MA, Lephart SM. Lower body fat improves physical and physiological performance in Army Soldiers. *Military Medicine*. 176(1): 35-43, 2011.
20. Sell TC, Abt JP, Lovalekar M, Crawford K, Nagai T, Deluzio JB, Smalley BW, McGrail MA, Rowe RS, Lephart SM. Warrior model for injury prevention and human performance-Eagle Tactical Athlete Program (ETAP) Part 1. *Journal Special Operations Medicine*. 10(4): 2-21, 2010.
21. Abt JP, Sell TC, Lovalekar M, Crawford K, Nagai T, Deluzio JB, Smalley BW, McGrail MA, Rowe RS, Lephart SM. Warrior model for injury prevention and human performance-Eagle Tactical Athlete Program (ETAP) Part 2. *Journal Special Operations Medicine*. 10(4): 22-33, 2010.
22. Sell TC, Chu Y, Abt JP, Nagai T, Deluzio J, McGrail MA, Rowe RS, Lephart SM. Minimal additional weight of combat equipment alters Air Assault Soldiers' landing biomechanics. *Military Medicine*. 175(1): 41-47, 2010.
23. Abt JP, Smoliga JM, Brick MB, Jolly JT, Lephart SM, Fu FH. Alterations in cycling mechanics resulting from core fatigue. *Journal of Strength and Conditioning Research*. 21(4): 1300-1304, 2007.
24. Abt JP, Sell TC, Laudner KG, Berga SL, Loucks TL, McCrory JL, Lephart SM. Variations in neuromuscular characteristics throughout the menstrual cycle. [Knee Surgery, Sports Traumatology, Arthroscopy](#). 15(7): 901-907, 2007.

PUBLISHED ABSTRACTS (SELECT)

1. Abt JP, FACSM, Heebner NR, Keenan KA, Lambert B, Nagai T, Royer SD, Williams N, Winters JD, Lephart SM, FACSM. Comparison of Physical and Physiological Characteristics based on Injury History. American College of Sports Medicine Annual Meeting; May 31-June 4, 2016; Boston, MA.
2. Heebner NR, Abt JP, FACSM, Nagai T, Lovalekar M, Lambert B, Williams N, Royer SD, Lephart SM, FACSM. Epidemiological analysis of injuries occurring in Marine Corps Forces Special Operations Personnel. American College of Sports Medicine Annual Meeting; May 31-June 4, 2016; Boston, MA.
3. Royer SD, Winters JD, Abt JP, FACSM, Heebner NR, Nagai T, Lovalekar M, Lambert B, Williams N, Lephart SM, FACSM. Physical and Physiological Comparison between Marine Corps Forces Special Operations Command Operators and Combat Support Personnel. American College of Sports Medicine Annual Meeting; May 31-June 4, 2016; Boston, MA.
4. Winters JD, Abt JP, FACSM, Nagai T, Lambert B, Williams N, Heebner NR, Royer SD, Lephart SM, FACSM. Association between Knee Strength and Landing Biomechanics in Marine Corps Forces Special Operations Command Operators. American College of Sports Medicine Annual Meeting; May 31-June 4, 2016; Boston, MA.
5. Kane SF, Abt JP, Kresta JY, Bakey JF, Parr JJ, Sell TC, Lephart SM. Residual Impact of Previous Injury on Musculoskeletal Characteristics in Special Forces Soldiers. American College of Sports Medicine Annual Meeting; May 26-30, 2015; San Diego, CA.
6. Abt JP, Eagle SR, Kresta JY, Bakey JF, Sell TC, Kane SF, Lephart SM. Identification of Asymmetrical and Suboptimal Agonist/Antagonist Strength in a Cohort of Special Forces Soldiers. American College of Sports Medicine Annual Meeting; May 26-30, 2015; San Diego, CA.
7. Lovalekar M, Abt J, Sell T, Nagai T, Haubenstricker J, Beck C, Yount D, Eagle S, Lephart S. Musculoskeletal injuries and associated healthcare utilization among Naval Special Warfare Sea, Air and Land Qualification Training students. 142nd Annual Meeting & Exposition of the American Public Health Association; November 15-19, 2014; New Orleans, LA. (In review)
8. Baker RA, Beals K, Darnell ME, Abt JP, Sell TC, Kane SF, Morgan JS, Benson PJ, Lephart SM. Dietary Protein Intake and Protein Supplement Use of United States Army Special Operations Command Operators. 2014 Food and Nutrition Conference and Expo - Academy of Nutrition and Dietetics Annual Meeting. October 18-21; Atlanta, GA. (Accepted)
9. Darnell ME, Beals K, Baker RA, Abt JP, Sell TC, Lephart SM. Dietary Intake and Quality in Navy Special Warfare Combatant-Craft Crewman. 2014 Food and Nutrition Conference and Expo - Academy of Nutrition and Dietetics Annual Meeting. October 18-21; Atlanta, GA. (Accepted)
10. Sell MA, Abt JP, Sell TC, Keenan KA, Allison KF, Lovalekar MT, Lephart SM. The Development and Assessment of Core Strength Clinical Measures: The Reliability and Validity of Medicine Ball Toss Tests. National Athletic Trainers' Association Annual Meeting; June 25-28, 2014; Indianapolis, IN.
11. Nagai T, Clark NC, Abt JP, Sell TC, Heebner NR, Smalley BW, Wirt MD, Lephart SM. The Effect of Target Position on the Accuracy of Cervical Spine Rotation Active Joint Position Sense. National Athletic Trainers' Association Annual Meeting; June 25-28, 2014; Indianapolis, IN

12. Wood DE, Abt JP, Sell TC, Beals K, Lovalekar MT, Oliver JM, Lephart SM. Block-Periodized Training Improves Physiological and Tactically-Relevant Performance in Naval Special Warfare Operators. National Athletic Trainers' Association Annual Meeting 2014, Indianapolis, IN, June 25-28.
13. Lovalekar M, Abt J, Sell TC, Chang Y, Lephart S. Using the capture-recapture approach to estimate the incidence of unintentional musculoskeletal injuries among Naval Special Warfare Sea, Air and Land Operators. 47th Annual Society for Epidemiologic Research Meeting; June 24 - 27, 2014; Seattle, WA.
14. Abt JP, Sell TC, Beals K, Allison KF, Nagai T, Wood DE, Lephart SM, FACSM. Physical/Physiological Comparison between Cohorts of Naval Special Warfare SEAL Operators and SEAL Qualification Training Students. American College of Sports Medicine Annual Meeting; May 27-31, 2014; Orlando, FL.
15. Allison KF, Abt JP, Sell TC, Beals K, Wood D, Lephart SM. The Relationship between Body Fat, Injury and Musculoskeletal/Physiological Performance in Naval Special Warfare Operators. American College of Sports Medicine Annual Meeting; May 27-31, 2014; Orlando, FL.
16. Baker RA, Darnell ME, Beals K, Lovalekar M, Frushour K, Abt JP, Sell TC, Lephart SM, FACSM. Dietary Intake of Special Warfare Combatant-Craft Crewman Compared to Sports Nutrition Recommendations. American College of Sports Medicine Annual Meeting; May 27-31, 2014; Orlando, FL.
17. Beals K, Lovalekar M, Frushour K, San-Adams T, Baker RA, Darnell ME, Abt JP, Sell TC, Lephart SM, FACSM. Dietary Supplement Habits of Special Warfare Combatant-Craft Crewman. American College of Sports Medicine Annual Meeting; May 27-31, 2014; Orlando, FL.
18. Nagai T, Lovalekar M, Allison KF, Abt JP, Sell TC, Smalley BW, Wirt MD, Lephart SM, FACSM. Prevalence of Neck Pain and Low Back Pain in a Combat Aviation Brigade. American College of Sports Medicine Annual Meeting; May 27-31, 2014; Orlando, FL.
19. Sell, TC, Abt JP, Lovaleker M, Bozich A, Benson P, Morgan J, Lephart SM, FACSM. Injury Epidemiology of US Army Special Operations Forces. American College of Sports Medicine Annual Meeting; May 27-31, 2014; Orlando, FL.
20. Nagai T, Allison KF, Keenan KA, Abt JP, Sell TC, Smalley BW, Wirt MD, Lephart SM. Gender Differences in Modifiable Musculoskeletal Characteristics in US Army Helicopter Pilots. Aerospace Medical Association Annual Meeting. San Diego, CA. May 11-15, 2014.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME KATHERINE A. BAIN		POSITION TITLE GRADUATE RESEARCH ASSISTANT	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education..)			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
James Madison University, Harrisonburg, VA	BS	2011	Kinesiology
Shenandoah University, Winchester, VA	MSAT	2015	Athletic Training
Shenandoah University, Winchester, VA	DPT	2015	Physical Therapy
University of Kentucky, Lexington, KY	PhD		Rehabilitation Sciences

POSITIONS AND EMPLOYMENT

2015 - 2018; PHYSICAL THERAPIST, VIRGINIA THERAPY AND FITNESS CENTER, RESTON, VA

2016 - 2018; ATHLETIC TRAINER, NOVA EAGLES MEN’S RUGBY LEAGUE, BRISTOW, VA

2016 – 2018; SOCIAL MEDIA MANAGER, VIRGINIA THERAPY AND FITNESS CENTER, RESTON, VA

2018 - PRESENT; GRADUATE RESEARCH ASSISTANT, REHABILITATION SCIENCES, LEXINGTON, KY

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS

2006 – PRESENT; AMERICAN HEART ASSOCIATION, CERTIFIED

2012 - PRESENT; NATIONAL ATHLETIC TRAINERS ASSOCIATION, MEMBER

2012 - PRESENT; VIRGINIA PHYSICAL THERAPY ASSOCIATION, MEMBER

2012 - PRESENT; AMERICAN PHYSICAL THERAPY ASSOCIATION, MEMBER

2015 - PRESENT; BOC CERTIFIED ATHLETIC TRAINER FOR VIRGINIA

2015 - PRESENT; VIRGINIA BOARD OF PHYSICAL THERAPY LICENSURE

2018 - PRESENT; BOC CERTIFIED ATHLETIC TRAINER FOR KENTUCKY

ADDITIONAL CLINICAL CERTIFICATIONS

2016 – LEVEL 1 AND 2 TRIGGER POINT DRY NEEDLING CERTIFIED, INSTITUTE OF ADVANCED MUSCULOSKELETAL TECHNIQUES (IMAT)

2017 – LEVEL 1 AND 2 CERTIFIED FOR SELECTIVE FUNCTIONAL MOVEMENT ASSESSMENT (SFMA)

2017 – LEVEL 1 CERTIFIED MYOFASCIAL RELEASE TECHNIQUE

HONORS AND AWARDS

2015 – WHO'S WHO AMONG STUDENTS IN AMERICAN UNIVERSITIES & COLLEGES, SHENANDOAH UNIVERSITY, WINCHESTER, VA

2015 – OUTSTANDING GRADUATE AWARD, SHENANDOAH UNIVERSITY, DIVISION OF PHYSICAL THERAPY, WINCHESTER, VA

2018 – TEAM PLAYER AWARD, VIRGINIA SPINE INSTITUTE, RESTON, VA

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME SCOTT CAROW	POSITION TITLE ASSISTANT CHIEF OF PHYSICAL THERAPY		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
US Military Academy, West Point, NY	BS	1993-1997	Engineering Management
Baylor University, Waco, TX	DPT	2003-2006	Physical Therapy
Baylor University, Waco, TX	DSc	2010-2011	Physical Therapy

RESEARCH AND PROFESSIONAL EXPERIENCE:

POSITIONS AND EMPLOYMENT

1997 - 2003 U.S. Army, Armor Officer

2003 - 2005 Student, U.S. Army-Baylor Doctoral Program in Physical Therapy, Fort Sam Houston, TX

2005 - 2006 Physical Therapy Intern, Wilford Hall Air Force Medical Center, Lackland Air Force Base, TX

2006 - 2007 Brigade Physical Therapist for 2nd Brigade, 10th Mountain Division, Camp Striker, Iraq

2007 - 2008 Staff Physical Therapist, Fort Drum, NY

2008 - 2010 Chief, Cadet Physical Therapy Clinic, West Point, NY

2010 - 2011 Resident, U.S. Army – Baylor Post-professional Sports Medicine Physical Therapy Program, West Point, NY

2010 - 2011 Resident, U.S. Army – Baylor Post-professional Sports Medicine Physical Therapy Program, West Point, NY

2012 - 2014 Chief of Physical Therapy, Fort Benning, GA

2014 - Assistant Chief of Physical Therapy Clinic and Army-Baylor Doctoral Internship Director, Fort Bliss, TX

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS

- Assistant Professor in the U.S. Army – Baylor University Physical Therapy Program
- Faculty for Military Musculoskeletal Residency Program
- Reviewer for Journal of Athletic Training
- Member, American Physical Therapy Association – including Sports, Orthopedics, and Federal Sections

HONORS

- 2014 Mary Lipscomb Hamrick Army Medical Specialist Corps fourth Line of Research Manuscript Award
- 2013 Achievement of Distinction – International Journal of Sports Physical Therapy Outstanding Research Manuscript Award

PUBLICATIONS

1. Miller J, Westrick R, **Carow S**, Fogarty B, Owens B, Gerber JP. (2015) Knee imaging in sports medicine. In Sports Physical Therapy Section, Imaging Course (1-22). Indianapolis, IN.
2. **Carow SD**, Haniuk E, Cameron KL, DiStefano L, Marshall SW, Beutler A, Padua D, Gerber JP. The Risk of Lower Extremity Injury Following the Implementation of an Injury Prevention Exercise Program. *J Ath Training* 2014;49(3):000–000.
3. Henry NE, **Carow SD**, Kocher BL. Osteochondroma fracture at the distal medial femur. *J Orthop Sports Phys Ther.* 44:6:457, 2014 June
4. **Carow SD**, Potter S. Fracture of the Lateral Femoral Condyle. *J Orthop Sports Phy Ther.* 43(12):933, 2013 Dec.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME: EAMONN DELAHUNT		POSITION TITLE ASSOCIATE PROFESSOR	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University College Dublin, Dublin, Ireland	BSc (Physiotherapy)	2003	Physiotherapy
University College Dublin, Dublin, Ireland	PhD	2006	Physiotherapy
University College Dublin, Dublin, Ireland	Professional Diploma	2015	Teaching & Learning
RESEARCH AND PROFESSIONAL EXPERIENCE:			
POSITIONS AND EMPLOYMENT			
09/2007-12/2013 College Lecturer, School of Physiotherapy and Performance Science, University College Dublin, Dublin, Ireland			
01/2014-04/2015 Senior Lecturer, School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin, Ireland			
05/2015-Present Associate Professor, School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin, Ireland			
OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS			
2006-Present Member: Irish Society of Chartered Physiotherapists			
2014-Present Member: European College of Sport Science			
2012-Present Co-chair: International Ankle Consortium			
HONORS			
2014 University College Dublin Fellowship in Teaching and Academic Development			
2012 Specialist Member of the Irish Society of Chartered Physiotherapists			
2012 University College Dublin College Teaching Award			
2009 University College Dublin Module Innovation Support Grant			
2004 University College Dublin Open Postgraduate Scholarship			
2003 IRCSET* Postgraduate Research Scholarship			
2003 Murray Surgical Prize in Physiotherapy			
2003 Professor P. Casey Bursary in Psychiatry			
2003 University College Dublin 3rd Year Scholarship in Physiotherapy			
2002 National University of Ireland Dr H.H. Stewart Scholarship in Physiotherapy			

PUBLISHED MANUSCRIPTS

1. Doherty C, Bleakley C, **Delahunt E**, Holden S. Treatment and prevention of acute and recurrent ankle sprain injury: an overview of systematic reviews with meta-analysis. *British Journal of Sports Medicine* [Accepted, In Press].
2. Wang D, De Vito G, Ditroilo M, **Delahunt E**. Different effect of local and general fatigue on knee joint stiffness. *Medicine and Science in Sports and Exercise* [Epub ahead of print].
3. Wang D, De Vito G, Ditroilo M, **Delahunt E**. Effect of sex and fatigue on muscle stiffness and musculoarticular stiffness of the knee joint in a young active population. *Journal of Sports Sciences* [Epub ahead of print].
4. Gribble PA, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller, C, Kaminski T, McKeon P, Refshauge K, Verhagen E, Vicenzino B, Wikstrom E, **Delahunt E**. 2016 consensus statement of the International Ankle Consortium: prevalence, impact and long-term consequences of lateral ankle sprains. *British Journal of Sports Medicine* [Epub ahead of print].
5. Gribble PA, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller, C, Kaminski T, McKeon P, Refshauge K, Verhagen E, Vicenzino B, Wikstrom E, **Delahunt E**. Evidence review for the 2016 consensus statement of the International Ankle Consortium: prevalence, impact and long-term consequences of lateral ankle sprains. *British Journal of Sports Medicine* [Epub ahead of print].
6. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Locomotive biomechanics in persons with chronic ankle instability and lateral ankle sprain copers. *Journal of Science and Medicine in Sport* 2016; 19: 524-530.
7. Holden S, Boreham C, Doherty C, Wang D, **Delahunt E**. A longitudinal investigation into the progression of dynamic postural stability performance in adolescents. *Gait and Posture* 2016; 48: 171-176.
8. Wu R, **Delahunt E**, Ditroilo M, Lowery M, De Vito G. Effects of age and sex on neuromuscular-mechanical determinants of muscle strength. *Age (Dordr)* 2016; 38: 57.
9. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Gait biomechanics in participants, six-months after first-time lateral ankle sprain. *International Journal of Sports Medicine* 2016; 37: 577-83.
10. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Sweeney K, Patterson MR, **Delahunt E**. Coordination and symmetry patterns during the drop vertical jump in participants with chronic ankle instability and lateral ankle sprain copers. *Physical Therapy* 2016; 96: 1152-1161.
11. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Dynamic balance deficits in individuals with chronic ankle instability compared to lateral ankle sprain copers, 1-year following a first-time lateral ankle sprain injury. *Knee Surgery Sports Traumatology and Arthroscopy* 2016; 24: 1086-1095.
12. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Single-leg drop landing movement strategies in participants with chronic ankle instability compared with lateral ankle sprain 'copers'. *Knee Surgery Sports Traumatology and Arthroscopy* 2016; 24: 1049-1059.
13. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Recovery from a first-time lateral ankle sprain and predictors of chronic ankle instability: a prospective cohort analysis. *American Journal of Sports Medicine* 2016; 44: 995-1003.
14. Holden S, Boreham C, **Delahunt E**. Sex differences in landing biomechanics and postural stability during adolescence: a systematic review with meta- analyses. *Sports Medicine* 2016; 46: 241-253.
15. Holden S, Boreham C, Doherty C, **Delahunt E**. Two dimensional knee valgus displacement as a predictor of patellofemoral pain in adolescent females. *Scandinavian Journal of Medicine and*

Science in Sports 2015 Dec 29. doi: 10.1111/sms.12633. [Epub ahead of print]

16. Fullam K, Caulfield B, Coughlan GF, McGroarty M, **Delahunt E**. Dynamic postural stability deficits following cryotherapy application to the ankle joint. *Journal of Athletic Training* 2015; 50: 893-904.
17. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Dynamic balance deficits 6-months following first-time acute lateral ankle sprain: a laboratory analysis. *Journal of Orthopaedic and Sports Physical Therapy* 2015; 45: 626-633.
18. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Sweeney K, Patterson MR, **Delahunt E**. Coordination and symmetry patterns during the drop vertical jump, 6-months after first-time lateral ankle sprain. *Journal of Orthopaedic Research* 2015; 33: 1537-1544.
19. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Lower limb inter-joint postural coordination 1-year after first-time ankle sprain. *Medicine and Science in Sports and Exercise* 2015; 47: 2398-2405.
20. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Single-leg drop landing movement strategies 6 months following first-time acute lateral ankle sprain injury. *Scandinavian Journal of Medicine and Science in Sports* 2015; 25: 806-817.
21. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Single-leg drop landing motor control strategies following acute ankle sprain injury. *Scandinavian Journal of Medicine and Science in Sports* 2015; 25: 525-533.
22. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Sweeney K, **Delahunt E**. Inter-joint coordination strategies during unilateral stance following first-time, acute lateral ankle sprain: a brief report. *Clinical Biomechanics (Bristol, Avon)* 2015; 30: 636-639.
23. **Delahunt E**, Thorborg K, Khan KM, Robinson P, Hölmich P, Weir A. Minimum reporting standards for clinically-relevant research on groin pain in athletes. *British Journal of Sports Medicine* 2015; 49: 775-781.
24. Weir A, Brukner P, **Delahunt E**, Ekstrand E, Griffin D, Khan KM, Lovell G, Meyers W, Muschaweck U, Orchard J, Paajanen H, Philippon M, Reboul G, Robinson P, Schache AG, Schilders E, Serner A, Silvers H, Thorborg K, Tyler T, Verrall G, de Vos RJ, Vukovic Z, Hölmich P. Doha Agreement meeting on terminology and definitions in groin pain in athletes. *British Journal of Sports Medicine* 2015; 49: 768-774.
25. Weir A, Hölmich P, Schache A, **Delahunt E**, de Vos RJ. Terminology and definitions on groin pain in athletes: building agreement using a short Delphi method. *British Journal of Sports Medicine* 2015; 49: 825-827.
26. Wang D, De Vito G, Ditroilo M, Fong DTP, **Delahunt E**. A comparison of muscle stiffness and musculoarticular stiffness of the knee joint in young athletic males and females. *Journal of Electromyography and Kinesiology* 2015; 25: 495-500.
27. Holden S, Boreham C, Doherty C, Wang D, **Delahunt E**. Clinical assessment of countermovement jump landing kinematics in early adolescence: sex differences and normative values. *Clinical Biomechanics (Bristol, Avon)* 2015; 30: 469-474.
28. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Laboratory measures of postural control during the Star Excursion Balance Test following acute ankle sprain. *Journal of Athletic Training* 2015; 50: 651-664.
29. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Inter-joint coordination strategies during unilateral stance 6-months following acute lateral ankle sprain. *Clinical Biomechanics (Bristol, Avon)* 2015; 30: 129-135.
30. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Lower extremity function during gait in participants with first time acute lateral ankle sprain compared to controls. *Journal of*

Electromyography and Kinesiology 2015; 25: 182-192.

31. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Lower extremity coordination and symmetry patterns following acute lateral ankle sprain during a drop vertical jump task. *Human Movement Science* 2014; 38C: 34-46.
32. Holden S, Boreham C, Doherty C, Wang D, **Delahunt E**. Dynamic postural stability in young adolescent male and female athletes. *Pediatric Physical Therapy* 2014; 26: 447-452.
33. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Postural control strategies during single limb stance following acute lateral ankle sprain. *Clinical Biomechanics (Bristol, Avon)* 2014; 29: 643-649.
34. Gribble PA, **Delahunt E**, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, van der Wees P, Vicenzino B, Wikstrom E. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *British Journal of Sports Medicine* 2014; 48: 1014-1018.
35. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, **Delahunt E**. Balance failure in single limb stance due to ankle sprain injury: an analysis of center of pressure using the fractal dimension method. *Gait & Posture* 2014; 40: 172-176.
36. Patterson MR, **Delahunt E**, Caulfield B. Peak knee adduction moment during gait in anterior cruciate ligament reconstructed females. *Clinical Biomechanics (Bristol, Avon)* 2014; 29: 138-142.
37. Patterson MR, **Delahunt E**, Sweeney K, Caulfield B. An ambulatory method of identifying anterior cruciate ligament reconstructed gait patterns. *Sensors* 2014; 14: 887-899.
38. Doherty C, **Delahunt E**, Caulfield B, Hertel J, Ryan J, Bleakley C. The incidence and prevalence of ankle sprain injury: a systematic review and meta-analysis of prospective epidemiological studies. *Sports Medicine* 2014; 44: 123-140.
39. Fullam K, Caulfield B, Coughlan GF, **Delahunt E**. Kinematic analysis of selected reach directions of the Star Excursion Balance Test compared to the Y-Balance Test. *Journal of Sport Rehabilitation* 2014; 23: 27-35.
40. Gribble PA, **Delahunt E**, Bleakley CM, Caulfield B, Docherty CL, Fong DT, Fourchet F, Hertel J, Hiller CE, Kaminski TW, McKeon PO, Refshauge KM, van der Wees P, Vicenzino W, Wikstrom EA. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Journal of Athletic Training* 2014; 49: 121-127.
41. Patterson MR, **Delahunt E**. A diagonal landing task to assess dynamic postural stability in ACL reconstructed females. *Knee* 2013; 20: 532-536.
42. Gribble PA, **Delahunt E**, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, van der Wees P, Vicenzino B, Wikstrom E. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Journal of Orthopaedic and Sports Physical Therapy* 2013; 43: 585-591.
43. **Delahunt E**, Sweeney L, Chawke M, Kelleher J, Murphy K, Patterson M, Prendiville A. Lower limb kinematics and dynamic postural stability in anterior cruciate ligament reconstructed female athletes. *Journal of Athletic Training* 2013; 48: 172-185.
44. **Delahunt E**, Cusack K, Wilson K, Doherty C. Joint mobilization acutely improves landing kinematics in chronic ankle instability. *Medicine and Science in Sports and Exercise* 2013; 45: 514-519.
45. Lin CW, **Delahunt E**, King E. Neuromuscular training for chronic ankle instability. *Physical Therapy* 2012; 92: 987-991.
46. **Delahunt E**, Sweeney L, Chawke M, Kelleher J, Murphy K, Patterson M, Prendiville A. Lower limb

- kinematic alterations during drop vertical jumps in female anterior cruciate ligament reconstructed athletes. *Journal of Orthopaedic Research* 2012; 30: 72-78.
47. **Delahunt E**, Prendiville A, Sweeney L, Chawke M, Kelleher J, Patterson M, Murphy K. Hip and knee joint kinematics during a diagonal jump landing in anterior cruciate ligament reconstructed females. *Journal of Electromyography and Kinesiology* 2012; 22: 598-606.
48. Hiller CE, Nightingale EJ, Lin CW, Coughlan GF, Caulfield B, **Delahunt E**. Characteristics of people with recurrent ankle sprains: a systematic review with meta-analysis. *British Journal of Sports Medicine* 2011; 45: 660-672.
49. **Delahunt E**, Coughlan GF, Caulfield B, Nightingale EJ, Lin CW, Hiller CE. Inclusion criteria when investigating insufficiencies in chronic ankle instability. *Medicine and Science in Sports and Exercise* 2010; 42: 2106-2121.
50. **Delahunt E**, McGrath A, Doran N, Coughlan GF. The effect of taping on actual and perceived dynamic postural stability in subjects with chronic ankle instability. *Archives of Physical Medicine and Rehabilitation* 2010; 91: 1383-1389.
51. Holmes A, **Delahunt E**. Treatment of common deficits associated with chronic ankle instability. *Sports Medicine* 2009; 39: 207-224.
52. **Delahunt E**, O'Driscoll J, Moran K. The effects of taping and exercise on ankle joint movement in subjects with chronic ankle instability: A preliminary investigation. *Archives of Physical Medicine and Rehabilitation* 2009; 90: 1418-1422.
53. **Delahunt E**, Monaghan K, Caulfield B. Ankle function during hopping in subjects with functional instability of the ankle joint. *Scandinavian Journal of Medicine and Science in Sports* 2007; 17: 641-648.
54. **Delahunt E**, Monaghan K, Caulfield B. Altered neuromuscular control and ankle joint kinematics during walking in subjects with functional instability of the ankle joint. *American Journal of Sports Medicine* 2006; 34: 1970-1976.
55. **Delahunt E**, Monaghan K, Caulfield B. Changes in lower limb kinematics, kinetics and muscle activity in subjects with functional instability of the ankle joint during a single leg drop jump. *Journal of Orthopaedic Research* 2006; 24: 1991-2000.

Editorial Board Membership

2015–present *British Journal of Sports Medicine*
2015–present *Journal of Athletic Training*
2013–present *Journal of Science and Medicine in Sport*
2008–present *Physiotherapy Practice and Research*

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME NICHOLAS R. HEEBNER	POSITION TITLE ASSISTANT PROFESSOR		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
Pennsylvania State University, University Park, PA	BS	2005-2009	Athletic Training/ Kinesiology
University of Pittsburgh, Pittsburgh, PA	MS	2009-2012	Sports Medicine
University of Pittsburgh, Pittsburgh, PA	PhD	2012-2015	Rehabilitation Science

RESEARCH AND PROFESSIONAL EXPERIENCE:

POSITIONS AND EMPLOYMENT

2009-2011	Graduate Assistant, Certified Athletic Trainer (UPMC Sports Medicine), University of Pittsburgh, Pittsburgh, PA
2009-2015	Certified / Athletic Trainer, Casual Call, UPMC, Department of Athletic Training and Development, Pittsburgh, PA
2011-2015	Graduate Student Researcher, University of Pittsburgh, School of Health and Rehabilitation Science, Neuromuscular Research Laboratory, Pittsburgh, PA
2015	Present Assistant Professor, Department of Rehabilitation Sciences, Athletic Training, University of Kentucky, Lexington, KY
2015	Laboratory Coordinator, Sport Medicine Research Institute, University of Kentucky, Lexington, KY

PUBLICATIONS

PEER REVIEWED MANUSCRIPTS

Heebner NR, Abt JP, Lovalekar M, Beals K, Sell TC, Morgan JS, Kane SF, Lephart SM.
Physical and performance characteristics related to unintentional musculoskeletal injury in
Special Forces Operators. J Athl Train. (Accepted pending revisions)

Heebner NR, Lovalekar M, Rafferty DM, Wohleber MF, Simonson AJ, Reinert AR, Sell
TC. Different landing tasks elicit different landing kinematics and kinetics at the knee. J Athl
Train. (In Review)

Johnson, CD., Williams, VJ., **Heebner, NR.**, Wohleber, MF., Simonson, AJ., Rafferty, DM., Reinert, A., Sell, TC. Relationship of performance on the Sensory Organization Test to landing characteristics. J Sports Science. (In Review)

Clark NC, Akins JA, **Heebner NR**, Sell TC, Abt JP, Lovalekar M, Lephart SM. Reliability and Measurement Precision of Concentric-to-Isometric and Eccentric-to-Isometric Knee Active Joint Position Sense Tests in Uninjured Physically Active Adults. Physical Therapy in Sport. 2016; 18: 38-45

Nagai T, Clark NC, Abt JP, Sell TC, **Heebner NR**, Smalley BW, Wirt MD, Lephart SM. The Effect of Target Position on the Accuracy of Cervical Spine Rotation Active Joint Position Sense. J Sport Rehab. 2016; 25(1): 58-63

Akins JS, **Heebner NR**, Lovalekar M, Sell TC. Reliability and Validity of Instrumented Soccer Equipment. J Appl. Biomech. 2015; 31(3): 195-201

Heebner NR, Akins JS, Lephart SM, Sell TC. Reliability and validity of an accelerometer based measure of static and dynamic postural stability. Gait and Posture. 2014; 41(2): 535-539

Nagai T, **Heebner NR**, Sell TC, Nakagawa T, Fu FH, Lephart SM. Restoration of Sagittal and Transverse Plane Proprioception Following Anatomic Double-Bundle ACL Reconstruction. Knee Surg Sports Traumatol Arthrosc, 2012; 21(9): 2048-2056

PEER REVIEWED ABSTRACTS

Mattacola CG, Han DY, Crots J, Glueck A, Abt JP, **Heebner NR**. Concussion characteristics in horse racing. 5th International Consensus Conference on Concussion in Sport. Oct 27 – 28th, Berlin, Germany.

Mattacola CG, Han DY, Crots J, Glueck A, Abt JP, **Heebner NR**. Effect of repeat testing on equine helmet impact attenuation. 5th International Consensus Conference on Concussion in Sport. Oct 27 – 28th, Berlin, Germany.

Heebner NR, Abt JP, Nagai T, Lovalekar M, Lambert B, Williams N, Winters JD, Royer S, Lephart SM. Epidemiological analysis of injuries occurring in Marine Corps Forces Special Operations, American College of Sports Medicine Annual Meeting; May 31 – June 4, 2016; Boston, MA.

Royer SD, Winters JD, Abt J, **Heebner NR**, Nagai T, Lovalekar M, Lambert B, Williams N, Lephart S. Physical and Physiological Comparison between Marine Corps Forces Special Operations Command Operators and Combat Support Personnel. American College of Sports Medicine Annual Meeting; June 1, 2016; Boston, MA.

Winters JD, Abt J, FACSM, Nagai T, Lambert B, Williams N, **Heebner NR**, Royer S, Lephart S, FACSM. Association between Knee Strength and Landing Biomechanics in

Marine Corps Forces Special Operations Command Operators. American College of Sports Medicine Annual Meeting; June 2, 2016; Boston, MA.

Nagai T, Eagle S, Abt JP, **Heebner NR**, Williams N, Lambert B, Winters JD, Royer SD, Lephart SM. Heart Rate and Variability of Marine Special Operations Students during Close Quarter Battle Training. American College of Sports Medicine Annual Meeting; May 31-June 4, 2016; Boston, MA.

Eagle S, Nagai T, Abt J, FACSM, **Heebner NR**, Williams N, Lambert B, Winters J, Royer S Lephart SM, FACSM. Task Description and Physiological Demand of Marine Special Operations Students during Amphibious Training. American College of Sports Medicine Annual Meeting; June 2, 2016; Boston, MA.

Whitehead PN, Sell TC, Lovalekar M, Darnell ME **Heebner NR**, Abt JP, Lephart SM. Better dynamic postural stability while wearing minimalist footwear in physically-active male adults. American College of Sports Medicine Annual Meeting; May 31 – June 4, 2016; Boston, MA.

Heebner LR, **Heebner NR**. Kidney Laceration in Soccer Player. National Athletic Trainers' Association Annual Meeting; June 22-25, 2016; Baltimore, MD.

Johnson C, Williams V, **Heebner NR**, Rafferty D, Wohleber M, Simonson A, Reinert A, Sell TC. The relationship between performance on the Sensory Organization Test and landing biomechanics during a single- and double-leg stop-jump. American Physical Therapy Association's Combined Sections Meeting. February 17-20, 2016. Anaheim, CA.

Darnell, ME., Whitehead, PN., **Heebner, NR.**, Beals, K., Sell, TC., Lephart, SM, FACSM. Effect of Carbohydrates on Landing Mechanics and Postural Stability During Intermittent High-Intensity Exercise to Fatigue. MARC-ACSM: November 6 – 7. Harrisburg, PA.

Heebner NR, Sell TC, Lovalekar M, Abt JP, Rafferty DM, Simonson AJ, Wohleber MF, Lephart SM. Comparison of knee kinematics and kinetics during different landing tasks. National Athletic Trainers' Association Annual Meeting; June 23-25, 2015; St. Louis, MO.

Rafferty DM, Simonson AJ, Wohleber MF, **Heebner NR**, Sell TC, Abt JA, Lephart SM. The effects of trunk and lower extremity strength on optimal landing mechanics during a one-legged drop landing task in Air Force Special Tactics Operators. National Athletic Trainers' Association Annual Meeting; June 23-25, 2015; St. Louis, MO.

Whitehead, P N.; Sell, T C.; Lovalekar, M; **Heebner, NR.**; Abt, J P.; and Lephart, S M. Better Dynamic Postural Stability While Wearing Minimalist Footwear in Physically-Active Male Adults. International Journal of Exercise Science: Conference Proceedings: 2015; 9(3): Article 93

Sell TC, **Heebner NR**, Pletcher E, Lephart SM. Reliability and Hamstring Activation during Rotational Dynamic Postural Stability in Healthy Recreational Athletes. American Physical Therapy Association, Combined Sections Meeting; Feb 4-7, 2015; Indianapolis, IN.

Heebner NR, Sell TC, Akins JS, Lephart SM. Correlation of Tibial Accelerations with Knee Kinematics and Kinetics during Single-leg Landings. National Athletic Trainers' Association Annual Meeting; June 25-28, 2014; Indianapolis, IN.

Nagai T, Clark NC, Abt JP, Sell TC, **Heebner NR**, Smalley BW, Wirt MD, Lephart SM. The Effect of Target Position on the Accuracy of Cervical Spine Rotation Active Joint Position Sense. National Athletic Trainers' Association Annual Meeting; June 25-28, 2014; Indianapolis, IN.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Helton, Gary L.

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Director of Army-Baylor Doctoral of Physical Therapy Internship

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Mississippi University for Women, Columbus, MS	BS	2008	Exercise Science
Baylor University, Texas	DPT	2011	Physical Therapy
Baylor University, West Point, NY	DSc	2017	Physical Therapy

Positions and Honors**Positions and Employment**

2004 - 2005	Evacuation Squad Leader, 526 Brigade Support Battalion, 2 nd Brigade Combat Team, 101 st Airborne Division, Fort Campbell, Kentucky
2005 - 2006	Evacuation Squad Leader, 526 Brigade Support Battalion, 2 nd Brigade Combat Team, 101 st Airborne Division, Baghdad, Iraq
2010 - 2011	Physical Therapy Intern, Texas Physical Therapy Specialist, Selma, Texas
2011 - 2012	Staff Physical Therapist, Martin Community Hospital, Fort Benning, Georgia
2012 - 2014	Physical Therapy Clinic OIC, Martin Army Community Hospital, Fort Benning, Georgia
2014 - 2015	Brigade Musculoskeletal Action Team Leader, 194 th Armored Brigade, Fort Benning, Georgia
2015 - 2015	Clinical Instructor/Mentor, Military Musculoskeletal Physical Therapy Residence
2015 - 2017	Fellow, Army-Baylor Doctoral Fellowship in Sports Medicine Physical Therapy West Point Academy, West Point, New York
2017 -	Director, Army-Baylor Doctoral of Physical Therapy Internship

Other Experience and Professional Memberships

American Physical Therapy Association
Orthopedic Section – American Physical Therapy Association
Sports Section – American Physical Therapy Association

Honors

2002	Distinguished Honor Graduate/High APFT Award, U.S. Army Basic Combat Training
2004	Honor Graduate/High APFT Award, Primary Leadership Development Course
2008	Honor Graduate/High APFT Award, AMEDD Office Basic Course

Publications

Refereed Articles

1. Childs JD, Teyhen DS, Van Wyngaarden JJ, Dougherty BF, Ladislav BJ, Helton GH, Robinson ME, Wu SS, George SZ. Predictors of Web-Based Follow-up Response in the Prevention of Low Back Pain in the Military Trial (POLM). BMC Musculoskeletal Disorders. 2011;12:132.
2. Zifchock R, Sulley M, Helton G, Freisinger G, Blackmon F, Wilson R, Goss D. Reliability of a Device to Assess Torsional Stiffness for Running Footwear. Journal of Footwear Science.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME MATTHEW C. HOCH, PhD, ATC	POSITION TITLE ASSISTANT PROFESSOR		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
East Stroudsburg University, East Stroudsburg, PA	BS	2002-2006	Athletic Training
Ohio University, Athens, OH	MS	2006-2008	Athletic Training
University of Kentucky, Lexington, KY	Certificate	2008-2010	Applied Biostatistics
University of Kentucky, Lexington, KY	PhD	2008-2011	Rehabilitation Sciences
RESEARCH AND PROFESSIONAL EXPERIENCE:			
PROFESSIONAL EXPERIENCE			
2006-2008	Graduate Assistant Athletic Trainer, Intercollegiate Athletics, Ohio University		
2008-2011	Doctoral Research Assistant, Division of Athletic Training, University of Kentucky		
2009-2011	Adjunct Faculty, Department of Exercise Science, Eastern Kentucky University		
2011-2017	Assistant Professor, Physical Therapy/Athletic Training, Old Dominion University		
2017-2018	Lecturer, Division of Athletic Training, University of Kentucky		
2018-Present	Assistant Professor, Division of Athletic Training, University of Kentucky		
PROFESSIONAL MEMBERSHIPS			
2002-Present	National Athletic Trainer's Association		
2009-Present	American College of Sports Medicine		
HONORS AND AWARDS			
2009	Doctoral Student Scholarship - <i>NATA Research and Education Foundation</i>		
2010	Doctoral Oral Presentation Finalist - <i>NATA Research and Education Foundation</i>		
2011	Robinson Award for Research Creativity - <i>University of Kentucky College of Health Sciences</i>		
2012	Doctoral Oral Presentation Finalist - <i>NATA Research and Education Foundation</i>		
2016	Young Investigators Initiative Fellow - <i>U.S. Bone & Joint initiative</i>		
2016	Outstanding Teaching Faculty Award – <i>Old Dominion University College of Health Sciences</i>		
2016	Researcher of the Year Award – <i>Virginia Athletic Trainers Association</i>		
2017	Hirschfield Faculty Excellence Award - <i>Old Dominion University College of Health Sciences</i>		
2018	Clint Thompson Clinical Practice Advancement Award – <i>Journal of Athletic Training</i>		

REFEREED JOURNAL ARTICLES (SELECTED FROM 84 PEER REVIEWED PUBLICATIONS)

1. **Hoch MC**, McKeon PO. Joint mobilization improves spatiotemporal postural control and range of motion in those with chronic ankle instability. *J Ortho Res*. 2011; 29(3):326-32.
2. **Hoch MC**, Staton GS, McKeon JM, Mattacola CG, McKeon PO. Dorsiflexion and dynamic postural control deficits are present in those with chronic ankle instability. *J Sci Med Sport*. 2012; 15(6):574-579.
3. **Hoch MC**, Mullineaux DR, Andreatta RD, McKeon JM, Mattacola CG, English R, McKeon PO. A 2-week joint mobilization intervention improves self-reported function, range of motion, and dynamic balance in those with chronic ankle instability. *J Ortho Res*. 2012; 30(11):1798-1804.
4. **Hoch MC**, McKeon PO, Andreatta RD. Plantar cutaneous vibrotactile detection threshold changes in chronic ankle instability. *Med Sci Sport Exer*. 2012; 44(4), 666-672.
5. **Hoch MC**, Staton GS, McKeon PO. Dorsiflexion range of motion significantly influences dynamic balance. *J Sci Med Sport*. 2011; 14(1), 90-92.
6. Houston MN, Van Lunen BL, **Hoch MC**. Health-related quality of life in individuals with chronic ankle instability. *J Athl Train*. 2014; 49(6):758-763.
7. Powell MP, Powden CP, Houston MN, **Hoch MC**. Plantar cutaneous sensitivity and balance in those with and without chronic ankle instability. *Clin J Sports Med*. 2014; 24(6):490-496.
8. Gilbreath JP, Gaven SL, Van Lunen BL, **Hoch MC**. The effects of mobilization with movement on dorsiflexion range of motion, dynamic balance, and self-reported function in individuals with chronic ankle instability. *Man Ther*. 2014; 19(2):152-157.
9. **Hoch MC**, Mullineaux DR, Andreatta RD, McKeon JM, Mattacola CG, English R, McKeon PO. Effect of a 2-week joint mobilization intervention on instrumented measures of single-limb balance and ankle mechanics in those with chronic ankle instability. *J Sport Rehabil*. 2014; 23(1):18-26.
10. Houston MN, Hoch JM, Van Lunen BL, **Hoch MC**. The development of summary components for the Disablement in the Physically Active Scale in collegiate athletes. *Qual Life Res*. 2015;24(11):2657-62.
11. Gabriner ML, Houston MN, Kirby JL, **Hoch MC**. Contributing factors to Star Excursion Balance Test performance in individuals with chronic ankle instability. *Gait Posture*. 2015; 41(4):912-916.
12. Houston MN, Hoch JM, **Hoch MC**. Patient-reported outcome measures in individuals with chronic ankle instability: A systematic review. *J Athl Train*. 2015;50(10):1019-33.
13. Houston MN, Gabriner M, Kirby J, Hoch JM, **Hoch MC**. Clinical and laboratory predictors of health-related quality of life in individuals with chronic ankle instability. *Phys Ther Sport*. 2015;6(2):169-175.
14. **Hoch MC**, Farwell KE, Gaven SL, Weinhandl JT. Weight-bearing dorsiflexion range of motion and landing biomechanics in individuals with chronic ankle instability. *J Athl Train*. 2015;50(8):833-839.
15. Gabriner M, Braun B, Houston MN, **Hoch MC**. The effectiveness of foot orthotics on improving postural control in individuals with chronic ankle instability: A critically appraised topic. *J Sport Rehabil*. 2015; 24(1):68-71.
16. Hogan KK, Powden CJ, **Hoch MC**. The influence of foot posture on static and dynamic postural control in those with chronic ankle instability. *Clin Biomech*. 2016; 38:63-67.

17. Mignogna C, Welsch LA, **Hoch MC**. The effects of short foot exercises on postural control: A critically appraised topic. *Int J Athl Ther Train*. 2016; 21(6): 8-12.
18. Snyder B, Munter A, Houston MN, Hoch JM, **Hoch MC**. Interrater and intrarater reliability of the Semmes-Weinstein monofilament 4-2-1 stepping algorithm in physically active adults. *Muscle Nerve*. 2016; 53(6): 918-924.
19. **Hoch MC**, Houston MN, Hoch JM. Development of the Quick-FAAM: a preliminary shortened version of the Foot and Ankle Ability Measure for chronic ankle instability. *Int J Athl Ther Train*. 2016;21(4):45-50.
20. Kirby JL, Houston MN, Gabriner ML, **Hoch MC**. Relationships between mechanical joint stability and somatosensory function in individual with chronic ankle instability. *Foot*. 2016; 28:1-6.
21. Houston MN, Hoch JM, Van Lunen BL, **Hoch MC**. The impact of injury on health-related quality of life in collegiate athletes. *J Sport Rehabil*. 2017;26(5):365-375.
22. Legner JA, Hoch JM, Lorete CJ, **Hoch MC**. The validity of the Quick-FAAM in patients seeking treatment for an acute or subacute foot or ankle health condition. *J Sport Rehabil*. 2017, e-pub only, doi.org/10.1123/jsr.2016-0089.
23. Powden CP, Hogan KK, Wikstrom EA, **Hoch MC**. The effect of two forms of talocrural joint traction on dorsiflexion range of motion and postural control in those with chronic ankle instability. *J Sport Rehabil*. 2017;26(3):239-244.
24. Burcal CJ, **Hoch MC**, Wikstrom EA. Effects of a stocking on plantar sensation in individuals with and without chronic ankle instability. *Muscle Nerve*. 2017;55(4):513-19.
25. Powden CP, Hoch JM, **Hoch MC**. The effectiveness of rehabilitation for improving health-related quality of life detriments in individuals with chronic ankle instability: Meta-analysis. *J Athl Train*. 2017; 52(8):753-765.
26. Powden CJ, Hoch JM, Jamali B, **Hoch MC**. The evaluation of response shift following a 4-week multimodal intervention for chronic ankle instability. *J Athl Train*. Accepted.
27. Hoch JM, Powden CJ, **Hoch MC**. Reliability, minimal detectable change, and responsiveness of the Quick-FAAM. *Phys Ther Sport*. In Press.
28. Hoch JM, Baez SE, Cramer RJ, **Hoch MC**. Differences in the modified Disablement in the Physically Active Scale in those with and without chronic ankle instability. *J Sport Rehabil*. In Press.
29. Powden CJ, Hoch JM, Jamali BE, **Hoch MC**. Effects of a 4-week multimodal intervention on disease-oriented and patient-oriented outcomes in individuals with chronic ankle instability. *J Athl Train*. In Press.
30. Feldbrugge CM, Powden CP, Pathoomvanh MM, **Hoch MC**. Static stretching and joint mobilizations for individuals with chronic ankle instability – a pilot study. *J Bodywork Movement Therapies*. In Press.
31. Hartley EM, **Hoch MC**, Boling MC. Y-Balance test performance and BMI are associated with ankle sprain injury in collegiate male athletes. *J Sci Med Sport*. In Press.
32. Houston MN, Hoch JM, Van Lunen BL, **Hoch MC**. Collegiate athletes with ankle sprain history exhibit greater fear-avoidance beliefs. *J Sport Rehabil*. In Press.

RESEARCH SUPPORT

Ongoing

United States Department of Defense, Office of Naval Research (PI: Abt, JP) 06/2018-06/2021

Marines Special Operations Preparedness (M-SCOPE)

The overall purpose of this project is to develop and deliver a MARSOC-specific operational preparedness ranking system.

Role: Co-Investigator

Southeastern Athletic Trainers Association Research Program (PI: Kosik, K) 04/2018-04/2019

Cartilage Deformation and Gait Biomechanics in Patients With and Without Chronic Ankle Instability

The goal of this study is to compare cartilage deformation following exercise and gait biomechanics in individuals with chronic ankle instability and healthy control subjects.

Role: Co-Investigator

Past

Eastern Athletic Trainer's Association Research Program (Powden, C /Hoch, MC) 09/2015-09/2016

The Evaluation of Response Shift and Functional Outcomes Following a 4-week Comprehensive, Evidence-based Rehabilitation Program in Individuals with Chronic Ankle Instability

The goal of this study is to examine the efficacy and response shift in patient-reported outcomes following a comprehensive evidence-based rehabilitation program for individuals with chronic ankle instability.

Role: Co-Principal Investigator

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME NATHAN JOHNSON	POSITION TITLE ASSISTANT PROFESSOR		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
Bellarmino University, Louisville, KY	BS	2006	Health Sciences
Bellarmino University, Louisville, KY	DPT	2004	Physical Therapy
University of Kentucky, Lexington, KY	PhD	2012	Anatomy and Neurobiology
RESEARCH AND PROFESSIONAL EXPERIENCE: POSITIONS AND EMPLOYMENT 2005 – 2006 Staff Physical Therapist, Cardinal Hill Rehabilitation Hospital, Spinal Cord Unit 2006 – 2012 Graduate Student, University of Kentucky, Anatomy and Neurobiology 2012 – 2014 Instructor, College of Medicine, University of Kentucky 2014 – Present Assistant Professor, College of Health Sciences, University of Kentucky HONORS 2004 Golden Wedge Award, Bellarmine University 2004 Richard H. Swigart Academic Excellence Award, Bellarmine University 2007 Sandy C. Marks, Jr. Student Poster Presentation Award, The 24th Annual Meeting American Association of Clinical Anatomists 2008-2009 Research Challenge Trust Fund (RCTF) Recipient 2009 National Institute on Drug Abuse (NIDA) T32 Training Grant 2009 Student Poster Presentation Award. The 2nd Annual Symposium on Cognitive Science 2015 KL2 Scholar Award 2016 National Institutes of Health (NIH) Loan Repayment Program Recipient			

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

PUBLICATIONS

1. Brown, C.B., **Johnson, N.F.**, Anderson-Mooney, A., Jicah, G.A., Shaw, L.M., Traojanowski, J.Q., Van Eldik, L.J., Schmitt, F.A., Smith, C.D., Gold, B.T. (Submitted) Development, validation and application of a new fornix template for studies of aging and preclinical Alzheimer's disease. *Clinical NeuroImage*
2. Brown, C.B., Hakun, J.G., Zhu Z., **Johnson, N.F.**, Gold, B.T. (accepted). White matter microstructure contributes to age-related declines in task-induced deactivation of the default mode network. *Frontiers in Neuroscience*.
3. **Johnson, N.F.**, Gold, B.T., Bailey, A.L., Clasey, J.L., Hakun, J.G., White, M., Long, D.E., Powell, D.K. (2015) Cardiorespiratory Fitness Modifies the Relationship between Myocardial Function and Cerebral Blood Flow in Older Adults. *NeuroImage*.
4. Hakun, J.G., Zhu Z., Brown C.A., **Johnson, N.F.**, Gold, B.T. (2015) Longitudinal alterations to brain function, structure, and cognitive performance in healthy older adults: A fMRI-DTI study. *Neuropsychologia*.
5. Hakun, J.G., Zhu Z., **Johnson, N.F.**, Gold, B.T. (2015) Evidence for reduced efficiency and successful compensation in older adults during task switching. *Cortex*.
6. Zhu Z., **Johnson N.F.**, Kim C., Gold B.T. (2015). Reduced frontal cortex efficiency is associated with lower white matter integrity in aging. *Cerebral Cortex*. 25(1):138-146
7. Zhu Z., Hakun, J.G., **Johnson, N.F.**, Gold, B.T. (2014) Age-related increases in right frontal activation during task-switching are mediated by reaction time and white matter microstructure. *Neuroscience*.
8. Kim, C., **Johnson, N.F.**, Gold, B.T. (2014) Conflict Adaptation in Prefrontal Cortex: Now You See It, Now You Don't. *Cortex*. 50: 76-850
9. Gold, B.T., **Johnson, N.F.**, Powell, D.P. (2013) Lifelong bilingualism contributes to cognitive reserve against white matter integrity declines in aging. *Neuropsychologia*. 51(13): 2841-2846
10. Gold, B.T., Kim, C., **Johnson, N.F.**, Kryscio, R.J., Smith, C.D. (2013). Lifelong bilingualism maintains neural efficiency for cognitive control in aging. *The Journal of Neuroscience*. 33: 387-396

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

PUBLISHED ABSTRACTS

1. Johnson, Z.R., Gold, B.T., Bailey, A.L., Clasey, J.L., Long D., Powell D.K., **Johnson, N.F.** Cardiorespiratory Fitness Is Associated with Executive Function in Older Adults (poster). 1st Kentucky Neuroscience Institute Symposium, 2016
2. **Johnson, N.F.**, Gold, B.T., Bailey, A.L., Clasey, J.L., Hakun, J.G., White, M., Long, D., Powell, D.K. Cardiorespiratory Fitness Modifies the Relationship between Cardiac Function and Cerebral Blood Flow in Older Adults (poster). IV Step Conference, 2016
3. Zhu, Z., Hakun, J.G., Brown, C.A., **Johnson, N.F.**, Gold, B.T. Functional connectivity helps older adults perform like younger adults (poster). The 4th Annual W.R. Markesbery Symposium of Aging and Dementia, 2014
4. Brown, C.A., Hakun, J.G., Zhu, Z., **Johnson, N.F.**, Gold, B.T. White matter integrity contributes to age-related changes in default-mode network activation (poster). The 4th Annual W.R. Markesbery Symposium of Aging and Dementia, 2014
5. Lee, F., Powell, D.K., Bailey A., Clasey, J., **Johnson, N.F.** High-density lipoprotein (HDL) cholesterol is associated with ventricular volume in cognitively healthy seniors (poster). Spring, 2014.
6. Zhu, Z., Hakun, J. G., **Johnson, N. F.**, Gold, B. T. Department of Anatomy and Neurobiology, University of Kentucky, KY. Mechanisms of age-related brain activation increases frontal cortex (poster). The 3rd Annual W.R. Markesbery Symposium of Aging and Dementia, 2013
7. Hakun, J. G., Zhu, Z., **Johnson, N. F.**, Gold, B. T. Department of Anatomy and Neurobiology, University of Kentucky, KY. Age-related Increases in Functional Brain Connectivity during Task Switching are Compensatory (poster). The 3rd Annual W.R. Markesbery Symposium of Aging and Dementia, 2013

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME KYLE B. KOSIK	POSITION TITLE POSTDOCTORAL SCHOLAR		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
Illinois State University, Normal, IL	BS	2012	Athletic Training
University of Virginia, Charlottesville, VA	MEd.	2013	Kinesiology- Athletic Training
University of Kentucky, Lexington, KY	PhD.	2017	Rehabilitation Science
University of Kentucky, Lexington, KY	Postdoctoral	2018	Rehabilitation Science
RESEARCH AND PROFESSIONAL EXPERIENCE: POSITIONS AND EMPLOYMENT 2012-2013 GRADUATE ATHLETIC TRAINING, VIRGINIA MILITARY INSTITUTE, LEXINGTON, VA 2013-2017 RESEARCH ASSISTANT, MUSCULOSKELETAL LABORATORY, UNIVERSITY OF KENTUCKY 2015-2016 VISITING ASSISTANT PROFESSOR, EASTERN KENTUCKY UNIVERSITY 2017- RESEARCH ASSISTANT, DEPARTMENT OF REHABILITATION SCIENCES, UNIVERSITY OF KENTUCKY OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS 2010- NATIONAL ATHLETIC TRAINERS' ASSOCIATION 2013- SOUTHEAST ATHLETIC TRAINERS' ASSOCIATION HONORS AND AWARDS 2012 ILLINOIS STATE UNIVERSITY MCGINNIS DISTINGUISHED SENIOR, SCHOOL OF KINESIOLOGY AND RECREATION 2011 IOTA TAU ALPHA NATIONAL HONOR SOCIETY ADF			

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

PUBLICATIONS (SELECT)

1. **Kosik KB**, Terada M, McCann RS, Thomas AC, Johnson NF, Gribble PA. Decreased Perceived Ankle and Knee Joint Health in Individuals with Chronic Ankle Instability. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2018.
2. **Kosik KB**, Gribble PA. The Effect of Joint Mobilization on Dynamic Postural Control in Patients with Chronic Ankle Instability: A Critically Appraised Topic. *Journal of Sports Rehabilitation*. 2018.
3. McCann RS, **Kosik KB**, Terada M, Crossett ID, Bolding B, Gribble PA. Isometric Hip Strength and Dynamic Stability of Individuals with Chronic Ankle Instability. *Journal of Athletic Training*. 2018.
4. McCann RS, **Kosik KB**, Terada M, Beard MQ, Buskirk GE, Gribble PA. Acute Lateral Ankle Sprain Prediction in Collegiate Women's Soccer Players. *International Journal of Sport Physical Therapy*. 2018.
5. Terada M, **Kosik KB**, Johnson N, Gribble PA. Altered Postural Control Variability in Older-Age Individuals with A History of Lateral Ankle Sprain. *Gait & Posture*. 2018.
6. **Kosik KB**, Terada M, McCann RS, Boland S, Gribble P. Comparison of Two Rehabilitation Protocols on Patient and Disease Oriented Outcomes in Chronic Ankle Instability Individuals. *International Journal of Athletic Therapy & Training*. 2017.
7. **Kosik KB**, McCann RS, Terada M, Gribble PA. Therapeutic Interventions for Improving Self-Reported Function in Patients with Chronic Ankle Instability: A Systematic Review. *British Journal of Sports Medicine*. 2017.
8. **Kosik KB**, Terada M, Drinkard CP, McCann RS, Gribble PA. An Examination of Corticomotor Plasticity in Individuals With and Without Chronic Ankle Instability. *Medicine & Science in Sports & Exercise*. 2017.
9. McCann RS, **Kosik KB**, Terada M, Gribble PA. Energy Dissipation Between Females with and without Chronic Ankle Instability. *Scandinavian Journal of Medicine and Science in Sports*, 2017.
10. McCann RS, **Kosik KB**, Terada M, Beard MQ, Buskirk GE, Gribble PA. Associations Between Functional and Isolated Performance Measures in Collegiate Women's Soccer Players. *Journal of Sport Rehabilitation*. 2017.

11. McCann RS, Crossett ID, Terada M, **Kosik KB**, Bolding BA, Gribble PA. Hip Strength and Star Excursion Balance Test Deficits of Patients with Chronic Ankle Instability. *Journal of Science Medicine Sport*. 2017.
12. McCann RS, **Kosik KB**, Terada M, Gribble PA. Residual Impairments and Activity Limitations at Return-to-Play from a Lateral Ankle Sprain. *International Journal of Athletic Therapy & Training*, 2017.
13. Terada M, **Kosik KB**, McCann RS, Gribble PA. Diaphragm Structural Integrity and Contractility in Individuals with and without Chronic Ankle Instability. *Medicine Science & Sports & Exercise*, 2017.
14. McCann RS, **Kosik KB**, Beard MQ, Terada M, Pietrosimone BG, Gribble PA. Variations in Star Excursion Balance Test Performance between High School and Collegiate Football Players. *Journal of Strength and Conditions Research*. 2015.
15. Gribble PA, Terada M, Beard Q, **Kosik KB**, Lepley AS, McCan RS, Pietrosimone BP, Thomas AC. Prediction of Lateral Ankle Sprains in Football Players Based on Clinical Tests and Body Mass Index. *American Journal of Sports Medicine*. 2015.

PUBLISHED ABSTRACTS (SELECT)

1. **Kosik KB** Terada M, McCann RS, Thomas AC, Johnson NF, Gribble PA. Differences in Temporal Gait Mechanics are Associated with Decreased Perceived Ankle Joint Health in Individuals with Chronic Ankle Instability. Presented at the 2018 Athletic Trainers Osteoarthritis Consortium Annual Meeting. June, 2018, New Orleans, LA.
2. **Kosik KB**, Johnson N, Thomas AC, Terada M, McCann RS, Gribble PA. Decreased Dynamic Postural Control and Weight-Bearing Dorsiflexion in Young-Adults and Middle-Aged Adults with Chronic Ankle Instability. Presented at the 2018 National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2018, New Orleans, LA.
3. McCann RS, **Kosik KB**, Terada M, Gribble PA. Prediction of Chronic Ankle Instability Following Return-to-Play from a Lateral Ankle Sprain. Presented at the 2018 National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2018, New Orleans, LA.
4. Terada M, **Kosik KB**, McCann RS, Gribble PA. Prediction Capability of the Star Excursion Balance Test for Recurrent Ankle Sprains in High School and College Student Athletes. Presented at the 2018 National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2018, New Orleans, LA.
5. Hartzell JT, **Kosik KB**, Hoch JM, Gribble PA, Hoch MC. Validity of the Quick-FAAM for Individuals with Chronic Ankle Instability and Ankle Sprain Copers. Presented at the 2018 National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2018, New Orleans, LA.

6. **Kosik KB**, McCann RS, Terada M, Gribble PA. Contributing Factors to the Identification of Functional Ankle Instability Questionnaire in Individuals with Chronic Ankle Instability. Presented at the 2017 International Ankle Symposium. September, 2017, Chapel Hill, NC.
7. Gribble PA, Gay E, **Kosik KB**, McCann RS, Terada M. Re-Examining Self-Reported Instability and Injury History to Differentiate Chronic Ankle Instability and Coper Patients. Presented at the 2017 International Ankle Symposium. September, 2017, Chapel Hill, NC.
8. McCann RS, **Kosik KB**, Terada M, Gribble PA. Prediction of Recurrent Injury Following Return-to-Play from an Ankle Sprain. Presented at the 2017 International Ankle Symposium. September, 2017, Chapel Hill, NC.
9. **Kosik KB**, Terada M, McCann RS, Gribble PA. Differences in Functional Capacity and Subjective Symptoms Related to Joint Degeneration in Those With and Without Chronic Ankle Instability. Presented at the 2017 National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2017, Houston, TX.
10. McCann RS, Terada M, **Kosik KB**, Gribble PA. The influence of Hip Strength on Landing Kinematics in Individuals with Chronic Ankle Instability. Presented at the 2017 National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2017, Houston, TX.
11. Drinkard CP, McCann RS, **Kosik KB**, Terada M, Gribble PA. The Association of Corticospinal Excitability and Inhibition with Ankle Kinematics in Chronic Ankle Instability Individuals. National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2017, Houston, TX.
12. Terada M, Morgan KD, **Kosik KB**, McCann RS, Gribble PA. Novel Postural Stability Assessments in Individuals with Chronic Ankle Instability Using Engineering Control Theory. National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2017, Houston, TX.
13. Gribble PA, Gay EM, **Kosik KB**, McCann RS, Terada M, Villasante AG. Influence of Self-Reported Function and Pain in Differentiating Chronic Ankle Instability and Lateral Ankle Sprain Copers. National Athletic Trainers' Association Annual Meeting & Clinical Symposium. June, 2017, Houston, TX.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME DAVID K. POWELL	POSITION TITLE ASSISTANT PROFESSOR		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
State University of New York at Geneseo	BA	1993	Physics
University of Kentucky, Lexington, KY	PhD	2001	Solid State Physics

RESEARCH AND PROFESSIONAL EXPERIENCE:

POSITIONS AND EMPLOYMENT

1996-2002 Research Assistant, Physics, University of Kentucky (UK)
 2001-2007 Physicist, MRI and Spectroscopy Center, UK
 2008-2013 Adjunct Professor, Biomedical Engineering, UK
 2013-Present Assistant Professor, Anatomy and Neurobiology, UK

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS

- Member, American Physics Society (APS)
- Member, American Institute of Physics (AIP)
- Member, Sigma Phi Sigma Honor Society
- Member, International Society for Magnetic Resonance in Medicine
- 1990-1993, Volunteer, Learning to Read, Rochester, NY
- 2003-2015, Administrative MRISC Committee - UKY MRISC
- 2005-2015, Coordinator for MRI compatible equipment - UKY MRISC
- 2007-2015, Portal Research Committee - UKY MRISC
- 2007-2015, Coordinator, 3T Siemens Trio and 7T Clinscan scanner usage - UKY MRISC
- Ad Hoc Manuscript Reviewer - Neurobiology of Aging, NMR in Biomedicine, Journal of Cognitive Neuroscience, Drug and Alcohol Dependence, Plus One
- Grant Reviewer – Center for Clinical and Translational Science

HONORS

2002 Magna Cum Laude, Awarded by University of Kentucky (UK) Physics Department
 1995 Nominated Academic Scholarship, Awarded by UK Physics Department

PUBLICATIONS

1. **Powell, D. P.** and Smith, C. Diffusion Tensor Imaging. In: *Advances in Medical Physics 2012*. 2012.
2. Hamlet SM, Haggerty CM, Suever JD, Wehner GJ, Grabau JD, Andres KN, Vandsburger MH, **Powell DK**, Sorrell VL, Fornwalt BK. An interactive videogame designed to

- improve respiratory navigator efficiency in children undergoing cardiovascular magnetic resonance. *J Cardiovasc Magn Reson*. 2016 Sep 6;18(1):54. PMID: 27599620
3. Hamlet SM, Haggerty CM, Suever JD, Wehner GJ, Andres KN, **Powell DK**, Fornwalt BK. Optimal configuration of respiratory navigator gating for the quantification of left ventricular strain using spiral cine displacement encoding with stimulated echoes (DENSE) MRI. *J Magn Reson Imaging*. 2016 Jul 26. doi: 10.1002/jmri.25389. [Epub ahead of print] PMID:27458823
 4. Pearson CM, Chester DS, **Powell D**, Wonderlich SA, Smith GT. Investigating the reinforcing value of binge anticipation. *Int J Eat Disord*. 2016 Jun;49(6):539-41. PMID:27184737
 5. Jing L, Binkley CM, Suever JD, Umasankar N, Haggerty CM, Rich J, Wehner GJ, Hamlet SM, **Powell DK**, Radulescu A, Kirchner HL, Epstein FH, Fornwalt BK. Cardiac remodeling and dysfunction in childhood obesity: a cardiovascular magnetic resonance study. *J Cardiovasc Magn Reson*. 2016 May 11;18(1):28. PMID:27165194
 6. Park SH, Liu Z, Sui Y, Helsley RN, Zhu B, **Powell DK**, Kern PA, Zhou C. IKK β Is Essential for Adipocyte Survival and Adaptive Adipose Remodeling in Obesity. *Diabetes*. 2016 Jun;65(6):1616-29. PMID:26993069
 7. Jiang Y, Huang H, Abner E, Broster LS, Jicha GA, Schmitt FA, Kryscio R, Andersen A, **Powell D**, Van Eldik L, Gold BT, Nelson PT, Smith C, Ding M. Alzheimer's Biomarkers are Correlated with Brain Connectivity in Older Adults Differentially during Resting and Task States. *Front Aging Neurosci*. 2016 Feb 8;8:15. PMID:26903858
 8. Chester DS, Lynam DR, Milich R, **Powell DK**, Andersen AH, DeWall CN. How do negative emotions impair self-control? A neural model of negative urgency. *Neuroimage*. 2016 May 15;132:43-50. PMID:26892861
 9. Pumphrey A, Yang Z, Ye S, **Powell DK**, Thalman S, Watt DS, Abdel-Latif A, Unrine J, Thompson K, Fornwalt B, Ferrauto G, Vandsburger M. Advanced cardiac chemical exchange saturation transfer (cardioCEST) MRI for in vivo cell tracking and metabolic imaging. *NMR Biomed*. 2016 Jan;29(1):74-83. PMID: 26684053
 10. Samir P. Patel, Taylor D. Smith, Jenna L. VanRooyen, David **Powell**, David H. Cox, Patrick G. Sullivan, and Alexander G. Rabchevsky. Serial Diffusion Tensor imaging In Vivo Predicts Long-Term Functional Recovery in Rats Following Spinal Cord Injury. *Journal of Neurotrauma*. E-PUB ahead of print
 11. Haggerty CM, Mattingly AC, Kramer SP, Binkley CM, Jing L, Suever JD, **Powell DK**, Charnigo RJ, Epstein FH, Fornwalt BK. Left ventricular mechanical dysfunction in diet-induced obese mice is exacerbated during inotropic stress: a cine DENSE cardiovascular magnetic resonance study. *J Cardiovasc Magn Reson*. 2015 Aug 27;17(1):75. PMID: 26310667
 12. Wehner GJ, Grabau JD, Suever JD, Haggerty CM, Jing L, **Powell DK**, Hamlet SM, Vandsburger MH, Zhong X, Fornwalt BK. 2D cine DENSE with low encoding frequencies accurately quantifies cardiac mechanics with improved image characteristics. *J Cardiovasc Magn Reson*. 2015 Nov 4;17(1):93. PMID: 26538111
 13. Chester DS, Lynam DR, **Powell DK**, DeWall CN. Narcissism is Associated with Weakened Frontostriatal Connectivity: A DTI Study. *Soc Cogn Affect Neurosci*. 2015 Jun 5. pii: nsv069. [Epub ahead of print] PubMed PMID: 26048178.
 14. Johnson NF, Gold BT, Bailey AL, Clasey JL, Hakun JG, White M, Long DE, **Powell DK**. Cardiorespiratory fitness modifies the relationship between myocardial function and

- cerebral blood flow in older adults. *Neuroimage*. 2015 May 30. pii: S1053-8119(15)00453-X. doi: 10.1016/j.neuroimage.2015.05.063. [Epub ahead of print] PubMed PMID: 26032886.
15. Wehner GJ, Suever JD, Haggerty CM, Jing L, **Powell DK**, Hamlet SM, Grabau JD, Mojsejenko WD, Zhong X, Epstein FH, Fornwalt BK. Validation of in vivo 2D displacements from spiral cine DENSE at 3T. *J Cardiovasc Magn Reson*. 2015 Jan 30;17(1):5. doi: 10.1186/s12968-015-0119-z. PubMed PMID: 25634468; PubMed Central PMCID: PMC4311418.
 16. Redzic M, **Powell DK**, Thomas DT. Vitamin D status is related to intramyocellular lipid in older adults. *Endocrine*. 2014 Dec;47(3):854-61. doi: 10.1007/s12020-014-0238-6. Epub 2014 Mar 28. PubMed PMID: 24676758; PubMed Central PMCID: PMC4386577.
 17. Suever JD, Wehner GJ, Haggerty CM, Jing L, Hamlet SM, Binkley CM, Kramer SP, Mattingly AC, **Powell DK**, Bilchick KC, Epstein FH, Fornwalt BK. Simplified post processing of cine DENSE cardiovascular magnetic resonance for quantification of cardiac mechanics. *J Cardiovasc Magn Reson*. 2014 Nov 28;16:94. doi: 10.1186/s12968-014-0094-9. PubMed PMID: 25430079; PubMed Central PMCID: PMC4246464.
 18. Haggerty CM, Kramer SP, Skrinjar O, Binkley CM, **Powell DK**, Mattingly AC, Epstein FH, Fornwalt BK. Quantification of left ventricular volumes, mass, and ejection fraction using cine displacement encoding with stimulated echoes (DENSE) MRI. *J Magn Reson Imaging*. 2014 Aug;40(2):398-406. doi: 10.1002/jmri.24350. Epub 2013 Oct 29. PubMed PMID: 24923710; PubMed Central PMCID: PMC4311752.
 19. **Powell D**, Caban-Holt A, Jicha G, Robertson W, Davis R, Gold BT, Schmitt FA, Head E. Frontal white matter integrity in adults with Down syndrome with and without dementia. *Neurobiol Aging*. 2014 Jul;35(7):1562-9. doi: 10.1016/j.neurobiolaging.2014.01.137. Epub 2014 Feb 4. PubMed PMID: 24582640; PubMed Central PMCID: PMC3992921.
 20. Niedowicz DM, Reeves VL, Platt TL, Kohler K, Beckett TL, **Powell DK**, Lee TL, Sexton TR, Song ES, Brewer LD, Latimer CS, Kraner SD, Larson KL, Ozcan S, Norris CM, Hersh LB, Porter NM, Wilcock DM, Murphy MP. Obesity and diabetes cause cognitive dysfunction in the absence of accelerated β -amyloid deposition in a novel murine model of mixed or vascular dementia. *Acta Neuropathol Commun*. 2014 Jun 10;2:64. doi: 10.1186/2051-5960-2-64. PubMed PMID: 24916066; PubMed Central PMCID: PMC4229778.
 21. Hamlet S, Wehner G, Suever J, **Powell D**, Haggerty C, et al. "Effect of variable breath-hold positions during cardiac magnetic resonance on measures of left ventricular mechanics. *Journal of cardiovascular magnetic resonance : official journal of the Society for Cardiovascular Magnetic Resonance*. 2014 January 16; 16(Suppl 1):78.
 22. Wehner G, Suever J, Haggerty C, Jing L, **Powell D**, et al. High resolution cine displacement encoding with stimulated echoes (DENSE) at 3T with navigator feedback for quantification of cardiac mechanics. *Journal of cardiovascular magnetic resonance : official journal of the Society for Cardiovascular Magnetic Resonance*. 2014 January 16; 16(Suppl 1):48.
 23. Suever JD, Wehner GJ, Jing L, **Powell DK**, Haggerty CM, et al. Quantification of right ventricular function from short-axis displacement-encoded images. *Journal of cardiovascular magnetic resonance : official journal of the Society for Cardiovascular Magnetic Resonance*. 2014 January 16; 16(Suppl 1):52.

24. Haggerty CM, Mattingly AC, Binkley CM, Kramer SP, **Powell DK**, et al. Characterizing the temporal evolution of altered cardiac mechanics in diet-induced obese mice using cine DENSE CMR. *Journal of cardiovascular magnetic resonance : official journal of the Society for Cardiovascular Magnetic Resonance*. 2014; 16(Suppl 1):297.
25. Kramer SP, **Powell DK**, Haggerty CM, Binkley CM, Mattingly AC, Cassis LA, Epstein FH, Fornwalt BK. Obesity reduces left ventricular strains, torsion, and synchrony in mouse models: a cine displacement encoding with stimulated echoes (DENSE) cardiovascular magnetic resonance study. *J Cardiovasc Magn Reson*. 2013 Dec 31;15:109. doi: 10.1186/1532-429X-15-109. PubMed PMID: 24380567; PubMed Central PMCID: PMC3882783.
26. Gold BT, Johnson NF, **Powell DK**. Lifelong bilingualism contributes to cognitive reserve against white matter integrity declines in aging. *Neuropsychologia*. 2013 Nov;51(13):2841-6. doi: 10.1016/j.neuropsychologia.2013.09.037. Epub 2013 Oct 5. PubMed PMID: 24103400; PubMed Central PMCID: PMC3856701.
27. Haggerty CM, Kramer SP, Binkley CM, **Powell DK**, Mattingly AC, Charnigo R, Epstein FH, Fornwalt BK. Reproducibility of cine displacement encoding with stimulated echoes (DENSE) cardiovascular magnetic resonance for measuring left ventricular strains, torsion, and synchrony in mice. *J Cardiovasc Magn Reson*. 2013 Aug 27;15:71. doi: 10.1186/1532-429X-15-71. PubMed PMID: 23981339; PubMed Central PMCID: PMC3765995.
28. Sudduth TL, **Powell DK**, Smith CD, Greenstein A, Wilcock DM. Induction of hyperhomocysteinemia models vascular dementia by induction of cerebral microhemorrhages and neuroinflammation. *J Cereb Blood Flow Metab*. 2013 May;33(5):708-15. doi: 10.1038/jcbfm.2013.1. Epub 2013 Jan 30. PubMed PMID: 23361394; PubMed Central PMCID: PMC3652696.

INVITED LECTURES, EXPERT, AND PEER REVIEW ACTIVITIES

- 2013 Small Animal Imaging, Translational CCTS Conference, Hyatt, Lexington, KY
- 2012 Animal cardiac, TBI, Lipid imaging, BME Seminar, Lexington, KY 2012
- 2012 Down Syndrome MRI (DTI, Spect, fMRI), Down Syndrome Conference, Louisville, KY
- 2012 Small Animal Imaging, Physiology Department Seminar, Lexington, KY
- 2011 Traumatic Brain Imaging, SCOBIRC, Lexington, KY
- 2011 Spectroscopy & Mouse Imaging, St Jude's, Memphis, TN
- 2011 Small Animal MRI, SCOBIRC, University of Kentucky, Lexington, KY
- 2010 Pennington Scientific Symposium, Baton Rouge
- 2009 Diffusion Tensor Imaging, Radiology Department University of Kentucky Symposia on Advanced Medical Imaging, Lexington, KY
- 2008 Diffusion Tensor Imaging, BME Department Seminar Series, Lexington, KY
- 2007 DTI fiber tracking and fractional anisotropy-reaction time correlations in visual word recognition, International Society for Magnetic Resonance in Medicine meeting, Berlin

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME KATHRYN E. ROBERTS

POSITION TITLE: RESEARCH COORDINATOR

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).

INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
William Woods University	Bachelor of Science	2010	Athletic Training
University of Kentucky	Master of Science	2012	Athletic Training

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

Certified Athletic Trainer/Wellness Consultant
 TRS Wellness: Therapy and Rehab Solutions
 Conway, AR
 July 2012-November 2014

Certified Athletic Trainer
 Soldier-Athlete Initiative: Musculoskeletal Action Team
 Fort Sill, OK
 December 2014-April 2015

Health Educator/ Research Fellow
 Oak Ridge Institute of Science and Energy
 Army Wellness Center of Joint Base Lewis-McChord
 Tacoma, WA
 October 2015-July 2018

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY.
DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

RESEARCH COORDINATOR

THE GENEVA FOUNDATION

FORT BLISS, TX

SEPTEMBER 2018-PRESENT

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME ERIK A. WIKSTROM	POSITION TITLE ASSISTANT PROFESSOR		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
Roanoke College, Salem, VA	BS	1997-2001	Athletic Training
University of Florida, Gainesville, FL	MS	2001-2003	Exercise and Sport Science
University of Florida, Gainesville, FL	PhD	2003-2007	Health and Human Performance

RESEARCH AND PROFESSIONAL EXPERIENCE:

POSITIONS AND EMPLOYMENT

- 2003-2004 Athletic Training Laboratory Coordinator, Department of Applied Physiology and Kinesiology, University of Florida
- 2004-2008 Lecturer and Director of Undergraduate Athletic Training, Department of Applied Physiology and Kinesiology, University of Florida
- 2008-2013 Assistant Professor, Department of Kinesiology, UNC Charlotte
- 2013-2015 Associate Professor with Tenure, Department of Kinesiology, UNC Charlotte
- 2015-Present Assistant Professor and Katherine Smith Gunter Fellow, Department of Exercise and Sport Science, University of North Carolina at Chapel Hill
- 2015-Present Co-Director, Sports Medicine Research Laboratory, University of North Carolina at Chapel Hill
- 2016-Present Associate Director, Human Movement Science PhD Program, University of North Carolina at Chapel Hill

HONORS

2003	Grinter Fellowship, Department of Applied Physiology and Kinesiology, University of Florida
2010	David H. Perrin Doctoral Dissertation Award, National Athletic Trainers' Association
2011	Fellow, American College of Sports Medicine
2012	Junior Investigator Award, UNC Charlotte Health Academy
2013	Ken Knight Award for Outstanding Research Manuscript, Journal of Athletic Training
2013	Research Excellence Award, College of Health and Human Services at UNC Charlotte

PUBLICATIONS

1. Gribble PA, Delahunt E, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, van der Wees P, Vicenzino B, **Wikstrom EA**. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *J Orthop Sports Phys Ther* 2013;43(8):585-591.
2. Burcal C, **Wikstrom EA**. The effect of instructions on postural-suprapostural interactions in three working memory tasks. *Gait Posture* 2014;40(2):310-314.
3. Cuğ M, **Wikstrom EA**. Learning effects associated with the least stable level of the biodex stability system during dual and single limb stance. *J Sport Sci Med* 2014; 13(2):387-392.
4. **Wikstrom EA**, Brown CN. Minimum reporting standard for copers in chronic ankle instability research *Sports Med* 2014;44(2):251-268.
5. Turner TH, **Wikstrom EA**, Guderian S, Turner MJ. An acute lateral ankle sprain significantly decreases physical activity across the lifespan. *J Sports Sci Med* 2015;14(3):556-561.
6. Liu K, Gustavsen G, **Wikstrom EA**, Royer, T, Glutting J, Kaminski TW. Increased ligament thickness exists in unstable ankles as measured by musculoskeletal ultrasound. *J Athl Train* 2015;50(2):193-198.
7. **Wikstrom EA**, Hubbard-Turner T, Woods SN, Guderian S, Turner MJ. Developing a mouse model of chronic ankle instability. *Med Sci Sports Exerc* 2015;47(4): 866-72

8. **Wikstrom EA**, Anderson RB, Hubbard-Turner T. Alterations in stair ascent and descent kinetics are present in those with post-traumatic ankle osteoarthritis. *Int J Athl Ther Train* 2015;20(6):37-43.
9. Cuğ M, **Wikstrom EA**, Golshaei B, Kirazci S. The effects of sex, limb dominance, and soccer participation on knee proprioception and dynamic postural control. *J Sport Rehab* 2016;25(1):31-39.
10. McKeon PO, **Wikstrom EA**. Sensory-targeted ankle rehabilitation strategies for chronic ankle instability. *Med Sci Sports Exerc* 2016;48(5):776-784.
11. Burcal CJ, **Wikstrom EA**. Plantar cutaneous sensitivity with and without cognitive loading in people with CAI, copers, and uninjured controls. *J Orthop Sports Phys Ther* 2016;26(1):1-24.
12. Burcal CJ, Drabik E, **Wikstrom EA**. Cognitive loading-induced postural control alterations are similar in those with chronic ankle instability and uninjured controls. *Gait Posture* 2016;48:95-98.
13. Turner MJ, Guderian S, **Wikstrom EA**, Huot JR, Peck BD, Arthur ST, Marino JS, Hubbard-Turner T. Altered left ventricular performance in aging physically active mice with an ankle sprain injury. *AGE* 2016; 38(1): 1-15.
14. Song K, Burcal CJ, Hertel J, **Wikstrom EA**. Increased visual utilization in chronic ankle instability: a meta-analysis. *Med Sci Sports Exerc* 2016;48(10):2046-2056.
15. Burcal CJ, Hoch MC, **Wikstrom EA**. Effects of a stocking on plantar cutaneous sensation in individuals with and without chronic ankle instability. *Muscle Nerve* 2016 Aug 4. [Epub ahead of print]
16. Burcal CJ, Trier AY, **Wikstrom EA**. Balance Training vs. Balance Training with STARS in CAI Patients: A randomized controlled trial. *J Sport Rehab* 2016 Aug 24:1-30. [Epub ahead of print]
17. Shah S, Thomas AC, Noone JM, Blanchette CM, **Wikstrom EA**. Incidence and cost of ankle sprains in the united states emergency departments. *Sports Health* 2016 Jul 29. [Epub ahead of print]
18. Gribble PA, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, van der Wees P, Vicenzino B, **Wikstrom EA**, Delahunt E. Evidence review for the 2016 international ankle consortium consensus statement on the prevalence, impact, and long-term consequences of lateral ankle sprains. *Br J Sports Med* 2016 Jun 3. [Epub ahead of print]
19. Gribble PA, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DTP, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, van der Wees P, Vicenzino B, **Wikstrom EA**,

Delahunt E. Consensus statement of the international ankle consortium: prevalence, impact and long-term consequences of lateral ankle sprains. *Br J Sports Med* 2016 2016 Jun 3. [Epub ahead of print]

20. Powden C, Hogan KK, **Wikstrom EA**, Hoch M. The effect of two forms of talocrural joint traction on dorsiflexion range of motion and postural control in those with chronic ankle instability. *J Sport Rehab* 2016 Aug 24:1-19. [Epub ahead of print]
21. Thomas AC, Hubbard-Turner T, **Wikstrom EA**, Palmieri-Smith R. Epidemiology of post-traumatic osteoarthritis. *J Athl Train* 2016 May 4. [Epub ahead of print]
22. **Wikstrom EA**, McKeon PO. Predicting Balance Improvements Following STARS Treatments in Chronic Ankle Instability Patients. *J Sci Med Sports* IN PRESS
23. **Wikstrom EA**, Song K, Lea A, Brown N. Comparative effectiveness of plantar massage techniques on postural control in those with chronic ankle instability. *J Athl Train* IN PRESS
24. Hubbard-Turner T, **Wikstrom EA**, Guderian S, Turner MJ. Acute ankle sprain in a mouse model: development of knee joint degeneration. *J Athl Train* IN PRESS
25. Song K, Kang TK, **Wikstrom EA**, Jun H, Lee SY. Effects of reduced plantar cutaneous sensation on static postural control in individuals with and without CAI. *J Sport Sci Med* IN PRESS
26. **Wikstrom EA**, Song K, Cuğ M, Bentley RL. Clinical Balance Measures in Chronic Ankle Instability Patients, Copers, and Uninjured Controls. *Athl Train Sports Health Care* IN PRESS
27. Roos KG, Kerr ZY, Mauntel TC, Djoko A, Dompier TP, **Wikstrom EA**. The epidemiology of lateral ligament complex ankle sprains in NCAA sports. *Am J Sports Med* IN PRESS
28. **Wikstrom EA**, McKeon PO. Predicting Manual Therapy Treatment Success in Chronic Ankle Instability Patients: Improving Self-Reported Function. *J Athl Train* IN PRESS

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** John Abt (ID: 727475)
- **Institution Affiliation:** University of Kentucky (ID: 409)
- **Institution Email:** john.abt@uky.edu
- **Institution Unit:** College of Health Sciences
- **Phone:** 8592181809

- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 1 Biomedical Investigators and Key Personnel
- **Stage:** Stage 2 - Refresher Course

- **Record ID:** 16587700
- **Completion Date:** 31-Jul-2018
- **Expiration Date:** 30-Jul-2021
- **Minimum Passing:** 80
- **Reported Score*:** 96

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Biomed Refresher 1 – History and Ethical Principles (ID: 975)	31-Jul-2018	2/2 (100%)
Biomed Refresher 1 - Research and HIPAA Privacy Protections (ID: 17261)	31-Jul-2018	4/4 (100%)
Biomed Refresher 1 – Informed Consent (ID: 980)	31-Jul-2018	2/2 (100%)
Biomed Refresher 1 – Regulations and Process (ID: 981)	31-Jul-2018	3/3 (100%)
Biomed Refresher 1 – Populations in Research Requiring Additional Considerations and/or Protections (ID: 985)	31-Jul-2018	2/2 (100%)
Biomed Refresher 1 – FDA-Regulated Research (ID: 987)	31-Jul-2018	2/3 (67%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	31-Jul-2018	4/4 (100%)
Biomed Refresher 1 – Research Involving Children (ID: 974)	31-Jul-2018	4/4 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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Collaborative Institutional Training Initiative (CITI Program)

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** John Abt (ID: 727475)
- **Institution Affiliation:** University of Kentucky (ID: 409)
- **Institution Email:** john.abt@uky.edu
- **Institution Unit:** College of Health Sciences
- **Phone:** 8592181809
- **Curriculum Group:** Human Research
- **Course Learner Group:** Group 1 Biomedical Investigators and Key Personnel
- **Stage:** Stage 2 - Refresher Course
- **Record ID:** 16587700
- **Report Date:** 31-Jul-2018
- **Current Score**:** 89

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Biomed Refresher 1 - Instructions (ID: 960)	09-Jan-2015	No Quiz
Biomed Refresher 1 – History and Ethical Principles (ID: 975)	31-Jul-2018	2/2 (100%)
Biomed Refresher 1 – Regulations and Process (ID: 981)	31-Jul-2018	3/3 (100%)
Biomed Refresher 1 – Informed Consent (ID: 980)	31-Jul-2018	2/2 (100%)
Biomed Refresher 1 – SBR Methodologies in Biomedical Research (ID: 982)	09-Jan-2015	2/3 (67%)
Biomed Refresher 1 – Records-Based Research (ID: 983)	09-Jan-2015	1/2 (50%)
Biomed Refresher 1 – Genetics Research (ID: 984)	09-Jan-2015	2/2 (100%)
Biomed Refresher 1 - Populations in Research Requiring Additional Considerations and/or Protections (ID: 985)	31-Jul-2018	2/2 (100%)
Biomed Refresher 1 – Research Involving Prisoners (ID: 973)	09-Jan-2015	2/2 (100%)
Biomed Refresher 1 – Research Involving Children (ID: 974)	31-Jul-2018	4/4 (100%)
Biomed Refresher 1 – Research Involving Pregnant Women, Fetuses, and Neonates (ID: 986)	09-Jan-2015	2/3 (67%)
Biomed Refresher 1 – FDA-Regulated Research (ID: 987)	31-Jul-2018	2/3 (67%)
Biomed Refresher 1 - Research and HIPAA Privacy Protections (ID: 17261)	31-Jul-2018	4/4 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	31-Jul-2018	4/4 (100%)
Hot Topics (ID: 487)	13-Jan-2011	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k94a4d0c8-5c46-417f-abfc-6e7d349a947f-16587700

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Email: support@citiprogram.org

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Web: <https://www.citiprogram.org>



Completion Date 23-Jul-2018
Expiration Date 22-Jul-2021
Record ID 27836356

This is to certify that:

Katherine Bain

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

University of Kentucky



Verify at www.citiprogram.org/verify/?wbb26c02c-e3a5-4f09-bd50-917288ae2e68-27836356



Completion Date 21-Jan-2016
Expiration Date 20-Jan-2019
Record ID 18443802

This is to certify that:

Meaghan Beck

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

University of Kentucky

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wd028749a-006f-48d5-94e1-ac3359302b25-18443802



Completion Date 06-Apr-2017
Expiration Date 05-Apr-2020
Record ID 22457173

This is to certify that:

Phillip Gribble

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

3 - Refresher Course

(Stage)

Under requirements set by:

University of Kentucky

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w6e8a7efd-f9db-405e-9b63-d2b1211e742c-22457173



Completion Date 31-Jul-2018
Expiration Date 30-Jul-2021
Record ID 28034655

This is to certify that:

Nicholas Heebner

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

2 - Refresher Course

(Stage)

Under requirements set by:

University of Kentucky

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wa944fd98-3a9d-4be7-ba25-0108a7e46ee6-28034655



Completion Date 08-Nov-2018

Expiration Date 07-Nov-2021

Record ID 29397461

This is to certify that:

Gary Helton

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 2. Principal investigators and Associate Investigators

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

William Beaumont Army Medical Center



Verify at www.citiprogram.org/verify/?waa7f7875-d945-43aa-ba7e-52e04d3f140c-29397461



Completion Date 10-Aug-2016
Expiration Date 10-Aug-2019
Record ID 12253603

This is to certify that:

Matthew Hoch

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

3 - Refresher Course

(Stage)

Under requirements set by:

University of Kentucky



Verify at www.citiprogram.org/verify/?w9b9c0909-8f7a-496f-abef-061a964094ae-12253603



Completion Date 03-Oct-2016
Expiration Date 03-Oct-2019
Record ID 19235009

This is to certify that:

Nathan Johnson

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

4 - Refresher Course

(Stage)

Under requirements set by:

University of Kentucky

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w7f9780a6-efcc-46ab-9a04-082a7bd66f96-19235009



Completion Date 11-Aug-2016
Expiration Date 11-Aug-2019
Record ID 20456397

This is to certify that:

Kyle Kosik

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

2 - Refresher Course

(Stage)

Under requirements set by:

University of Kentucky

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w2475737f-e3cc-442c-899e-da14b6a6922c-20456397



Completion Date 10-Mar-2017
Expiration Date 09-Mar-2020
Record ID 22580264

This is to certify that:

David Powell

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 1 Biomedical Investigators and Key Personnel

(Course Learner Group)

2 - Refresher Course

(Stage)

Under requirements set by:

University of Kentucky



Verify at www.citiprogram.org/verify/?we237cdbb-1c15-4306-9f56-b9b243af8f76-22580264



Completion Date 13-Nov-2018
Expiration Date 12-Nov-2021
Record ID 29385334

This is to certify that:

Kathryn Roberts

Has completed the following CITI Program course:

Human Research

(Curriculum Group)

Group 2. Principal investigators and Associate Investigators

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

William Beaumont Army Medical Center



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Completion Date 28-Aug-2015
Expiration Date N/A
Record ID 17058114

This is to certify that:

Erik Wikstrom

Has completed the following CITI Program course:

Biomedical Responsible Conduct of Research (Curriculum Group)
Biomedical Responsible Conduct of Research (Course Learner Group)
1 - RCR (Stage)

Under requirements set by:

University of North Carolina at Chapel Hill



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Completion Date 28-Aug-2015
Expiration Date 25-Aug-2025
Record ID 17057843

This is to certify that:

Erik Wikstrom

Has completed the following CITI Program course:

Human Research (Curriculum Group)
Group 1 Biomedical Research: (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

University of North Carolina at Chapel Hill



Verify at www.citiprogram.org/verify/?wd1aaabcc-1050-4055-8725-20563e700b23-17057843

Ankle Dorsiflexion Range of Motion

	Right	Left
Trial 1		
Trial 1		
Trial 1		
Note		

Ankle Instability Instrument (AII)

Ankle Instability Instrument

Instructions

This form will be used to categorize your ankle instability. A separate form should be used for the right and left ankles. Please fill out the form completely. If you have any questions, please ask the administrator of the survey. Thank you for your participation.

1. Have you ever sprained an ankle? ☐ Yes ☐ No
 2. Have you ever seen a doctor for an ankle sprain? ☐ Yes ☐ No
If yes,
 - 2a. How did the doctor categorize your most serious ankle sprain?
☐ Mild (grade 1) ☐ Moderate (grade 2) ☐ Severe (grade 3)
 3. Did you ever use a device (such as crutches) because you could not bear weight due to an ankle sprain? ☐ Yes ☐ No
If yes,
 - 3a. In the most serious case, how long did you need to use the device?
☐ 1–3 days ☐ 4–7 days ☐ 1–2 weeks ☐ 2–3 weeks ☐ >3 weeks
 4. Have you ever experienced a sensation of your ankle "giving way"? ☐ Yes ☐ No
If yes,
 - 4a. When was the last time your ankle "gave way"?
☐ <1 month ☐ 1–6 months ago ☐ 6–12 months ago ☐ 1–2 years ago ☐ >2 years
 5. Does your ankle ever feel unstable while walking on a flat surface? ☐ Yes ☐ No
 6. Does your ankle ever feel unstable while walking on uneven ground? ☐ Yes ☐ No
 7. Does your ankle ever feel unstable during recreational or sport activity? ☐ Yes ☐ No ☐ N/A
 8. Does your ankle ever feel unstable while going *up* stairs? ☐ Yes ☐ No
 9. Does your ankle ever feel unstable while going *down* stairs? ☐ Yes ☐ No
-

1. Name of instrument	<i>Ankle Osteoarthritis Scale</i>
2. What it is designed to assess (specific anatomic area)	<i>Ankle osteoarthritis</i>
3. Method of administration (patient, clinician, or combined)	<i>Patient administered</i>
4. How to obtain the instrument	Domsic RT, Saltzman CL. Ankle osteoarthritis scale. <i>Foot Ankle Int.</i> 1998;19:466–471.
5. Cost involved in obtaining instrument	<i>None</i>
6. Method of design	<i>Modification of Foot Function Index</i>
7. Statistical validation	<i>Reliability, Criterion and Construct Validity</i>
8. Normative data available	<i>None</i>
9. Disease-specific data available	<i>None</i>
10. References for scientific basis and reference data	Domsic RT, Saltzman CL. (see reference in #4)
11. Scoring module	<i>Accounts for missing/not applicable values</i>
12. What kind of total and subscales do you get	<i>Pain, Disability, Total</i>
13. Format and number of questions	<i>18 questions, visual analogue scale</i>
14. Time for administration	<i>Less than 10 minutes</i>
15. Additional notes	<i>None</i>
16. The questionnaire	<i>See page S74</i>

Ankle Osteoarthritis Scale (AOS)

PAIN

The line next to each item represents the amount of pain you typically had in each situation. On the far left is “no pain” and on the far right is “the worst pain imaginable.” Place a mark on the line to indicate how bad your ankle pain was in each of the following situations during the past week. If you were not involved in one or more of these situations, mark that item NA.

HOW SEVERE WAS YOUR ANKLE PAIN:

1.	At its worst?	No pain	_____	Worst pain imaginable	NA
2.	Before you get up in the morning?	No pain	_____	Worst pain imaginable	
3.	When you walked barefoot?	No pain	_____	Worst pain imaginable	
4.	When you stood barefoot?	No pain	_____	Worst pain imaginable	
5.	When you walked wearing shoes?	No pain	_____	Worst pain imaginable	
6.	When you stood wearing shoes?	No pain	_____	Worst pain imaginable	
7.	When you walked wearing shoe inserts or braces?	No pain	_____	Worst pain imaginable	
8.	When you stood wearing shoe inserts or braces?	No pain	_____	Worst pain imaginable	
9.	At the end of the day?	No pain	_____	Worst pain imaginable	

_____/_____ = ____%

DISABILITY

The line next to each item represents the amount of difficulty you had performing an activity. On the far left is “no difficulty” and on the far right is “so difficult, unable.” Place a mark on the line to indicate how much difficulty you had performing each activity because of your ankle during the past week. If you did not perform an activity during the past week, place an “X” in the column under the heading NA.

HOW MUCH DIFFICULTY DID YOU HAVE:

					NA
1.	Walking around the house?	No difficulty	_____	So difficult, unable	
2.	Walking outside on uneven ground?	No difficulty	_____	So difficult, unable	
3.	Walking four or more blocks?	No difficulty	_____	So difficult, unable	
4.	Climbing stairs?	No difficulty	_____	So difficult, unable	
5.	Descending stairs?	No difficulty	_____	So difficult, unable	
6.	Standing on tip toes?	No difficulty	_____	So difficult, unable	
7.	Getting out of a chair?	No difficulty	_____	So difficult, unable	
8.	Climbing up or down curbs?	No difficulty	_____	So difficult, unable	
9.	Walking fast or running?	No difficulty	_____	So difficult, unable	

_____/_____ = ____%

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1. Name of instrument	<i>Clinical Grade Scale–d'Aubigne and Postel</i>
2. What it is designed to assess (specific anatomic area)	<i>Hip function</i>
3. Method of administration (patient, clinician, or combined)	<i>Combined</i>
4. How to obtain the instrument	Matta JM. Operative treatment of acetabular fractures through the ilioinguinal approach: a 10-year perspective. <i>Clin Orthop</i> . 1994;305:10–19.
5. Cost involved in obtaining instrument	<i>None</i>
6. Method of design	<i>Not identified</i>
7. Statistical validation	<i>None</i>
8. Normative data available	<i>None</i>
9. Disease-specific data available	<i>Several reports in the literature with large samples for acetabulum fractures</i>
10. References for scientific basis and reference data	Kerboull M, Gardes J-C, Merle d'Aubigne R. Bilan de l'arthroplastie totale de la hanche. <i>La Presse Medicale</i> . 1970;78:2457–2461. Matta JM. (see reference in #4) Merle d'Aubigne R, Postel M. Functional results of hip arthroplasty with acrylic prosthesis. <i>J Bone Joint Surg Am</i> . 1954;86:451–475.
11. Scoring module	<i>None</i>
12. What kind of total and subscales do you get	<i>Pain, Ambulation, ROM, total (18 points = best function, categorized by excellent = poor)</i>
13. Format and number of questions	<i>Summated rating scale, 3 questions</i>
14. Time of administration	<i>Estimated 5 minutes</i>
15. Additional notes	<i>Categorization of scores excellent – poor changed over time. There are multiple variations of this scale in the literature with slightly different questions and point values. The one presented here is the latest published version identified.</i>
16. The questionnaire	<i>See below</i>

Clinical Grade Scale (d'Aubigne & Postel)

Degree of pain

- 6 = none
- 5 = slight or intermittent
- 4 = pain after ambulation but disappears
- 3 = moderately severe, permits ambulation
- 2 = severe, prevents ambulation

Degree of ambulation

- 6 = normal
- 5 = no cane, but slight limp
- 4 = long distance with cane/crutch
- 3 = limited even with support
- 2 = very limited
- 1 = nonambulatory

Range of motion

	Right	Left
Flexion	_____	_____
Abduction	_____	_____
Adduction	_____	_____
External rotation	_____	_____
Internal rotation	_____	_____
Total	_____	_____

Percent of injured hip = (total injured ROM/total normal ROM)

- 6 = 95–100%
- 5 = 80–95%
- 4 = 70–80%
- 3 = 60–70%
- 2 = < 50%

Clinical grade: total points (pain + ambulation + ROM)

- 18 = excellent
- 15–17 = good
- 13–14 = fair
- < 13 = poor

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Please tick the ONE statement in EACH question that BEST describes your ankles.

	LEFT	RIGHT	Score
1. I have pain in my ankle			
Never	☐	☐	5
During sport	☐	☐	4
Running on uneven surfaces	☐	☐	3
Running on level surfaces	☐	☐	2
Walking on uneven surfaces	☐	☐	1
Walking on level surfaces	☐	☐	0
2. My ankle feels UNSTABLE			
Never	☐	☐	4
Sometimes during sport (not every time)	☐	☐	3
Frequently during sport (every time)	☐	☐	2
Sometimes during daily activity	☐	☐	1
Frequently during daily activity	☐	☐	0
3. When I make SHARP turns, my ankle feels UNSTABLE			
Never	☐	☐	3
Sometimes when running	☐	☐	2
Often when running	☐	☐	1
When walking	☐	☐	0
4. When going down the stairs, my ankle feels UNSTABLE			
Never	☐	☐	3
If I go fast	☐	☐	2
Occasionally	☐	☐	1
Always	☐	☐	0
5. My ankle feels UNSTABLE when standing on ONE leg			
Never	☐	☐	2
On the ball of my foot	☐	☐	1
With my foot flat	☐	☐	0
6. My ankle feels UNSTABLE when			
Never	☐	☐	3
I hop from side to side	☐	☐	2
I hop on the spot	☐	☐	1
When I jump	☐	☐	0
7. My ankle feels UNSTABLE when			
Never	☐	☐	4
I run on uneven surfaces	☐	☐	3
I jog on uneven surfaces	☐	☐	2
I walk on uneven surfaces	☐	☐	1
I walk on a flat surface	☐	☐	0
8. TYPICALLY, when I start to roll over (or "twist") on my ankle, I can stop it			
Immediately	☐	☐	3
Often	☐	☐	2
Sometimes	☐	☐	1
Never	☐	☐	0
I have never rolled over on my ankle	☐	☐	3
9. After a TYPICAL incident of my ankle rolling over, my ankle returns to "normal"			
Almost immediately	☐	☐	3
Less than one day	☐	☐	2
1-2 days	☐	☐	1
More than 2 days	☐	☐	0
I have never rolled over on my ankle	☐	☐	3

Ankle Dorsiflexion Range of Motion

	Right	Left
Trial 1		
Trial 1		
Trial 1		
Note		

Ankle Instability Instrument (AII)

Ankle Instability Instrument

Instructions

This form will be used to categorize your ankle instability. A separate form should be used for the right and left ankles. Please fill out the form completely. If you have any questions, please ask the administrator of the survey. Thank you for your participation.

1. Have you ever sprained an ankle? ☐ Yes ☐ No
 2. Have you ever seen a doctor for an ankle sprain? ☐ Yes ☐ No
If yes,
 - 2a. How did the doctor categorize your most serious ankle sprain?
☐ Mild (grade 1) ☐ Moderate (grade 2) ☐ Severe (grade 3)
 3. Did you ever use a device (such as crutches) because you could not bear weight due to an ankle sprain? ☐ Yes ☐ No
If yes,
 - 3a. In the most serious case, how long did you need to use the device?
☐ 1–3 days ☐ 4–7 days ☐ 1–2 weeks ☐ 2–3 weeks ☐ >3 weeks
 4. Have you ever experienced a sensation of your ankle “giving way”? ☐ Yes ☐ No
If yes,
 - 4a. When was the last time your ankle “gave way”?
☐ <1 month ☐ 1–6 months ago ☐ 6–12 months ago ☐ 1–2 years ago ☐ >2 years
 5. Does your ankle ever feel unstable while walking on a flat surface? ☐ Yes ☐ No
 6. Does your ankle ever feel unstable while walking on uneven ground? ☐ Yes ☐ No
 7. Does your ankle ever feel unstable during recreational or sport activity? ☐ Yes ☐ No ☐ N/A
 8. Does your ankle ever feel unstable while going *up* stairs? ☐ Yes ☐ No
 9. Does your ankle ever feel unstable while going *down* stairs? ☐ Yes ☐ No
-

1. Name of instrument	<i>Ankle Osteoarthritis Scale</i>
2. What it is designed to assess (specific anatomic area)	<i>Ankle osteoarthritis</i>
3. Method of administration (patient, clinician, or combined)	<i>Patient administered</i>
4. How to obtain the instrument	Domsic RT, Saltzman CL. Ankle osteoarthritis scale. <i>Foot Ankle Int.</i> 1998;19:466–471.
5. Cost involved in obtaining instrument	<i>None</i>
6. Method of design	<i>Modification of Foot Function Index</i>
7. Statistical validation	<i>Reliability, Criterion and Construct Validity</i>
8. Normative data available	<i>None</i>
9. Disease-specific data available	<i>None</i>
10. References for scientific basis and reference data	Domsic RT, Saltzman CL. (see reference in #4)
11. Scoring module	<i>Accounts for missing/not applicable values</i>
12. What kind of total and subscales do you get	<i>Pain, Disability, Total</i>
13. Format and number of questions	<i>18 questions, visual analogue scale</i>
14. Time for administration	<i>Less than 10 minutes</i>
15. Additional notes	<i>None</i>
16. The questionnaire	<i>See page S74</i>

Ankle Osteoarthritis Scale (AOS)

PAIN

The line next to each item represents the amount of pain you typically had in each situation. On the far left is “no pain” and on the far right is “the worst pain imaginable.” Place a mark on the line to indicate how bad your ankle pain was in each of the following situations during the past week. If you were not involved in one or more of these situations, mark that item NA.

HOW SEVERE WAS YOUR ANKLE PAIN:

1.	At its worst?	No pain	_____	Worst pain imaginable	NA
2.	Before you get up in the morning?	No pain	_____	Worst pain imaginable	
3.	When you walked barefoot?	No pain	_____	Worst pain imaginable	
4.	When you stood barefoot?	No pain	_____	Worst pain imaginable	
5.	When you walked wearing shoes?	No pain	_____	Worst pain imaginable	
6.	When you stood wearing shoes?	No pain	_____	Worst pain imaginable	
7.	When you walked wearing shoe inserts or braces?	No pain	_____	Worst pain imaginable	
8.	When you stood wearing shoe inserts or braces?	No pain	_____	Worst pain imaginable	
9.	At the end of the day?	No pain	_____	Worst pain imaginable	

_____/_____ = ____%

DISABILITY

The line next to each item represents the amount of difficulty you had performing an activity. On the far left is “no difficulty” and on the far right is “so difficult, unable.” Place a mark on the line to indicate how much difficulty you had performing each activity because of your ankle during the past week. If you did not perform an activity during the past week, place an “X” in the column under the heading NA.

HOW MUCH DIFFICULTY DID YOU HAVE:

					NA
1.	Walking around the house?	No difficulty	_____	So difficult, unable	
2.	Walking outside on uneven ground?	No difficulty	_____	So difficult, unable	
3.	Walking four or more blocks?	No difficulty	_____	So difficult, unable	
4.	Climbing stairs?	No difficulty	_____	So difficult, unable	
5.	Descending stairs?	No difficulty	_____	So difficult, unable	
6.	Standing on tip toes?	No difficulty	_____	So difficult, unable	
7.	Getting out of a chair?	No difficulty	_____	So difficult, unable	
8.	Climbing up or down curbs?	No difficulty	_____	So difficult, unable	
9.	Walking fast or running?	No difficulty	_____	So difficult, unable	

_____/_____ = ____%

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1. Name of instrument	<i>Clinical Grade Scale–d'Aubigne and Postel</i>
2. What it is designed to assess (specific anatomic area)	<i>Hip function</i>
3. Method of administration (patient, clinician, or combined)	<i>Combined</i>
4. How to obtain the instrument	Matta JM. Operative treatment of acetabular fractures through the ilioinguinal approach: a 10-year perspective. <i>Clin Orthop</i> . 1994;305:10–19.
5. Cost involved in obtaining instrument	<i>None</i>
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7. Statistical validation	<i>None</i>
8. Normative data available	<i>None</i>
9. Disease-specific data available	<i>Several reports in the literature with large samples for acetabulum fractures</i>
10. References for scientific basis and reference data	Kerboull M, Gardes J-C, Merle d'Aubigne R. Bilan de l'arthroplastie totale de la hanche. <i>La Presse Medicale</i> . 1970;78:2457–2461. Matta JM. (see reference in #4) Merle d'Aubigne R, Postel M. Functional results of hip arthroplasty with acrylic prosthesis. <i>J Bone Joint Surg Am</i> . 1954;86:451–475.
11. Scoring module	<i>None</i>
12. What kind of total and subscales do you get	<i>Pain, Ambulation, ROM, total (18 points = best function, categorized by excellent = poor)</i>
13. Format and number of questions	<i>Summated rating scale, 3 questions</i>
14. Time of administration	<i>Estimated 5 minutes</i>
15. Additional notes	<i>Categorization of scores excellent – poor changed over time. There are multiple variations of this scale in the literature with slightly different questions and point values. The one presented here is the latest published version identified.</i>
16. The questionnaire	<i>See below</i>

Clinical Grade Scale (d'Aubigne & Postel)

Degree of pain

- 6 = none
- 5 = slight or intermittent
- 4 = pain after ambulation but disappears
- 3 = moderately severe, permits ambulation
- 2 = severe, prevents ambulation

Degree of ambulation

- 6 = normal
- 5 = no cane, but slight limp
- 4 = long distance with cane/crutch
- 3 = limited even with support
- 2 = very limited
- 1 = nonambulatory

Range of motion

	Right	Left
Flexion	_____	_____
Abduction	_____	_____
Adduction	_____	_____
External rotation	_____	_____
Internal rotation	_____	_____
Total	_____	_____

Percent of injured hip = (total injured ROM/total normal ROM)

- 6 = 95–100%
- 5 = 80–95%
- 4 = 70–80%
- 3 = 60–70%
- 2 = < 50%

Clinical grade: total points (pain + ambulation + ROM)

- 18 = excellent
- 15–17 = good
- 13–14 = fair
- < 13 = poor

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Please tick the ONE statement in EACH question that BEST describes your ankles.

	LEFT	RIGHT	Score
1. I have pain in my ankle			
Never	☐	☐	5
During sport	☐	☐	4
Running on uneven surfaces	☐	☐	3
Running on level surfaces	☐	☐	2
Walking on uneven surfaces	☐	☐	1
Walking on level surfaces	☐	☐	0
2. My ankle feels UNSTABLE			
Never	☐	☐	4
Sometimes during sport (not every time)	☐	☐	3
Frequently during sport (every time)	☐	☐	2
Sometimes during daily activity	☐	☐	1
Frequently during daily activity	☐	☐	0
3. When I make SHARP turns, my ankle feels UNSTABLE			
Never	☐	☐	3
Sometimes when running	☐	☐	2
Often when running	☐	☐	1
When walking	☐	☐	0
4. When going down the stairs, my ankle feels UNSTABLE			
Never	☐	☐	3
If I go fast	☐	☐	2
Occasionally	☐	☐	1
Always	☐	☐	0
5. My ankle feels UNSTABLE when standing on ONE leg			
Never	☐	☐	2
On the ball of my foot	☐	☐	1
With my foot flat	☐	☐	0
6. My ankle feels UNSTABLE when			
Never	☐	☐	3
I hop from side to side	☐	☐	2
I hop on the spot	☐	☐	1
When I jump	☐	☐	0
7. My ankle feels UNSTABLE when			
Never	☐	☐	4
I run on uneven surfaces	☐	☐	3
I jog on uneven surfaces	☐	☐	2
I walk on uneven surfaces	☐	☐	1
I walk on a flat surface	☐	☐	0
8. TYPICALLY, when I start to roll over (or "twist") on my ankle, I can stop it			
Immediately	☐	☐	3
Often	☐	☐	2
Sometimes	☐	☐	1
Never	☐	☐	0
I have never rolled over on my ankle	☐	☐	3
9. After a TYPICAL incident of my ankle rolling over, my ankle returns to "normal"			
Almost immediately	☐	☐	3
Less than one day	☐	☐	2
1-2 days	☐	☐	1
More than 2 days	☐	☐	0
I have never rolled over on my ankle	☐	☐	3

Activities of Daily Living Subscale

Please Answer **every question** with **one response** that most closely describes your condition within the past week.

If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

[illegible]

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale
Page 2

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Home responsibilities	☐	☐	☐	☐	☐	☐
Activities of daily living	☐	☐	☐	☐	☐	☐
Personal care	☐	☐	☐	☐	☐	☐
Light to moderate work (standing, walking)	☐	☐	☐	☐	☐	☐
Heavy work (push/pulling, climbing, carrying)	☐	☐	☐	☐	☐	☐
Recreational activities	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities.

___ . 0 %

**Foot and Ankle Ability Measure (FAAM)
Sports Subscale**

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Running	☐	☐	☐	☐	☐	☐
Jumping	☐	☐	☐	☐	☐	☐
Landing	☐	☐	☐	☐	☐	☐
Starting and stopping quickly	☐	☐	☐	☐	☐	☐
Cutting/lateral Movements	☐	☐	☐	☐	☐	☐
Ability to perform Activity with your Normal technique	☐	☐	☐	☐	☐	☐
Ability to participate In your desired sport As long as you like	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during your sports related activities from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

_____. 0%

Overall, how would you rate your current level of function?

☐ Normal ☐ Nearly Normal ☐ Abnormal ☐ Severely Abnormal

Godin Leisure-Time Exercise Questionnaire

INSTRUCTIONS

In this excerpt from the Godin Leisure-Time Exercise Questionnaire, the individual is asked to complete a self-explanatory, brief four-item query of usual leisure-time exercise habits.

CALCULATIONS

For the first question, weekly frequencies of strenuous, moderate, and light activities are multiplied by nine, five, and three, respectively. Total weekly leisure activity is calculated in arbitrary units by summing the products of the separate components, as shown in the following formula:

$$\text{Weekly leisure activity score} = (9 \times \text{Strenuous}) + (5 \times \text{Moderate}) + (3 \times \text{Light})$$

The second question is used to calculate the frequency of weekly leisure-time activities pursued “long enough to work up a sweat” (see questionnaire).

EXAMPLE

Strenuous = 3 times/wk

Moderate = 6 times/wk

Light = 14 times/wk

$$\text{Total leisure activity score} = (9 \times 3) + (5 \times 6) + (3 \times 14) = 27 + 30 + 42 = 99$$

Godin, G., Shephard, R. J.. (1997) [Godin Leisure-Time Exercise Questionnaire](#). Medicine and Science in Sports and Exercise. 29 June Supplement: S36-S38.

Godin Leisure-Time Exercise Questionnaire

1. During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

**Times Per
Week**

a) STRENUOUS EXERCISE

(HEART BEATS RAPIDLY)

(e.g., running, jogging, hockey, football, soccer,
squash, basketball, cross country skiing, judo,
roller skating, vigorous swimming,
vigorous long distance bicycling)

b) MODERATE EXERCISE

(NOT EXHAUSTING)

(e.g., fast walking, baseball, tennis, easy bicycling,
volleyball, badminton, easy swimming, alpine skiing,
popular and folk dancing)

c) MILD EXERCISE

(MINIMAL EFFORT)

(e.g., yoga, archery, fishing from river bank, bowling,
horseshoes, golf, snow-mobiling, easy walking)

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN

SOMETIMES

NEVER/RARELY

1. D

2. D

3. D

Health History Questionnaire

Participant # _____

Name: _____

Age: _____ Height: _____ Weight: _____

Sex: M F

1. How many hours and days do you participate in physical activities? : _____

2. Which foot do you kick a ball with?: Right _____ Left _____

3. Have you sprained your ankle?: Yes No

If Yes, which have you sprained, **RIGHT** or **LEFT** ankle? _____

How many times have you sprained your ankle? _____

When was the most recent? _____

Have you received any treatments from allied health care professionals? Yes No

If Yes, please provide what treatments you received and how long you received the treatment

4. Have you ever experienced more than 2 repeated episodes of your ankle “giving way” in the past 12 months? and how many?

Yes No

a. How many repeated episodes of “giving-way” have you experienced following an initial ankle sprain

b. When was the last time your ankle “gave way”?

___<1 month ___1-6 months ago ___ 6-12 months ago ___1-2 years ago ___>2years

5. Have you modified your activity and occupational involvement due to ankle injury ?

Yes _____ No _____

If yes, please provide more detail information: _____

6. If no, are you using any assistive device, such as ankle brace? Yes _____ No _____

7. Do you feel that you risk injury when playing your sport? Yes_____ No_____
- a. Do you use an ankle brace or taping when playing sport? Yes_____ No_____
- i. Comments:_____
8. Are you concerned about environmental conditions such as a wet playing field, a hard court or the type of gym floor when involved in your sport? Yes_____ No_____
9. Have you had a concussion in the past twelve months? Yes_____ No_____
- If yes, explain:_____
10. Have you ever experienced a head injury beside concussion? Yes No
- If Yes, what was the injury? _____
- when was the most recent? _____
11. Have you ever suffered from a significant back injury causing you to interrupt your sports activity? Yes No
- If Yes, when was the most recent incident? _____
- What was the cause of the back injury/pain? _____
12. Have you ever suffered from a fracture to any part of your leg, knee, ankle, hip, back, thigh, or foot? Yes No
- If Yes, when did the fracture occur? _____
- Which bone (s) was fractured? _____
13. Have you ever suffered from a significant hip/thigh injury causing you to interrupt your sports activity? Yes No
- a) If Yes, when was the most recent incident? _____
- What injuries have your experienced? _____
- b) Did the injury require surgery? Yes No
- If yes, when was the surgery? _____
14. Have you ever suffered from a significant knee injury causing you to interrupt your sports activity? Yes No
- a) If Yes, when was the most recent incident? _____
- What injuries have your experienced? _____
- b) Did the injury require surgery? Yes No
- If yes, when was the surgery? _____

15. Have you ever suffered from a significant lower leg injury causing you to interrupt your sports activity? Yes No

c) If Yes, when was the most recent incident? _____
What injuries have you experienced? _____

d) Did the injury require surgery? Yes No
If yes, when was the surgery? _____

16. Have you ever suffered from a significant ankle/foot injury (other than ankle sprains) causing you to interrupt your sports activity?

Yes No
a) If Yes, when was the most recent incident? _____
What injuries have you experienced? _____

b) Did the injury require surgery? Yes No
If yes, when was the surgery? _____

17. Do you suffer from vertigo, or any other neurological disorders?: Yes____ No____

If Yes, explain: _____

18. Are you currently suffering from the effects of a cold or flu?: Yes____ No____

IDENTIFICATION OF FUNCTIONAL ANKLE INSTABILITY (IdFAI)

Instructions: This form will be used to categorize your ankle stability status. A separate form should be used for the right and left ankles. Please fill out the form completely and if you have any questions, please ask the administrator. Thank you for your participation.

Please carefully read the following statement:

"Giving way" is described as a temporary uncontrollable sensation of instability or rolling over of one's ankle.

I am completing this form for my **RIGHT/LEFT** ankle (circle one).

1.) Approximately how many times have you sprained your ankle? _____

2.) When was the last time you sprained your ankle?

☐ Never ☐ > 2 years ☐ 1-2 years ☐ 6-12 months ☐ 1-6 months ☐ < 1 month
0 1 2 3 4 5

3.) If you have seen an athletic trainer, physician, or healthcare provider how did he/she categorize your most serious ankle sprain?

☐ Have not seen someone ☐ Mild (Grade I) ☐ Moderate (Grade II) ☐ Severe (Grade III)
0 1 2 3

4.) If you have ever used crutches, or other device, due to an ankle sprain how long did you use it?

☐ Never used a device ☐ 1-3 days ☐ 4-7 days ☐ 1-2 weeks ☐ 2-3 weeks ☐ > 3 weeks
0 1 2 3 4 5

5.) When was the last time you had "giving way" in your ankle?

☐ Never ☐ > 2 years ☐ 1-2 years ☐ 6-12 months ☐ 1-6 months ☐ < 1 month
0 1 2 3 4 5

6.) How often does the "giving way" sensation occur in your ankle?

☐ Never ☐ Once a year ☐ Once a month ☐ Once a week ☐ Once a day
0 1 2 3 4

7.) Typically when you start to roll over (or 'twist') on your ankle can you stop it?

☐ Never rolled over ☐ Immediately ☐ Sometimes ☐ Unable to stop it
0 1 2 3

8.) Following a typical incident of your ankle rolling over, how soon does it return to 'normal'?

☐ Never rolled over ☐ Immediately ☐ < 1 day ☐ 1-2 days ☐ > 2 days
0 1 2 3 4

9.) During "Activities of daily life" how often does your ankle feel **UNSTABLE**?

☐ Never ☐ Once a year ☐ Once a month ☐ Once a week ☐ Once a day
0 1 2 3 4

10.) During "Sport/or recreational activities" how often does your ankle feel **UNSTABLE**?

☐ Never ☐ Once a year ☐ Once a month ☐ Once a week ☐ Once a day
0 1 2 3 4

Subject # _____

Sex: M F

Age _____

Height _____

Weight _____

Right leg length _____

Left Leg Length _____

Anterior Reach		
Right Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Left Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Posteriormedial Reach		
Right Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Left Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Posteriorlateral Reach		
Right Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Left Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Right Composite Score		
	Raw	Normalized

Left Composite Score		
	Raw	Normalized

SHORT FORM-36 (SF36) SURVEY

Please answer the following questions about your health. Select **ONLY ONE ANSWER**

1. In general, would you say your health is:

1. Excellent
2. Very Good
3. Good
4. Fair
5. Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

1. Much better now than one year ago
2. Somewhat better now than one year ago
3. About the same as one year ago
4. Somewhat worse now than one year ago
5. Much worse than one year ago

The following items (question 3 to 12) are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

5. Lifting or carrying groceries.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

6. Climbing several flights of stairs.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

7. Climbing one flight of stairs.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

8. Bending, kneeling, or stooping.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

9. Walking more than a mile.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

10. Walking several blocks.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

11. Walking one block.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

12. Bathing or dressing yourself.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

During **the past 4 weeks**, have you had any of the following problems (Question 13-16) with your work or other regular daily activities **as a result of your PHYSICAL HEALTH?**

13. Cut down the amount of time you spent on work or other activities.

1. Yes
2. No

14. Accomplished less than you would like.

1. Yes
2. No

15. Were limited in the kind of work or other activities.

1. Yes
2. No

16. Had difficulty performing the work or other activities (for example, it took extra effort).

1. Yes
2. No

During **the past 4 weeks**, have you had any of the following problems (Question 17-19) with your work or other regular daily activities as a result of any **EMOTIONAL PROBLEMS (such as feeling depressed or anxious)**?

17. Cut down the amount of time you spent on work or other activities.

1. Yes
2. No

18. Accomplished less than you would like.

1. Yes
2. No

19. Didn't do work or other activities as carefully as usual.

1. Yes
2. No

20. During **the past 4 weeks**, to what extent has **your physical health OR emotional problems interfered with your normal social activities with family, friends, neighbors, or groups**?

1. Not at all
2. Slightly
3. Moderately
4. Quite a bit
5. Extremely

21. How much bodily pain have you had during the past 4 weeks?

1. None
2. Very mild
3. Mild
4. Moderate
5. Severe
6. Very severe

22. During the past 4 weeks how much did **pain** interfere with your normal work (including both work outside the home and housework)?

1. Not at all
2. A little bit
3. Moderately
4. Quite a bit
5. Extremely

These questions (**Question 23-31**) are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks....

23. Did you feel full of pep?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

24. Have you been a very nervous person?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

25. Have you felt so down in the dumps that nothing could cheer you up?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

26. Have you felt calm and peaceful?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

27. Did you have a lot of energy?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

28. Have you felt downhearted and blue?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

29. Did you feel worn out?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

30. Have you been a happy person?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

31. Did you feel tired?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

32. During **the past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

How true or false is the following statement
(Question 33-36)?

33. I seem to get sick a little easier than other people.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

34. I am as healthy as anybody I know.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

35. I expect my health to get worse.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

36. My health is excellent.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

Demographics

Participant #		
Group		
Involved Limb:	Right	Left
Dominant Limb	Right	Left
Age		
Height	Inches:	Centimeters:
Sex	Male	Female
Weight	Pounds:	Kilograms:
Physical Activity Level	Days/week:	Hours/ day:

Order of Testing

Muscle Order	1st:
	2nd:

Participant ID: _____
Session: _____

Date: _____

Preparation

Swim

Cap: sagittal _____
 frontal _____

DF_ MVIC: _____

Hot spot

coordinates: _____

Average: **#DIV/0!**

Resting MT: _____

PF_ MVIC: _____

Active MT: _____

Average: **#DIV/0!**

CSP Testing

% machine output 0 120%
active

PF_ MVIC #DIV/0! 5%
target #DIV/0! 20%

Notes:

[illegible]

A large grid of 20 rows and 10 columns of empty square boxes, intended for handwriting practice. Each box is a simple square outline, and the grid is evenly spaced.

1. $\frac{1}{2} \times \frac{1}{2} \times \frac{1}{2} = \frac{1}{8}$

+ = MEP; - = too low to be MEP; ↑=value higher than average; ↓= value lower than average

Activities of Daily Living Subscale

Please Answer **every question** with **one response** that most closely describes your condition within the past week.

If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

[illegible]

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale
Page 2

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Home responsibilities	☐	☐	☐	☐	☐	☐
Activities of daily living	☐	☐	☐	☐	☐	☐
Personal care	☐	☐	☐	☐	☐	☐
Light to moderate work (standing, walking)	☐	☐	☐	☐	☐	☐
Heavy work (push/pulling, climbing, carrying)	☐	☐	☐	☐	☐	☐
Recreational activities	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during you usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities.

___ . 0 %

**Foot and Ankle Ability Measure (FAAM)
Sports Subscale**

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Running	☐	☐	☐	☐	☐	☐
Jumping	☐	☐	☐	☐	☐	☐
Landing	☐	☐	☐	☐	☐	☐
Starting and stopping quickly	☐	☐	☐	☐	☐	☐
Cutting/lateral Movements	☐	☐	☐	☐	☐	☐
Ability to perform Activity with your Normal technique	☐	☐	☐	☐	☐	☐
Ability to participate In your desired sport As long as you like	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during your sports related activities from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

_____. 0%

Overall, how would you rate your current level of function?

☐ Normal ☐ Nearly Normal ☐ Abnormal ☐ Severely Abnormal

Godin Leisure-Time Exercise Questionnaire

INSTRUCTIONS

In this excerpt from the Godin Leisure-Time Exercise Questionnaire, the individual is asked to complete a self-explanatory, brief four-item query of usual leisure-time exercise habits.

CALCULATIONS

For the first question, weekly frequencies of strenuous, moderate, and light activities are multiplied by nine, five, and three, respectively. Total weekly leisure activity is calculated in arbitrary units by summing the products of the separate components, as shown in the following formula:

$$\text{Weekly leisure activity score} = (9 \times \text{Strenuous}) + (5 \times \text{Moderate}) + (3 \times \text{Light})$$

The second question is used to calculate the frequency of weekly leisure-time activities pursued “long enough to work up a sweat” (see questionnaire).

EXAMPLE

Strenuous = 3 times/wk

Moderate = 6 times/wk

Light = 14 times/wk

$$\text{Total leisure activity score} = (9 \times 3) + (5 \times 6) + (3 \times 14) = 27 + 30 + 42 = 99$$

Godin, G., Shephard, R. J.. (1997) [Godin Leisure-Time Exercise Questionnaire](#). Medicine and Science in Sports and Exercise. 29 June Supplement: S36-S38.

Godin Leisure-Time Exercise Questionnaire

1. During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

**Times Per
Week**

**a) STRENUOUS EXERCISE
(HEART BEATS RAPIDLY)**

(e.g., running, jogging, hockey, football, soccer,
squash, basketball, cross country skiing, judo,
roller skating, vigorous swimming,
vigorous long distance bicycling)

**b) MODERATE EXERCISE
(NOT EXHAUSTING)**

(e.g., fast walking, baseball, tennis, easy bicycling,
volleyball, badminton, easy swimming, alpine skiing,
popular and folk dancing)

**c) MILD EXERCISE
(MINIMAL EFFORT)**

(e.g., yoga, archery, fishing from river bank, bowling,
horseshoes, golf, snow-mobiling, easy walking)

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN

SOMETIMES

NEVER/RARELY

1. D

2. D

3. D

Health History Questionnaire

Participant # _____

Name: _____

Age: _____ Height: _____ Weight: _____

Sex: M F

1. How many hours and days do you participate in physical activities? : _____

2. Which foot do you kick a ball with?: Right _____ Left _____

3. Have you sprained your ankle?: Yes No

If Yes, which have you sprained, **RIGHT** or **LEFT** ankle? _____

How many times have you sprained your ankle? _____

When was the most recent? _____

Have you received any treatments from allied health care professionals? Yes No

If Yes, please provide what treatments you received and how long you received the treatment

4. Have you ever experienced more than 2 repeated episodes of your ankle “giving way” in the past 12 months? and how many?

Yes No

a. How many repeated episodes of “giving-way” have you experienced following an initial ankle sprain

b. When was the last time your ankle “gave way”?

___<1 month ___1-6 months ago ___ 6-12 months ago ___1-2 years ago ___>2years

5. Have you modified your activity and occupational involvement due to ankle injury ?

Yes _____ No _____

If yes, please provide more detail information: _____

6. If no, are you using any assistive device, such as ankle brace? Yes _____ No _____

7. Do you feel that you risk injury when playing your sport? Yes_____ No_____
- a. Do you use an ankle brace or taping when playing sport? Yes_____ No_____
- i. Comments:_____
8. Are you concerned about environmental conditions such as a wet playing field, a hard court or the type of gym floor when involved in your sport? Yes_____ No_____
9. Have you had a concussion in the past twelve months? Yes_____ No_____
- If yes, explain:_____
10. Have you ever experienced a head injury beside concussion? Yes No
- If Yes, what was the injury? _____
- when was the most recent? _____
11. Have you ever suffered from a significant back injury causing you to interrupt your sports activity? Yes No
- If Yes, when was the most recent incident? _____
- What was the cause of the back injury/pain? _____
12. Have you ever suffered from a fracture to any part of your leg, knee, ankle, hip, back, thigh, or foot? Yes No
- If Yes, when did the fracture occur? _____
- Which bone (s) was fractured? _____
13. Have you ever suffered from a significant hip/thigh injury causing you to interrupt your sports activity? Yes No
- a) If Yes, when was the most recent incident? _____
- What injuries have your experienced? _____
- b) Did the injury require surgery? Yes No
- If yes, when was the surgery? _____
14. Have you ever suffered from a significant knee injury causing you to interrupt your sports activity? Yes No
- a) If Yes, when was the most recent incident? _____
- What injuries have your experienced? _____
- b) Did the injury require surgery? Yes No
- If yes, when was the surgery? _____

15. Have you ever suffered from a significant lower leg injury causing you to interrupt your sports activity? Yes No

c) If Yes, when was the most recent incident? _____
What injuries have you experienced? _____

d) Did the injury require surgery? Yes No
If yes, when was the surgery? _____

16. Have you ever suffered from a significant ankle/foot injury (other than ankle sprains) causing you to interrupt your sports activity?

Yes No
a) If Yes, when was the most recent incident? _____
What injuries have you experienced? _____

b) Did the injury require surgery? Yes No
If yes, when was the surgery? _____

17. Do you suffer from vertigo, or any other neurological disorders?: Yes____ No____

If Yes, explain: _____

18. Are you currently suffering from the effects of a cold or flu?: Yes____ No____

IDENTIFICATION OF FUNCTIONAL ANKLE INSTABILITY (IdFAI)

Instructions: This form will be used to categorize your ankle stability status. A separate form should be used for the right and left ankles. Please fill out the form completely and if you have any questions, please ask the administrator. Thank you for your participation.

Please carefully read the following statement:

"Giving way" is described as a temporary uncontrollable sensation of instability or rolling over of one's ankle.

I am completing this form for my **RIGHT/LEFT** ankle (circle one).

1.) Approximately how many times have you sprained your ankle? _____

2.) When was the last time you sprained your ankle?

☐ Never ☐ > 2 years ☐ 1-2 years ☐ 6-12 months ☐ 1-6 months ☐ < 1 month
0 1 2 3 4 5

3.) If you have seen an athletic trainer, physician, or healthcare provider how did he/she categorize your most serious ankle sprain?

☐ Have not seen someone ☐ Mild (Grade I) ☐ Moderate (Grade II) ☐ Severe (Grade III)
0 1 2 3

4.) If you have ever used crutches, or other device, due to an ankle sprain how long did you use it?

☐ Never used a device ☐ 1-3 days ☐ 4-7 days ☐ 1-2 weeks ☐ 2-3 weeks ☐ > 3 weeks
0 1 2 3 4 5

5.) When was the last time you had "giving way" in your ankle?

☐ Never ☐ > 2 years ☐ 1-2 years ☐ 6-12 months ☐ 1-6 months ☐ < 1 month
0 1 2 3 4 5

6.) How often does the "giving way" sensation occur in your ankle?

☐ Never ☐ Once a year ☐ Once a month ☐ Once a week ☐ Once a day
0 1 2 3 4

7.) Typically when you start to roll over (or 'twist') on your ankle can you stop it?

☐ Never rolled over ☐ Immediately ☐ Sometimes ☐ Unable to stop it
0 1 2 3

8.) Following a typical incident of your ankle rolling over, how soon does it return to 'normal'?

☐ Never rolled over ☐ Immediately ☐ < 1 day ☐ 1-2 days ☐ > 2 days
0 1 2 3 4

9.) During "Activities of daily life" how often does your ankle feel **UNSTABLE**?

☐ Never ☐ Once a year ☐ Once a month ☐ Once a week ☐ Once a day
0 1 2 3 4

10.) During "Sport/or recreational activities" how often does your ankle feel **UNSTABLE**?

☐ Never ☐ Once a year ☐ Once a month ☐ Once a week ☐ Once a day
0 1 2 3 4

Subject # _____

Sex: M F

Age _____

Height _____

Weight _____

Right leg length _____

Left Leg Length _____

Anterior Reach		
Right Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Left Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Posteriormedial Reach		
Right Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Left Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Posteriorlateral Reach		
Right Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Left Stance Leg		
	Raw	Normalized
Trial 1		
Trial 2		
Trial 3		
AVG		

Right Composite Score		
	Raw	Normalized

Left Composite Score		
	Raw	Normalized

SHORT FORM-36 (SF36) SURVEY

Please answer the following questions about your health. Select **ONLY ONE ANSWER**

1. In general, would you say your health is:

1. Excellent
2. Very Good
3. Good
4. Fair
5. Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

1. Much better now than one year ago
2. Somewhat better now than one year ago
3. About the same as one year ago
4. Somewhat worse now than one year ago
5. Much worse than one year ago

The following items (question 3 to 12) are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

5. Lifting or carrying groceries.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

6. Climbing several flights of stairs.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

7. Climbing one flight of stairs.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

8. Bending, kneeling, or stooping.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

9. Walking more than a mile.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

10. Walking several blocks.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

11. Walking one block.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

12. Bathing or dressing yourself.

1. Yes, limited a lot
2. Yes, limited a little
3. No, not limited at all

During **the past 4 weeks**, have you had any of the following problems (Question 13-16) with your work or other regular daily activities **as a result of your PHYSICAL HEALTH?**

13. Cut down the amount of time you spent on work or other activities.

1. Yes
2. No

14. Accomplished less than you would like.

1. Yes
2. No

15. Were limited in the kind of work or other activities.

1. Yes
2. No

16. Had difficulty performing the work or other activities (for example, it took extra effort).

1. Yes
2. No

During **the past 4 weeks**, have you had any of the following problems (Question 17-19) with your work or other regular daily activities as a result of any **EMOTIONAL PROBLEMS (such as feeling depressed or anxious)**?

17. Cut down the amount of time you spent on work or other activities.

1. Yes
2. No

18. Accomplished less than you would like.

1. Yes
2. No

19. Didn't do work or other activities as carefully as usual.

1. Yes
2. No

20. During **the past 4 weeks**, to what extent has **your physical health OR emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

1. Not at all
2. Slightly
3. Moderately
4. Quite a bit
5. Extremely

21. How much bodily pain have you had during the past 4 weeks?

1. None
2. Very mild
3. Mild
4. Moderate
5. Severe
6. Very severe

22. During the past 4 weeks how much did **pain** interfere with your normal work (including both work outside the home and housework)?

1. Not at all
2. A little bit
3. Moderately
4. Quite a bit
5. Extremely

These questions (**Question 23-31**) are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks....

23. Did you feel full of pep?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

24. Have you been a very nervous person?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

25. Have you felt so down in the dumps that nothing could cheer you up?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

26. Have you felt calm and peaceful?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

27. Did you have a lot of energy?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

28. Have you felt downhearted and blue?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

29. Did you feel worn out?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

30. Have you been a happy person?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

31. Did you feel tired?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

32. During **the past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

1. All of the time
2. Most of the time
3. Some of the time
4. A little of the time
5. None of the time

How true or false is the following statement
(Question 33-36)?

33. I seem to get sick a little easier than other people.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

34. I am as healthy as anybody I know.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

35. I expect my health to get worse.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

36. My health is excellent.

1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

Demographics

Participant #		
Group		
Involved Limb:	Right	Left
Dominant Limb	Right	Left
Age		
Height	Inches:	Centimeters:
Sex	Male	Female
Weight	Pounds:	Kilograms:
Physical Activity Level	Days/week:	Hours/ day:

Order of Testing

Muscle Order	1st:
	2nd:

Participant ID: _____
Session: _____

Date: _____

Preparation

Swim

Cap: sagittal _____
 frontal _____

DF_ MVIC: _____

Hot spot
coordinates: _____

Average: **#DIV/0!**

Resting MT: _____

PF_ MVIC: _____

Active MT: _____

Average: **#DIV/0!**

CSP Testing

% machine output 0 120%
active

PF_ MVIC #DIV/0! 5%
target #DIV/0! 20%

Notes:

[illegible]

A large grid of 20 rows and 10 columns of empty square boxes, intended for handwriting practice. Each box is a simple square outline, and the grid is evenly spaced.

1. $\frac{1}{2} \times \frac{1}{2} \times \frac{1}{2} = \frac{1}{8}$

+ = MEP; - = too low to be MEP; ↑=value higher than average; ↓= value lower than average

Respondent: John Abt
Department: Rehabilitation Science
Email: john.abt@uky.edu
Phone:
Login ID: JPAB222

Submitted On: March 3, 2016, 9:53 am CT
Last Revision: March 3, 2016, 9:52 am CT
Printed On: February 14, 2018, 1:05 pm CT

QUESTION 1 - COI.2015.03
(Answered on: March 3, 2016, 5:09 am CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 2 - COI.2015.04
(Answered on: March 3, 2016, 5:10 am CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : Yes

QUESTION 3 - COI.2015.05
(Answered on: March 3, 2016, 9:49 am CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity.

What must be disclosed

Each Investigator must disclose all significant financial interests (SFI) that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI" means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

Respondent: John Abt
Department: Rehabilitation Science
Email: john.abt@uky.edu
Phone:
Login ID: JPAB222

Submitted On: March 3, 2016, 9:53 am CT
Last Revision: March 3, 2016, 9:52 am CT
Printed On: February 14, 2018, 1:05 pm CT

How do I complete a financial disclosure

Upon certifying your training today, you will complete the online Financial Conflict of Interest Disclosure statement. This disclosure is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. The Disclosure Statement has 5 questions with one additional question for PHS Investigators. Investigators may access their Disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise a Disclosure Statement within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my disclosure or my revised disclosure

Disclosure Statements will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Disclosure Statement, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this presentation. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

Questionnaire Report For: University of Kentucky and UK HealthCare Conflict of Interest Questionnaire



Respondent: John Abt
Department: Rehabilitation Science
Email: john.abt@uky.edu
Phone:
Login ID: JPAB222

Submitted On: March 3, 2016, 9:53 am CT
Last Revision: March 3, 2016, 9:52 am CT
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1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

Excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 4 - COI.2015.06

Respondent: John Abt
Department: Rehabilitation Science
Email: john.abt@uky.edu
Phone:
Login ID: JPAB222

Submitted On: March 3, 2016, 9:53 am CT
Last Revision: March 3, 2016, 9:52 am CT
Printed On: February 14, 2018, 1:05 pm CT

(Answered on: March 3, 2016, 9:49 am CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1
I DO NOT have financial interest in publicly traded entities to report

QUESTION 5 - COI.2015.07
(Answered on: March 3, 2016, 9:49 am CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 6 - COI.2015.09
(Answered on: March 3, 2016, 9:50 am CT)

During the past 12 months, or at any time during CY 2015, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

Entity 1
I DO NOT have intellectual property income to report

QUESTION 7 - COI.2015.11
(Answered on: March 3, 2016, 9:52 am CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2015.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 8 - COI.2015.15
(Answered on: March 3, 2016, 9:52 am CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree



Respondent: John Abt
Department: Rehabilitation Science
Email: john.abt@uky.edu
Phone:
Login ID: JPAB222

Submitted On: March 3, 2016, 9:53 am CT
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Printed On: February 14, 2018, 1:05 pm CT

QUESTION 9 - COI.2015.16
(Answered on: March 3, 2016, 9:52 am CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Katherine Bain
Department: Rehabilitation Science
Email: katherine.bain@uky.edu
Phone:
Login ID: kaba266

Submitted On: September 7, 2018, 10:15 am CT
Last Revision: September 7, 2018, 10:15 am CT

Printed On: November 12, 2018, 8:53 am CT

QUESTION 1 - COI.2017.01
(Answered on: September 7, 2018, 10:06 am CT)

Because of your position at the University, you are required to complete a Conflict of Interest Disclosure Statement. Unless indicated otherwise, the requested information applies to any activities during the previous calendar year.

- For each outside activity, equity interest and/or family association, you will be asked to complete a Conflict of Interest Disclosure Statement in its entirety.
- If you are unsure whether an outside activity, equity interest or family association is covered by a question, please disclose it.
- You may also be required to complete additional disclosures per the University's [Research Conflict of Interest and Financial Disclosure Policy, AR 7:2](#), if you engage in covered research projects. Please review AR 7:2 to determine whether that policy applies to you.
- This completed Statement shall constitute a part of your University personnel records and shall be entitled to the same degree of confidentiality as other such records.

Response : I have read and understand the purpose of this survey, stated above.

QUESTION 2 - COI.2017.03
(Answered on: September 7, 2018, 10:06 am CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 3 - COI.2017.04
(Answered on: September 7, 2018, 10:09 am CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : No

QUESTION 4 - COI.2017.05
(Answered on: September 7, 2018, 10:10 am CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity. Additionally, individuals listed as sub-investigators on human subjects' research projects are required to complete a financial disclosure.

Respondent: Katherine Bain
 Department: Rehabilitation Science
 Email: katherine.bain@uky.edu
 Phone:
 Login ID: kaba266

Submitted On: September 7, 2018, 10:15 am CT
 Last Revision: September 7, 2018, 10:15 am CT

Printed On: November 12, 2018, 8:53 am CT

What must be disclosed

Investigators within the Colleges of Medicine, Nursing, Health Sciences, Pharmacy, Dentistry and Public Health must disclose all significant financial interests (SFI), regardless of value. Investigators in the other Colleges throughout campus are required to disclose SFI that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI", for individuals outside of the above-mentioned Colleges, means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, and federal, state, or local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK must be disclosed.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

How do I complete a financial disclosure

Upon certifying your training today by clicking the box at the end of the training information, you will complete the online Financial Conflict of Interest Disclosure questionnaire. This questionnaire is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. Investigators may access their disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise the responses to their questionnaire within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my questionnaire or my revised questionnaire

Questionnaires will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Questionnaire, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed on extramurally funded research

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the

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conditions in the management plan.

How are FCOI regulations enforced for extramurally funded research

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this section. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

For PHS funded investigators outside of the Colleges referenced above, excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

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Submitted On: September 7, 2018, 10:15 am CT
Last Revision: September 7, 2018, 10:15 am CT

Printed On: November 12, 2018, 8:53 am CT

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 5 - COI.2017.06

(Answered on: September 7, 2018, 10:11 am CT)

During the past 12 months or at any time during CY2017, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1

I DO NOT have financial interest in publicly traded entities to report

QUESTION 6 - COI.2017.07

(Answered on: September 7, 2018, 10:12 am CT)

During the past 12 months or at any time during CY2017, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1

I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 7 - COI.2017.08

(Answered on: September 7, 2018, 10:12 am CT)

The OIG defines Physician-Owned Distributorships (PODs) as entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures that the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

During CY 2017, did you maintain any financial interest in a POD, or benefit from any business transaction between UK HealthCare and a POD

Entity 1

I DO NOT have interests in PODs to report

QUESTION 8 - COI.2017.09

(Answered on: September 7, 2018, 10:13 am CT)

Respondent: Katherine Bain
Department: Rehabilitation Science
Email: katherine.bain@uky.edu
Phone:
Login ID: kaba266

Submitted On: September 7, 2018, 10:15 am CT
Last Revision: September 7, 2018, 10:15 am CT

Printed On: November 12, 2018, 8:53 am CT

During the past 12 months, or at any time during CY 2017, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

Entity 1
I DO NOT have intellectual property income to report

QUESTION 9 - COI.2017.10
(Answered on: September 7, 2018, 10:13 am CT)

Please identify any individuals that you directly or indirectly supervise within UK HealthCare, AND with whom you have a family or close personal relationship.

Entity 1
I DO NOT have family or close personal relationships to report

QUESTION 10 - COI.2017.11
(Answered on: September 7, 2018, 10:13 am CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, Health Sciences, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2017.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 11 - COI.2017.13
(Answered on: September 7, 2018, 10:14 am CT)

Please indicate whether you are currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program.

Response : I AM NOT currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program

QUESTION 12 - COI.2017.14
(Answered on: September 7, 2018, 10:14 am CT)

On an ongoing basis, I agree to disclose to the Chief Compliance Officer and/or Executive Vice President for Health Affairs any potential conflicts of interest that may arise in the course of my official duties on behalf of UK HealthCare.

Response : I agree

QUESTION 13 - COI.2017.15
(Answered on: September 7, 2018, 10:14 am CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.



Respondent: Katherine Bain
Department: Rehabilitation Science
Email: katherine.bain@uky.edu
Phone:
Login ID: kaba266

Submitted On: September 7, 2018, 10:15 am CT
Last Revision: September 7, 2018, 10:15 am CT

Printed On: November 12, 2018, 8:53 am CT

Response : I agree

QUESTION 14 - COI.2017.16
(Answered on: September 7, 2018, 10:15 am CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Meaghan Beck
Department: College of Health Sciences
Email: meaghan.beck@uky.edu
Phone:
Login ID: mcbe237

Submitted On: September 14, 2016, 9:30 am CT
Last Revision: September 14, 2016, 9:30 am CT
Printed On: May 31, 2018, 8:16 am CT

QUESTION 1 - COI.2015.03
(Answered on: September 14, 2016, 9:29 am CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 2 - COI.2015.04
(Answered on: September 14, 2016, 9:29 am CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : Yes

QUESTION 3 - COI.2015.05
(Answered on: September 14, 2016, 9:29 am CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity.

What must be disclosed

Each Investigator must disclose all significant financial interests (SFI) that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI" means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

Respondent: Meaghan Beck
Department: College of Health Sciences
Email: meaghan.beck@uky.edu
Phone:
Login ID: mcbe237

Submitted On: September 14, 2016, 9:30 am CT
Last Revision: September 14, 2016, 9:30 am CT
Printed On: May 31, 2018, 8:16 am CT

How do I complete a financial disclosure

Upon certifying your training today, you will complete the online Financial Conflict of Interest Disclosure statement. This disclosure is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. The Disclosure Statement has 5 questions with one additional question for PHS Investigators. Investigators may access their Disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise a Disclosure Statement within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my disclosure or my revised disclosure

Disclosure Statements will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Disclosure Statement, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this presentation. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

Questionnaire Report For: University of Kentucky and UK HealthCare Conflict of Interest Questionnaire



Respondent: Meaghan Beck
Department: College of Health Sciences
Email: meaghan.beck@uky.edu
Phone:
Login ID: mcbe237

Submitted On: September 14, 2016, 9:30 am CT
Last Revision: September 14, 2016, 9:30 am CT
Printed On: May 31, 2018, 8:16 am CT

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

Excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 4 - COI.2015.06

Respondent: Meaghan Beck
Department: College of Health Sciences
Email: meaghan.beck@uky.edu
Phone:
Login ID: mcbe237

Submitted On: September 14, 2016, 9:30 am CT
Last Revision: September 14, 2016, 9:30 am CT
Printed On: May 31, 2018, 8:16 am CT

(Answered on: September 14, 2016, 9:30 am CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1
I DO NOT have financial interest in publicly traded entities to report

QUESTION 5 - COI.2015.07
(Answered on: September 14, 2016, 9:30 am CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 6 - COI.2015.09
(Answered on: September 14, 2016, 9:30 am CT)

During the past 12 months, or at any time during CY 2015, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

Entity 1
I DO NOT have intellectual property income to report

QUESTION 7 - COI.2015.11
(Answered on: September 14, 2016, 9:30 am CT)

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Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2015.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 8 - COI.2015.15
(Answered on: September 14, 2016, 9:30 am CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree

Questionnaire Report For: University of Kentucky and UK HealthCare Conflict of Interest Questionnaire



Respondent: Meaghan Beck
Department: College of Health Sciences
Email: meaghan.beck@uky.edu
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Submitted On: September 14, 2016, 9:30 am CT
Last Revision: September 14, 2016, 9:30 am CT
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QUESTION 9 - COI.2015.16
(Answered on: September 14, 2016, 9:30 am CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Phillip Gribble
Department: Rehabilitation Science
Email: phillip.gribble@uky.edu
Phone:
Login ID: PAGR224

Submitted On: March 9, 2016, 1:44 pm CT
Last Revision: March 9, 2016, 1:44 pm CT
Printed On: February 14, 2018, 1:04 pm CT

QUESTION 1 - COI.2015.03
(Answered on: March 5, 2016, 12:00 pm CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 2 - COI.2015.04
(Answered on: March 5, 2016, 12:01 pm CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : No

QUESTION 3 - COI.2015.05
(Answered on: March 5, 2016, 12:01 pm CT)

Background

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Respondent: Phillip Gribble
Department: Rehabilitation Science
Email: phillip.gribble@uky.edu
Phone:
Login ID: PAGR224

Submitted On: March 9, 2016, 1:44 pm CT
Last Revision: March 9, 2016, 1:44 pm CT
Printed On: February 14, 2018, 1:04 pm CT

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If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Disclosure Statement, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced

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Training

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Who must disclose sponsored travel

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Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

Questionnaire Report For: University of Kentucky and UK HealthCare Conflict of Interest Questionnaire



Respondent: Phillip Gribble
Department: Rehabilitation Science
Email: phillip.gribble@uky.edu
Phone:
Login ID: PAGR224

Submitted On: March 9, 2016, 1:44 pm CT
Last Revision: March 9, 2016, 1:44 pm CT
Printed On: February 14, 2018, 1:04 pm CT

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

Excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 4 - COI.2015.06

Respondent: Phillip Gribble
Department: Rehabilitation Science
Email: phillip.gribble@uky.edu
Phone:
Login ID: PAGR224

Submitted On: March 9, 2016, 1:44 pm CT
Last Revision: March 9, 2016, 1:44 pm CT
Printed On: February 14, 2018, 1:04 pm CT

(Answered on: March 9, 2016, 1:44 pm CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1
I DO NOT have financial interest in publicly traded entities to report

QUESTION 5 - COI.2015.07
(Answered on: March 9, 2016, 1:44 pm CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 6 - COI.2015.09
(Answered on: March 9, 2016, 1:44 pm CT)

During the past 12 months, or at any time during CY 2015, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

Entity 1
I DO NOT have intellectual property income to report

QUESTION 7 - COI.2015.11
(Answered on: March 9, 2016, 1:44 pm CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2015.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 8 - COI.2015.15
(Answered on: March 9, 2016, 1:44 pm CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree



Respondent: Phillip Gribble
Department: Rehabilitation Science
Email: phillip.gribble@uky.edu
Phone:
Login ID: PAGR224

Submitted On: March 9, 2016, 1:44 pm CT
Last Revision: March 9, 2016, 1:44 pm CT
Printed On: February 14, 2018, 1:04 pm CT

QUESTION 9 - COI.2015.16
(Answered on: March 9, 2016, 1:44 pm CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Nicholas Heebner
Department: Rehabilitation Science
Email: nick.heebner@uky.edu
Phone:
Login ID: NHE232

Submitted On: March 3, 2016, 2:50 pm CT
Last Revision: March 3, 2016, 2:50 pm CT
Printed On: February 14, 2018, 1:05 pm CT

QUESTION 1 - COI.2015.03
(Answered on: March 3, 2016, 2:48 pm CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 2 - COI.2015.04
(Answered on: March 3, 2016, 2:49 pm CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : No

QUESTION 3 - COI.2015.05
(Answered on: March 3, 2016, 2:49 pm CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity.

What must be disclosed

Each Investigator must disclose all significant financial interests (SFI) that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI" means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

Respondent: Nicholas Heebner
Department: Rehabilitation Science
Email: nick.heebner@uky.edu
Phone:
Login ID: NHE232

Submitted On: March 3, 2016, 2:50 pm CT
Last Revision: March 3, 2016, 2:50 pm CT
Printed On: February 14, 2018, 1:05 pm CT

How do I complete a financial disclosure

Upon certifying your training today, you will complete the online Financial Conflict of Interest Disclosure statement. This disclosure is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. The Disclosure Statement has 5 questions with one additional question for PHS Investigators. Investigators may access their Disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise a Disclosure Statement within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my disclosure or my revised disclosure

Disclosure Statements will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Disclosure Statement, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this presentation. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

Questionnaire Report For: University of Kentucky and UK HealthCare Conflict of Interest Questionnaire



Respondent: Nicholas Heebner
Department: Rehabilitation Science
Email: nick.heebner@uky.edu
Phone:
Login ID: NHE232

Submitted On: March 3, 2016, 2:50 pm CT
Last Revision: March 3, 2016, 2:50 pm CT
Printed On: February 14, 2018, 1:05 pm CT

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

Excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 4 - COI.2015.06

Respondent: Nicholas Heebner
Department: Rehabilitation Science
Email: nick.heebner@uky.edu
Phone:
Login ID: NHE232

Submitted On: March 3, 2016, 2:50 pm CT
Last Revision: March 3, 2016, 2:50 pm CT
Printed On: February 14, 2018, 1:05 pm CT

(Answered on: March 3, 2016, 2:49 pm CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1
I DO NOT have financial interest in publicly traded entities to report

QUESTION 5 - COI.2015.07
(Answered on: March 3, 2016, 2:49 pm CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 6 - COI.2015.09
(Answered on: March 3, 2016, 2:50 pm CT)

During the past 12 months, or at any time during CY 2015, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

Entity 1
I DO NOT have intellectual property income to report

QUESTION 7 - COI.2015.11
(Answered on: March 3, 2016, 2:50 pm CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2015.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 8 - COI.2015.15
(Answered on: March 3, 2016, 2:50 pm CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree



Respondent: Nicholas Heebner
Department: Rehabilitation Science
Email: nick.heebner@uky.edu
Phone:
Login ID: NHE232

Submitted On: March 3, 2016, 2:50 pm CT
Last Revision: March 3, 2016, 2:50 pm CT
Printed On: February 14, 2018, 1:05 pm CT

QUESTION 9 - COI.2015.16
(Answered on: March 3, 2016, 2:50 pm CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

QUESTION 1 - COI.2017.01
(Answered on: March 20, 2018, 3:41 am CT)

Because of your position at the University, you are required to complete a Conflict of Interest Disclosure Statement. Unless indicated otherwise, the requested information applies to any activities during the previous calendar year.

- For each outside activity, equity interest and/or family association, you will be asked to complete a Conflict of Interest Disclosure Statement in its entirety.
- If you are unsure whether an outside activity, equity interest or family association is covered by a question, please disclose it.
- You may also be required to complete additional disclosures per the University's [Research Conflict of Interest and Financial Disclosure Policy, AR 7:2](#), if you engage in covered research projects. Please review AR 7:2 to determine whether that policy applies to you.
- This completed Statement shall constitute a part of your University personnel records and shall be entitled to the same degree of confidentiality as other such records.

Response : I have read and understand the purpose of this survey, stated above.

QUESTION 2 - COI.2017.02
(Answered on: March 20, 2018, 3:42 am CT)

Pursuant to the UK HealthCare Conflict of Interest/Confidentiality Policy, I hereby certify the following:

- 1) I am a person identified as having to file an annual disclosure statement under either UKHC policy [A01-160 Annual Disclosure of Financial Conflicts of Interest](#), or [Practice Plan AR](#) or both. If you are unable to access the links provided, you may view the policies located in the Document Library.
- 2) I have received, read and understand the [Conflict of Interest](#) and [Confidentiality](#) Policies and agree to comply with my obligations under the Policies. If you are unable to access the links provided, you may view the policies located in the Document Library.
- 3) I have received, read and understand UKHC policy A01-160 and/or Practice Plan AR and agree to comply with my obligations under the same.
- 4) I agree to maintain the confidentiality of all matters which are sensitive or proprietary relating to my employment.

Response : I agree

QUESTION 3 - COI.2017.03
(Answered on: March 20, 2018, 3:42 am CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 4 - COI.2017.04
(Answered on: March 20, 2018, 3:42 am CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : Yes

QUESTION 5 - COI.2017.05
(Answered on: March 20, 2018, 3:44 am CT)

Background

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity. Additionally, individuals listed as sub-investigators on human subjects' research projects are required to complete a financial disclosure.

What must be disclosed

Investigators within the Colleges of Medicine, Nursing, Health Sciences, Pharmacy, Dentistry and Public Health must disclose all significant financial interests (SFI), regardless of value. Investigators in the other Colleges throughout campus are required to disclose SFI that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI", for individuals outside of the above-mentioned Colleges, means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, and federal, state, or local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK must be disclosed.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

How do I complete a financial disclosure

Upon certifying your training today by clicking the box at the end of the training information, you will complete the online Financial Conflict of Interest Disclosure questionnaire. This questionnaire is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. Investigators may access their disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise the responses to their questionnaire within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

What happens once I submit my questionnaire or my revised questionnaire

Questionnaires will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Questionnaire, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed on extramurally funded research

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced for extramurally funded research

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this section. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

For PHS funded investigators outside of the Colleges referenced above, excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

are designed to safeguard the research. In addition, prior to expending funds on a PHS award.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 6 - COI.2017.06

(Answered on: March 20, 2018, 3:44 am CT)

During the past 12 months or at any time during CY2017, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1

I DO NOT have financial interest in publicly traded entities to report

QUESTION 7 - COI.2017.07

(Answered on: March 20, 2018, 3:50 am CT)

During the past 12 months or at any time during CY2017, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1

I have financial interest in non-publicly traded entities to report

This information pertains to:

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

Self

Please provide the name of the non-publicly traded entity.

Human Kinetics

Please select the type of interest you have in this non-publicly traded entity (please check all that apply).

Scientific advisory board or peer review panel member

Please select the approximate value of this interest.

\$500 to \$999

Please provide the dollar amount.

600.00

.....
Entity 2

I have financial interest in non-publicly traded entities to report

This information pertains to:

Spouse

Please provide the name of the non-publicly traded entity.

Human Kinetics

Please select the type of interest you have in this non-publicly traded entity (please check all that apply).

Scientific advisory board or peer review panel member

Please select the approximate value of this interest.

\$500 to \$999

Please provide the dollar amount.

600.00

.....
Entity 3

I have financial interest in non-publicly traded entities to report

This information pertains to:

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

Spouse

Please provide the name of the non-publicly traded entity.

Old Dominion University Research Foundation

Please select the type of interest you have in this non-publicly traded entity (please check all that apply).

Consultant (paid or unpaid)

Please select the approximate value of this interest.

\$5000 to \$9999

Please provide the dollar amount.

9999.00

Does this entity support your research or other sponsored activity

No

QUESTION 8 - COI.2017.08

(Answered on: March 20, 2018, 3:52 am CT)

The OIG defines Physician-Owned Distributorships (PODs) as entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures that the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

During CY 2017, did you maintain any financial interest in a POD, or benefit from any business transaction between UK HealthCare and a POD

.....
Entity 1

I DO NOT have interests in PODs to report

QUESTION 9 - COI.2017.09

(Answered on: March 20, 2018, 3:52 am CT)

During the past 12 months, or at any time during CY 2017, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

.....
Entity 1

I DO NOT have intellectual property income to report

QUESTION 10 - COI.2017.10

(Answered on: March 20, 2018, 3:52 am CT)

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

Please identify any individuals that you directly or indirectly supervise within UK HealthCare, AND with whom you have a family or close personal relationship.

Entity 1
I have family or close personal relationships to report

Please provide the name of the individual.
Johanna Hoch

Please provide the nature of relationship.
Spouse

Please provide the individual's position with UK HealthCare.
Assistant Professor

QUESTION 11 - COI.2017.11
(Answered on: March 20, 2018, 3:52 am CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, Health Sciences, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2017.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 12 - COI.2017.12
(Answered on: March 20, 2018, 3:52 am CT)

Over the past 12 months, or at any time during CY 2017, have you received remuneration from any entity outside of UK HealthCare, other than those listed in the previous questions

Entity 1
I DO NOT have other outside activities to report

QUESTION 13 - COI.2017.13
(Answered on: March 20, 2018, 3:52 am CT)

Please indicate whether you are currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program.

Response : I AM NOT currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program

QUESTION 14 - COI.2017.14

Respondent: Matthew Hoch
Department: Rehabilitation Science
Email: matt.hoch@uky.edu
Phone:
Login ID: mcho222

Submitted On: March 20, 2018, 3:53 am CT
Last Revision: March 20, 2018, 3:53 am CT
Printed On: May 31, 2018, 8:17 am CT

(Answered on: March 20, 2018, 3:52 am CT)

On an ongoing basis, I agree to disclose to the Chief Compliance Officer and/or Executive Vice President for Health Affairs any potential conflicts of interest that may arise in the course of my official duties on behalf of UK HealthCare.

Response : I agree

QUESTION 15 - COI.2017.15
(Answered on: March 20, 2018, 3:53 am CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree

QUESTION 16 - COI.2017.16
(Answered on: March 20, 2018, 3:53 am CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Nathan Johnson
Department: Rehabilitation Science
Email: Nathan.Johnson@uky.edu
Phone:
Login ID: NFJOHN2

Submitted On: August 24, 2017, 8:56 am CT
Last Revision: August 24, 2017, 8:55 am CT
Printed On: February 14, 2018, 1:07 pm CT

QUESTION 1 - COI.2016.01

(Answered on: August 24, 2017, 8:52 am CT)

Pursuant to the UK HealthCare Conflict of Interest/Confidentiality Policy, I hereby certify the following:

- 1) I am a person identified as having to file an annual disclosure statement under either UKHC policy [A01-160 Annual Disclosure of Financial Conflicts of Interest](#), or [Practice Plan AR](#) or both. If you are unable to access the links provided, you may view the policies located in the Document Library.
- 2) I have received, read and understand the [Conflict of Interest](#) and [Confidentiality](#) Policies and agree to comply with my obligations under the Policies. If you are unable to access the links provided, you may view the policies located in the Document Library.
- 3) I have received, read and understand UKHC policy A01-160 and/or Practice Plan AR and agree to comply with my obligations under the same.
- 4) I agree to maintain the confidentiality of all matters which are sensitive or proprietary relating to my employment.

Response : I agree

QUESTION 2 - COI.2016.02

(Answered on: August 24, 2017, 8:52 am CT)

Because of your position at the University, you are required to complete a Conflict of Interest Disclosure Statement. Unless indicated otherwise, the requested information applies to any activities during the previous calendar year.

- For each outside activity, equity interest and/or family association, you will be asked to complete a Conflict of Interest Disclosure Statement in its entirety.
- If you are unsure whether an outside activity, equity interest or family association is covered by a question, please disclose it.
- You may also be required to complete additional disclosures per the University's [Research Conflict of Interest and Financial Disclosure Policy, AR 7:2](#), if you engage in covered research projects. Please review AR 7:2 to determine whether that policy applies to you.
- This completed Statement shall constitute a part of your University personnel records and shall be entitled to the same degree of confidentiality as other such records.

Response : I have read and understand the purpose of this survey, stated above.

QUESTION 3 - COI.2016.03

(Answered on: August 24, 2017, 8:52 am CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 4 - COI.2016.04

(Answered on: August 24, 2017, 8:53 am CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : No

QUESTION 5 - COI.2016.05

(Answered on: August 24, 2017, 8:53 am CT)

Do you have any current or proposed research with a United States Department of Defense agency, NASA, or a foreign entity AND/OR does your research

Respondent: Nathan Johnson
 Department: Rehabilitation Science
 Email: Nathan.Johnson@uky.edu
 Phone:
 Login ID: NFJOHN2

Submitted On: August 24, 2017, 8:56 am CT
 Last Revision: August 24, 2017, 8:55 am CT
 Printed On: February 14, 2018, 1:07 pm CT

involve items related to military/space technology, satellites, missiles, explosives, or military vehicles/vessels

Response : No

QUESTION 6 - COI.2016.06

(Answered on: August 24, 2017, 8:54 am CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity. Additionally, individuals listed as sub-investigators on human subjects' research projects are required to complete a financial disclosure.

What must be disclosed

Investigators within the Colleges of Medicine, Nursing, Health Sciences, Pharmacy, Dentistry and Public Health must disclose all significant financial interests (SFI), regardless of value. Investigators in the other Colleges throughout campus are required to disclose SFI that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI", for individuals outside of the above-mentioned Colleges, means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

How do I complete a financial disclosure

Upon certifying your training today by clicking the box at the end of the training information, you will complete the online Financial Conflict of Interest Disclosure questionnaire. This questionnaire is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. Investigators may access their Disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise the responses to their questionnaire within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

Respondent: Nathan Johnson
 Department: Rehabilitation Science
 Email: Nathan.Johnson@uky.edu
 Phone:
 Login ID: NFJOHN2

Submitted On: August 24, 2017, 8:56 am CT
 Last Revision: August 24, 2017, 8:55 am CT
 Printed On: February 14, 2018, 1:07 pm CT

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my questionnaire or my revised questionnaire

Questionnaires will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Questionnaire, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed on extramurally funded research

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced for extramurally funded research

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this section. Training must be repeated at the time of annual disclosure, if an Investigator is found to be non-compliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science

Respondent: Nathan Johnson
 Department: Rehabilitation Science
 Email: Nathan.Johnson@uky.edu
 Phone:
 Login ID: NFJOHN2

Submitted On: August 24, 2017, 8:56 am CT
 Last Revision: August 24, 2017, 8:55 am CT
 Printed On: February 14, 2018, 1:07 pm CT

13. Substance Abuse and Mental Health Services Administration (SAMHSA)

For PHS funded investigators outside of the Colleges referenced above, excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/reg/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelly.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 7 - COI.2016.07

(Answered on: August 24, 2017, 8:54 am CT)

During the past 12 months or at any time during CY2016, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1

I DO NOT have financial interest in publicly traded entities to report

Respondent: Nathan Johnson
Department: Rehabilitation Science
Email: Nathan.Johnson@uky.edu
Phone:
Login ID: NFJOHN2

Submitted On: August 24, 2017, 8:56 am CT
Last Revision: August 24, 2017, 8:55 am CT
Printed On: February 14, 2018, 1:07 pm CT

QUESTION 8 - COI.2016.08
(Answered on: August 24, 2017, 8:54 am CT)

During the past 12 months or at any time during CY2016, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

.....
Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 9 - COI.2016.09
(Answered on: August 24, 2017, 8:54 am CT)

The OIG defines Physician-Owned Distributorships (PODs) as entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures that the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

During CY 2016, did you maintain any financial interest in a POD, or benefit from any business transaction between UK HealthCare and a POD

.....
Entity 1
I DO NOT have interests in PODs to report

QUESTION 10 - COI.2016.10
(Answered on: August 24, 2017, 8:55 am CT)

During the past 12 months, or at any time during CY 2016, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

.....
Entity 1
I DO NOT have intellectual property income to report

QUESTION 11 - COI.2016.11
(Answered on: August 24, 2017, 8:55 am CT)

Please identify any individuals that you directly or indirectly supervise within UK HealthCare, AND with whom you have a family or close personal relationship.

.....
Entity 1
I DO NOT have family or close personal relationships to report

QUESTION 12 - COI.2016.12
(Answered on: August 24, 2017, 8:55 am CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, Health Sciences, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2016.

Respondent: Nathan Johnson
Department: Rehabilitation Science
Email: Nathan.Johnson@uky.edu
Phone:
Login ID: NFJOHN2

Submitted On: August 24, 2017, 8:56 am CT
Last Revision: August 24, 2017, 8:55 am CT
Printed On: February 14, 2018, 1:07 pm CT

Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 13 - COI.2016.13
(Answered on: August 24, 2017, 8:55 am CT)

Over the past 12 months, or at any time during CY 2016, have you received remuneration from any entity outside of UK HealthCare, other than those listed in the previous questions

Entity 1
I DO NOT have other outside activities to report

QUESTION 14 - COI.2016.14
(Answered on: August 24, 2017, 8:55 am CT)

Please indicate whether you are currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program.

Response : I AM NOT currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program

QUESTION 15 - COI.2016.15
(Answered on: August 24, 2017, 8:55 am CT)

On an ongoing basis, I agree to disclose to the Chief Compliance Officer and/or Executive Vice President for Health Affairs any potential conflicts of interest that may arise in the course of my official duties on behalf of UK HealthCare.

Response : I agree

QUESTION 16 - COI.2016.16
(Answered on: August 24, 2017, 8:55 am CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree

QUESTION 17 - COI.2016.17
(Answered on: August 24, 2017, 8:55 am CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: Kyle Kosik
Department: Health Sciences
Email: KKO238@uky.edu
Phone:
Login ID: KKO238

Submitted On: March 3, 2016, 9:28 am CT
Last Revision: March 3, 2016, 9:28 am CT
Printed On: May 31, 2018, 8:18 am CT

QUESTION 1 - COI.2015.03
(Answered on: March 3, 2016, 9:26 am CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 2 - COI.2015.04
(Answered on: March 3, 2016, 9:27 am CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : No

QUESTION 3 - COI.2015.05
(Answered on: March 3, 2016, 9:27 am CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity.

What must be disclosed

Each Investigator must disclose all significant financial interests (SFI) that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI" means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

Respondent: Kyle Kosik
Department: Health Sciences
Email: KKO238@uky.edu
Phone:
Login ID: KKO238

Submitted On: March 3, 2016, 9:28 am CT
Last Revision: March 3, 2016, 9:28 am CT
Printed On: May 31, 2018, 8:18 am CT

How do I complete a financial disclosure

Upon certifying your training today, you will complete the online Financial Conflict of Interest Disclosure statement. This disclosure is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. The Disclosure Statement has 5 questions with one additional question for PHS Investigators. Investigators may access their Disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise a Disclosure Statement within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my disclosure or my revised disclosure

Disclosure Statements will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Disclosure Statement, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this presentation. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

Questionnaire Report For: University of Kentucky and UK HealthCare Conflict of Interest Questionnaire



Respondent: Kyle Kosik
Department: Health Sciences
Email: KKO238@uky.edu
Phone:
Login ID: KKO238

Submitted On: March 3, 2016, 9:28 am CT
Last Revision: March 3, 2016, 9:28 am CT
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1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

Excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelley.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 4 - COI.2015.06

Respondent: Kyle Kosik
Department: Health Sciences
Email: KKO238@uky.edu
Phone:
Login ID: KKO238

Submitted On: March 3, 2016, 9:28 am CT
Last Revision: March 3, 2016, 9:28 am CT
Printed On: May 31, 2018, 8:18 am CT

(Answered on: March 3, 2016, 9:27 am CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

.....
Entity 1
I DO NOT have financial interest in publicly traded entities to report

QUESTION 5 - COI.2015.07
(Answered on: March 3, 2016, 9:27 am CT)

During the past 12 months or at any time during CY2015, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

.....
Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 6 - COI.2015.09
(Answered on: March 3, 2016, 9:27 am CT)

During the past 12 months, or at any time during CY 2015, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

.....
Entity 1
I DO NOT have intellectual property income to report

QUESTION 7 - COI.2015.11
(Answered on: March 3, 2016, 9:27 am CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2015.

.....
Entity 1
I DO NOT have sponsored or reimbursed travel to report

QUESTION 8 - COI.2015.15
(Answered on: March 3, 2016, 9:28 am CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree



Respondent: Kyle Kosik
Department: Health Sciences
Email: KKO238@uky.edu
Phone:
Login ID: KKO238

Submitted On: March 3, 2016, 9:28 am CT
Last Revision: March 3, 2016, 9:28 am CT
Printed On: May 31, 2018, 8:18 am CT

QUESTION 9 - COI.2015.16
(Answered on: March 3, 2016, 9:28 am CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

Respondent: David Powell
Department: Anatomy and Neurobiology
Email: david.k.powell@uky.edu
Phone:
Login ID: DKPOWE2

Submitted On: May 10, 2017, 3:15 pm CT
Last Revision: May 10, 2017, 3:24 pm CT
Printed On: February 14, 2018, 1:08 pm CT

QUESTION 1 - COI.2016.01

(Answered on: May 10, 2017, 3:10 pm CT)

Pursuant to the UK HealthCare Conflict of Interest/Confidentiality Policy, I hereby certify the following:

- 1) I am a person identified as having to file an annual disclosure statement under either UKHC policy [A01-160 Annual Disclosure of Financial Conflicts of Interest](#), or [Practice Plan AR](#) or both. If you are unable to access the links provided, you may view the policies located in the Document Library.
- 2) I have received, read and understand the [Conflict of Interest](#) and [Confidentiality](#) Policies and agree to comply with my obligations under the Policies. If you are unable to access the links provided, you may view the policies located in the Document Library.
- 3) I have received, read and understand UKHC policy A01-160 and/or Practice Plan AR and agree to comply with my obligations under the same.
- 4) I agree to maintain the confidentiality of all matters which are sensitive or proprietary relating to my employment.

Response : I agree

QUESTION 2 - COI.2016.02

(Answered on: May 10, 2017, 3:10 pm CT)

Because of your position at the University, you are required to complete a Conflict of Interest Disclosure Statement. Unless indicated otherwise, the requested information applies to any activities during the previous calendar year.

- For each outside activity, equity interest and/or family association, you will be asked to complete a Conflict of Interest Disclosure Statement in its entirety.
- If you are unsure whether an outside activity, equity interest or family association is covered by a question, please disclose it.
- You may also be required to complete additional disclosures per the University's [Research Conflict of Interest and Financial Disclosure Policy, AR 7:2](#), if you engage in covered research projects. Please review AR 7:2 to determine whether that policy applies to you.
- This completed Statement shall constitute a part of your University personnel records and shall be entitled to the same degree of confidentiality as other such records.

Response : I have read and understand the purpose of this survey, stated above.

QUESTION 3 - COI.2016.03

(Answered on: May 10, 2017, 3:10 pm CT)

Are you involved in human subjects research or clinical investigations

Response : Yes

QUESTION 4 - COI.2016.04

(Answered on: May 10, 2017, 3:11 pm CT)

Does your work involve a pending or funded grant, cooperative agreement or contract from a Public Health Service (PHS) agency, including any sub-award from another institution

Response : Yes

REVISION 1 FOR QUESTION 5 - COI.2016.05.R1

(Revised on: May 10, 2017, 3:24 pm CT)

Do you have any current or proposed research with a United States Department of Defense agency, NASA, or a foreign entity AND/OR does your research involve items related to military/space technology, satellites, missiles, explosives, or military vehicles/vessels

Respondent: David Powell
Department: Anatomy and Neurobiology
Email: david.k.powell@uky.edu
Phone:
Login ID: DKPOWE2

Submitted On: May 10, 2017, 3:15 pm CT
Last Revision: May 10, 2017, 3:24 pm CT
Printed On: February 14, 2018, 1:08 pm CT

Response : Yes

QUESTION 6 - COI.2016.06
(Answered on: May 10, 2017, 3:13 pm CT)

Background

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24th, 2012. Grantees were to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each "investigator" on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, "Investigator" means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity. Additionally, individuals listed as sub-investigators on human subjects' research projects are required to complete a financial disclosure.

What must be disclosed

Investigators within the Colleges of Medicine, Nursing, Health Sciences, Pharmacy, Dentistry and Public Health must disclose all significant financial interests (SFI), regardless of value. Investigators in the other Colleges throughout campus are required to disclose SFI that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI", for individuals outside of the above-mentioned Colleges, means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, federal, state, local governments. Specifically excluded is income from seminars, lectures or teaching from federal, state, local government, institution of higher education, academic teaching hospital, medical center or research institute affiliated with institution of higher education.
- Intellectual property rights and interests upon receipt of income from an entity other than UK.

What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

How do I complete a financial disclosure

Upon certifying your training today by clicking the box at the end of the training information, you will complete the online Financial Conflict of Interest Disclosure questionnaire. This questionnaire is required annually in March of each year. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. Investigators may access their Disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise the responses to their questionnaire within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

Respondent: David Powell
 Department: Anatomy and Neurobiology
 Email: david.k.powell@uky.edu
 Phone:
 Login ID: DKPOWE2

Submitted On: May 10, 2017, 3:15 pm CT
 Last Revision: May 10, 2017, 3:24 pm CT
 Printed On: February 14, 2018, 1:08 pm CT

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value.

What happens once I submit my questionnaire or my revised questionnaire

Questionnaires will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether or not an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Questionnaire, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

How are FCOIs managed on extramurally funded research

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced for extramurally funded research

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, and fail to provide information needed for a review. Sanctions may be imposed for violation, including being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this section. Training must be repeated at the time of annual disclosure, if an Investigator is found to be non-compliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Investigators on PHS-funded projects must disclose sponsored travel of any amount. PHS encompasses the following agencies:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

For PHS funded investigators outside of the Colleges referenced above, excluded from disclosure is travel reimbursed or sponsored for spouse and dependent

Respondent: David Powell
 Department: Anatomy and Neurobiology
 Email: david.k.powell@uky.edu
 Phone:
 Login ID: DKPOWE2

Submitted On: May 10, 2017, 3:15 pm CT
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 Printed On: February 14, 2018, 1:08 pm CT

children, travel paid from a UK account, and reimbursed or sponsored travel paid by a Federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Additional regulations for PHS investigators:

Prior to expending funds, UK must report to PHS any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, value of SFI in ranges and the elements of the management plan which are designed to safeguard the research. In addition, prior to expending funds on a PHS award, UK must post to a public website certain information about any SFI held by investigators related to the PHS award that is determined to be an FCOI; website is updated annually and with each new FCOI. The elements posted to the website include investigator name, title, and role on the project as well as the name of the entity, nature of the SFI, and the approximate value.

PHS policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to PHS.

What happens in the event of non-compliance with PHS regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

Retrospective Review and Mitigation Plan

If an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, PHS will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to PHS and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations and request addendum to related previous publications. PHS may request further information and may impose additional conditions.

You have completed the required training on Financial Disclosure and Conflict of Interest.

Additional resources:

- PHS Regulation (42 CFR § Part 50) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

Thank you for your attention to this important requirement!

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Kelley Davis in the Office of Sponsored Projects Administration at (859) 257-0579 or kelly.king@uky.edu.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 7 - COI.2016.07

(Answered on: May 10, 2017, 3:14 pm CT)

During the past 12 months or at any time during CY2016, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any publicly traded entity

Entity 1

I DO NOT have financial interest in publicly traded entities to report

QUESTION 8 - COI.2016.08

(Answered on: May 10, 2017, 3:14 pm CT)

Respondent: David Powell
Department: Anatomy and Neurobiology
Email: david.k.powell@uky.edu
Phone:
Login ID: DKPOWE2

Submitted On: May 10, 2017, 3:15 pm CT
Last Revision: May 10, 2017, 3:24 pm CT
Printed On: February 14, 2018, 1:08 pm CT

During the past 12 months or at any time during CY2016, have you or any member of your family received remuneration from, own equity interest in, or have any other financial interest in any non-publicly traded entity

Entity 1
I DO NOT have financial interest in non-publicly traded entities to report

QUESTION 9 - COI.2016.09
(Answered on: May 10, 2017, 3:14 pm CT)

The OIG defines Physician-Owned Distributorships (PODs) as entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures that the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

During CY 2016, did you maintain any financial interest in a POD, or benefit from any business transaction between UK HealthCare and a POD

Entity 1
I DO NOT have interests in PODs to report

QUESTION 10 - COI.2016.10
(Answered on: May 10, 2017, 3:14 pm CT)

During the past 12 months, or at any time during CY 2016, have you or any member of your family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University

Entity 1
I DO NOT have intellectual property income to report

QUESTION 11 - COI.2016.11
(Answered on: May 10, 2017, 3:14 pm CT)

Please identify any individuals that you directly or indirectly supervise within UK HealthCare, AND with whom you have a family or close personal relationship.

Entity 1
I DO NOT have family or close personal relationships to report

QUESTION 12 - COI.2016.12
(Answered on: May 10, 2017, 3:14 pm CT)

Faculty members in the Colleges of Medicine, Nursing, Dentistry, Pharmacy, Health Sciences, and Public Health are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are a PHS-funded investigator. Additionally, PHS-funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2016.

Entity 1
I DO NOT have sponsored or reimbursed travel to report

Respondent: David Powell
Department: Anatomy and Neurobiology
Email: david.k.powell@uky.edu
Phone:
Login ID: DKPOWE2

Submitted On: May 10, 2017, 3:15 pm CT
Last Revision: May 10, 2017, 3:24 pm CT
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QUESTION 13 - COI.2016.13
(Answered on: May 10, 2017, 3:14 pm CT)

Over the past 12 months, or at any time during CY 2016, have you received remuneration from any entity outside of UK HealthCare, other than those listed in the previous questions

.....
Entity 1
I DO NOT have other outside activities to report

QUESTION 14 - COI.2016.14
(Answered on: May 10, 2017, 3:14 pm CT)

Please indicate whether you are currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program.

Response : I AM NOT currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program

QUESTION 15 - COI.2016.15
(Answered on: May 10, 2017, 3:14 pm CT)

On an ongoing basis, I agree to disclose to the Chief Compliance Officer and/or Executive Vice President for Health Affairs any potential conflicts of interest that may arise in the course of my official duties on behalf of UK HealthCare.

Response : I agree

QUESTION 16 - COI.2016.16
(Answered on: May 10, 2017, 3:14 pm CT)

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Response : I agree

QUESTION 17 - COI.2016.17
(Answered on: May 10, 2017, 3:14 pm CT)

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

Response : I agree

IRBIS Conflict of Interest Disclosure: 18-32062 (RCOIP)**Discloser Information**

Name:	Erik Wikstrom (730066198)	Dept:	Exercise and Sport Science (318600)
Email:	ewikstro@email.unc.edu	Project Title:	Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation
Address:	CB: CB# 8605 311 Woollen Gym , Chapel Hill, NC 27599 , USA	Related Number:	18-1538
Phone Number:	(919) 962-2260	Sponsor(s):	University of Kentucky (UK) (12545)
Title:	Assistant Professor	Project Role:	Principal Investigator

General Questions**1) Income/Honorarium**

In the past 12 months or in the next 12 months, have you or your immediate family (spouse/partner or dependent children) received or expect to receive income, honoraria, royalties, personal gifts, loans, gratuities or anything of value from an entity or vendor related to this activity. Income from your primary employer should not be included.

No

2) Ownership/Equity Interest

Do you or a family member currently hold or plan to hold equity interest in an entity or vendor related to this activity. Please exclude mutual funds and blind trust funds from your answer unless you have direct control over the investments.

No

3) Gifts

Has an entity or vendor related to this activity given a gift to the University, UNC Medical Center, or affiliated foundations where the gift was designated for your benefit, your family members, your research or your research team?

No

4) External Positions

Do you or a family member hold a position(s), paid or unpaid, with an entity or vendor associated with this activity?

No

5) University Resources

Are there University resources used to conduct this project that are not funded by the sponsor(s) of this project (e.g. personnel, products, facilities, equipment, etc.)?

No

6) Intellectual Property

Are you or a family member an inventor on licensed (or under negotiation) Intellectual Property being evaluated or used in this project/activity?

No

Does any entity involved in this project currently hold rights or negotiating rights to additional IP for which you or your family members are listed as inventors?

No

7) Participants

Will there be any students involved in the proposed study?

Yes

Student Type	Explanation	Restrictions	Restriction Explanation
Graduate	PhD advisor	No	

Do any UNC students work for payment at an external entity involved in this project?

No

8) University or Institutional Interests

To the best of your knowledge, does UNC-CH have licensed Intellectual Property, including copyright, for any process, treatment, product, device or technology being used or evaluated in this study?

No

Does UNC-CH have any ownership interest in a company involved in the study either as a sponsor or supplier? An example would be a start-up company by a UNC faculty member. Please answer to the best of your knowledge.

No

9) Other

Do you refer any entity involved in this project as a vendor to other University offices?

No

10) Additional Information

N/A

I certify that the information provided above is complete and accurate to the best of my knowledge.

Signature: Electronic Signature Received (Erik Wikstrom) **Date:** 06/06/2018

By signing in the appropriate space, the Approver is indicating only that he/she has seen and reviewed this application.

Department: Exercise and Sport Science

Signature: Electronic Signature Received (Erik Wikstrom) **Date:** 06/06/2018

Name & Title: Erik Wikstrom, Assistant Professor

Brooke Army Medical Center		Financial or Commitment Conflict of Interest Disclosure Form - Researcher	
Department of Clinical Investigation		PI	Protocol #
Office of the Institutional Review Board		Phillip Gribble	44172
Protocol Title			
Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation			
General Instructions: Please read each of the items below and mark the box which best applies. All items must be completed for the form to be accepted for IRB review. All investigators (principal and associate), research staff and collaborators who are engaged in the research protocol must answer all of the below questions and sign this document. In the event of identified conflicts, please address the questions in the free text space.			
Potential Financial Conflicts of Interest Related to Research			
☐ YES ☒ NO	Do any of the involved investigators or their immediate family (spouse, dependent children or domestic partner) have consulting arrangements, management responsibilities or equity holdings exceeding \$5,000 in the Sponsoring party, vendor(s), provider(s) of goods or subcontractor(s)?		
☐ YES ☒ NO	Do any of the involved investigators or their immediate family have any financial relationship exceeding \$5,000 with the Sponsoring party, including receipt of grants, honoraria, income, stock or stock options (not including mutual funds) as payment?		
☐ YES ☒ NO	Are any investigators a member of an advisory board or have an academic appointment with the Sponsoring party?		
☐ YES ☒ NO	Do any investigators receive gift funds exceeding \$5,000 from the Sponsoring party?		
☐ YES ☒ NO	Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property (e.g. patents, copyrights, licensing agreements) utilized in this protocol?		
If the answer to any of the above is YES, please detail the involved party and the nature of the financial conflict below.			
If the answer to any of the above is YES, please detail a proposed mitigation plan for each financial conflict below.			
Potential Conflicts of Commitment Related to Research			
☐ YES ☒ NO	In the next 12 months, are there any barriers due to other professional or personal commitments that will prevent you from executing your duties as described in your appointment to the IRB? Consider planned TDY, deployment, departmental duties and reasonably foreseeable additional duties.		
If the answer to any of the above is YES, please detail a proposed mitigation plan for the conflict below (eg: appointed acting PI)			
READ AND ACKNOWLEDGE: If any relationships exist which may lead to a conflict for myself or my research team, I understand that I have certain obligations. For financial conflicts, I must include a statement in the consent form to disclose this relationship. The consent form should disclose what institutions or companies are involved in the study through funding, cooperative research agreements or by providing drugs or equipment. For commitment conflicts, I am responsible for developing a mitigation plan to ensure the safe and timely conduct of the research. I also understand that this disclosure is only valid for one year from the date of signature, but that a potential or perceived conflict of interest arising prior to required renewal must be disclosed to the BAMC IRB within 30 days.			
Principal Investigator Name		Signature	Date
Phillip Gribble			

READ AND ACKNOWLEDGE: As a member of the research team, I understand that if any relationships exist which may lead to a conflict, must notify the principal investigator immediately. The principal investigator will coordinate changes to duties or relevant documents and be required to notify the IRB. I also understand that this disclosure is only valid for one year from the date of signature, but that a potential or perceived conflict of interest arising prior to required renewal must be disclosed to the BAMC IRB by the principal investigator within 30 days.

[illegible]

MEMORANDUM

TO: Phillip Gribble, PhD, ATC, FNATA
Professor, Director Division of Athletic Training
University of Kentucky
Department of Rehabilitation Sciences, College of Health Sciences
206C Charles T. Wethington Building
Lexington, KY 40536-0200

FROM: Amy S. Kolasa, MS, CIP
Reliance Manager
Office of Research Integrity/IRB
University of Kentucky

SUBJECT: Protocol #44172

DATE: November 7, 2018

The purpose of this correspondence is to confirm that the University of Kentucky (UK) Office of Research Integrity (ORI) has reviewed the information you provided regarding the involvement of a paid consultant on your project #44172 entitled, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation."

ORI has determined that the paid consultant is not engaged in the conduct of human subjects research on this project, and therefore UK IRB approval is not required for their participation. The UK ORI further notes that the paid consultant will receive only de-identified data for this project.

No further action is required by the UK IRB.

If you have any questions regarding this memorandum or need further information regarding the UK ORI determination, please contact Amy Kolasa at the UK Office of Research Integrity at (859) 257-9425.

see blue.

November 7, 2016

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

RE: Fiscal Year 2017-2018 (FY17-18) Joint Program Committee 8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRM RP) Neuromusculoskeletal Injuries Rehabilitation Research Award (NMSIRRA)

Dr. Gribble:

Please accept this endorsement of your grant proposal titled “Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation” being submitted to the Fiscal Year 2017-2018 (FY17-18) Joint Program Committee 8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRM RP) Neuromusculoskeletal Injuries Rehabilitation Research Award (NMSIRRA).

In my capacity as the Dean of the College of Health Sciences I will ensure you and your research team have the resources and access to laboratory facilities necessary to carry out the deliverables outlined in the proposal. I will ensure your research group is provided with the requisite infrastructure to successfully meet the aims of the study. I endorse your research personnel, aims of the proposed study, and enthusiastically lend my assistance to ensure its productive completion.

Respectfully,



Scott M. Lephart, PhD



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

DEPARTMENT of EXERCISE *and* SPORT SCIENCE

209 FETZER HALL
CAMPUS BOX 8700
CHAPEL HILL, NC 27599-8700

T 919-962-0017/0018
F 919-962-0489
www.unc.edu/depts/exercise

October 3, 2016

Dr. Phillip Gribble

Associate Professor, Director Division of Athletic Training
University of Kentucky, College of Health Services
206c Charles T. Wethington Building, Lexington, KY 40536

Re: Erik Wikstrom & the DOD Proposal on Treating Lateral Ankle Sprains to Prevent Chronic Ankle Instability Development

Dear Dr. Gribble:

I am writing to enthusiastically confirm organizational support for Dr. Erik Wikstrom's role in your "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation" proposal. Dr. Wikstrom Co-directs the Sports Medicine Research Laboratory in the Department of Exercise and Sport Science at UNC-Chapel Hill. He has unrestricted access to this space as well as the Neuromuscular Research Laboratory and the equipment necessary for conducting the proposed research. Further, I confirm that all computer software necessary for conducting the proposed project is available to Dr. Wikstrom and both the Sports Medicine and Neuromuscular Research Laboratories via site licenses and volume purchase agreements held by the Department and/or the University.

Sincerely,

A handwritten signature in black ink, appearing to read "Darin Padua".

Darin Padua, PhD, ATC
Chair, Department of Exercise & Sport Science
University of North Carolina at Chapel Hill



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 N. PIEDRAS STREET
EL PASO, TX 79920-5001

13 November 2018

Dr. Gribble,

This letter is in support of your grant submission "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation". I strongly support your proposal for this study and believe the aims of the proposed study will have an important and profound impact on the treatment of orthopaedic injuries and rehabilitation at military treatment facilities. I am confident in your ability to oversee the guidance of this project and the collaborative research team you compiled to execute this study. I am also confident in MAJ Helton's abilities to conduct this study and by collaborating with you on this project hope his clinical and military experience as a Physical Therapist with the United States Army will be beneficial. As the Soldiers enrolled in this study will be patients undergoing physical rehabilitation, I authorize access to this population for recruitment. I verify sufficient support and resources to collaborate with you on your research.

Sincerely,

SCOTT D. CAROW
Lieutenant Colonel, U.S. Army
Chief, Physical Therapy



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 NORTH PIEDRAS
EL PASO, TX 79920

REPLY TO
ATTENTION OF

October 25, 2016

Dr. Gribble,

This letter is in support of your grant submission "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation". I strongly support your research proposal and believe the aims of this study will have an immediate impact on military personnel and recovery from and prevention of ankle injuries. I am confident in MAJ Scott Carow's abilities to conduct this study and by collaborating with you on this project hope that his clinical and military experience as a Physical Therapist with the United States Army will be beneficial. As the Soldiers enrolled in this study will be patients undergoing physical rehabilitation I authorize access to this population for recruitment.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Houck", is written over the printed name.

KEVIN M. HOUCK
Lieutenant Colonel, US Army
Chief, Physical Therapy

November 3, 2016

Clinical & Rehabilitative Medicine Research Program – Neuromusculoskeletal Injuries Rehabilitation Research Award (W81XWH-17-DMRDP-CRMRP-NMSIRRA)

RE: Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation

Dr. Gribble:

Please accept this endorsement of your grant proposal titled “Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation” being submitted to the CRMRP Neuromusculoskeletal Injuries Rehabilitation Research Award. As the Director of the University of Kentucky Sports Medicine Research Institute, I will ensure that we have the resources (equipment, facilities, personnel) and access necessary to carry out the deliverables outlined in the proposal.

As a collaborator, I endorse the research personnel, aims of the proposed study, and enthusiastically lend my assistance to ensure its productive completion. I strongly support your research proposal and believe the aims of this study will address a significant issue in both civilian and military populations and ultimately remove the short term and long term barriers associated with physical recovery. I am confident in your abilities to conduct this study and by collaborating with you on this project I hope that my clinical experience as an athletic trainer and research experience in the orthopaedic and Department of Defense communities will be beneficial.

Respectfully,



John P. Abt, PhD, ATC

see blue.™

November 12, 2018

Dr. Gribble:

This letter is in support of your grant submission “Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation”. I strongly support your research proposal and believe the aims of this study will have an immediate and profound impact on individuals who sustain ankle sprains in both the military and civilian populations. I am confident in your abilities to conduct this study.

Sincerely,



Katherine Bain, PT, DPT, ATC, MSAT
Graduate Student Researcher
College of Health Science
University of Kentucky

see blue.



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 NORTH PIEDRAS
EL PASO, TX 79920

REPLY TO
ATTENTION OF

October 25, 2016

Dr. Gribble,

This letter is in support of your grant submission "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation". I strongly support your proposal for this study and believe the aims of the proposed study will have an important and profound impact on the treatment of orthopaedic injuries and rehabilitation at military treatment facilities. I am confident in your abilities to oversee the guidance of this project and believe the collaborative research sites and clinical treatment facilities, including military treatment facilities, will provide adequate resources to complete the proposed studies. I am also confident in the abilities of the PI's of study sites to successfully execute the respective project. I hope that my clinical and military experience will be beneficial for this project. I verify sufficient support and resources to collaborate with you on your research.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott D. Carow", is positioned above the printed name.

Scott D. Carow
Major, US Army
Assistant Chief, Physical Therapy



**UCD School of Public Health,
Physiotherapy and Sports Science**

UCD Health Sciences Centre,
University College Dublin,
Belfield, Dublin 4, Ireland

T +353 1 716 6500
F +353 1 716 6501

DATE: 3 NOVEMBER 2016

Dr. Gribble,

This letter is in support of your grant submission “Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation” to the Clinical & Rehabilitative Medicine Research Program – Neuromusculoskeletal Injuries Rehabilitation Research Award. I strongly support your proposal for this study and believe the aims of the proposed study will directly impact the long-term negative outcomes associated with lateral ankle sprains and chronic instability patients. The result of this study may lead to new clinical practice guidelines to rehabilitate orthopaedic injuries at military treatment facilities. I am confident in your abilities to oversee the guidance of this project and I hope that my clinical and research experience will be beneficial for this project. I verify sufficient support and resources to collaborate with you on your research.

Sincerely,

Eamonn Delahunt

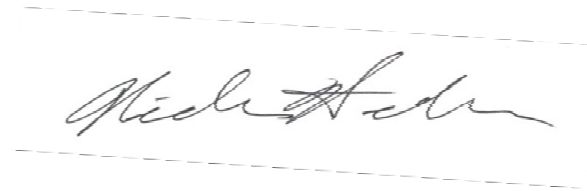
Eamonn Delahunt, PhD, BSc, PDip UTL, SMISCP

November 3, 2016

Dr. Gribble:

This letter is in support of your grant submission “Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation”. I strongly support your research proposal and believe the aims of this study will have an immediate and profound impact on individuals who sustain ankle sprains in both the military and civilian populations. I am confident in your abilities to conduct this study and by collaborating with you on this project believe that my clinical experience as a certified athletic trainer and position as the research coordinator of the Sports Medicine Research Laboratory at the University of Kentucky will be beneficial.

Sincerely,



Nicholas R. Heebner, PhD, ATC
Laboratory Manager, Sports Medicine Research Institute
Assistant Professor
College of Health Science
University of Kentucky



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 N. PIEDRAS STREET
EL PASO, TX 79920-5001

7 November 2018

Dr. Gribble,

This letter is in support of your grant submission "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation". I strongly support your proposal for this study and believe the aims of the proposed study will have an important and profound impact on the treatment of orthopaedic injuries and rehabilitation at military treatment facilities. I am confident in your ability to oversee the guidance of this project and the collaborative research team you compiled to execute this study. I am also confident in the abilities of the PIs of study sites to successfully execute the project. I verify sufficient support and resources to collaborate with you on your research.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary L. Helton", is positioned above the typed name.

GARY L. HELTON
MAJ, U.S. Army
Director, Army Baylor DPT Internship

November 12, 2018

Dr. Gribble:

This letter is in support of your grant “Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation”. I strongly support your research proposal and believe the aims of this study will have an immediate and profound impact on individuals who sustain lateral ankle sprains in both the military and civilian populations. I am confident in your abilities to conduct this study and by collaborating with you on this project I will commit my skills and expertise as a researcher in the Sports Medicine Research Institute at the University of Kentucky to the successful execution of the study and interpretation of the findings.

Sincerely,



Matthew C. Hoch, PhD, ATC
Assistant Professor
Sports Medicine Research Institute
College of Health Science
University of Kentucky

see blue.

November 3, 2016

Clinical & Rehabilitative Medicine Research Program – Neuromusculoskeletal Injuries Rehabilitation Research Award (W81XWH-17-DMRDP-CRMRP-NMSIRRA)

RE: Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation

Dear Dr. Gribble:

Please accept this letter as an indication of my support of your grant proposal “Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation” that is being submitted to the Clinical & Rehabilitative Medicine Research Program – Neuromusculoskeletal Injuries Rehabilitation Research Award. As a co-investigator, I agree with the aims of the study, and I am looking forward to working with you and the research team toward its completion. As a Physical Therapist, I understand the importance of physical recovery from an injury and am confident that I can contribute to this project.

Sincerely,



Nathan F. Johnson, PT, DTP, Ph.D.
Assistant Professor, Department of Rehabilitation Sciences

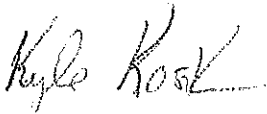
see blue.

November 13, 2018

Dr. Gribble:

This letter is in support of your grant entitled "Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation". I am in strong support of this research proposal because the aims of this grant will have a direct and immediate impact among active military personnel and civilian populations who suffer from the debilitating effects of an ankle sprain. I am confident in your abilities to conduct this study.

Sincerely,



Kyle B. Kosik, PhD, ATC
Postdoctoral Research Scholar
College of Health Science
University of Kentucky

see blue.



**Magnetic Resonance Imaging
& Spectroscopy Center**

31 Whitney Hendrickson Bldg.

MRISC Building

800 Rose Street

Lexington, KY 40506-0098

Phone: (859) 323-1112

Fax: (859) 323-1068

www.mri.uky.edu

November 3, 2016

Dr. Phillip Gribble
Associate Professor
Division of Athletic Training
Department of Rehabilitation Sciences
University of Kentucky
Lexington, KY 40536

Dear Phillip,

I write in strong support of your grant application "Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation" to the Clinical & Rehabilitative Medicine Research Program – Neuromusculoskeletal Injuries Rehabilitation Research Award. The 25-year old Magnetic Resonance Imaging and Spectroscopy Center and I are well positioned to help you use MRI as a diagnostic tool for your research. My responsibilities for your study will be to develop the necessary sequences, maintain quality control, analyze your MRI data, and train your research staff how to properly analyze the MRI data. I will also be available for regular communication with you, your staff, your students, and co-investigators. I look forward to continuing our collaboration.

Sincerely,

David K. Powell, PhD
Assistant Professor
Anatomy and Neurobiology/MRISC
University of Kentucky
Lexington, KY 40536



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 N. PIEDRAS STREET
EL PASO, TX 79920-5001

13 November 2018

Dr. Gribble,

This letter is in support of your grant submission "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation". I strongly support your proposal for this study and believe the aims of the proposed study will have an important and profound impact on the treatment of orthopaedic injuries and rehabilitation at military treatment facilities. I am confident in your ability to oversee the guidance of this project and the collaborative research team you compiled to execute this study. I am also confident in the abilities of the PIs of study sites to successfully execute the project. I verify sufficient support and resources to collaborate with you on your research.

Sincerely,

A handwritten signature in cursive script, reading "Kathryn E Roberts", is positioned above the printed name.

KATHRYN E ROBERTS, MS, ATC, CSCS
Research Coordinator
The Geneva Foundation



UNC
COLLEGE OF
ARTS & SCIENCES

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

DEPARTMENT OF EXERCISE AND SPORT SCIENCE

November 7, 2016

FETZER HALL
CAMPUS BOX 8700
CHAPEL HILL, NC 27599-8700

T 919.962.0017
F 919.962.0489
<http://exss.unc.edu>

Dr. Phillip Gribble
Associate Professor, Director Division of Athletic Training
University of Kentucky, College of Health Services
206c Charles T. Wethington Building, Lexington, KY 40536

Re: DOD Proposal on Treating Lateral Ankle Sprains

Dear Dr. Gribble:

I write to express my enthusiastic support of your DOD proposal entitled "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation" and to our continued collaborations. As you know, I am particularly interested in elucidating the causal mechanisms of and preventing chronic ankle instability, a musculoskeletal condition that is far more prevalent and costly than most people realize. As a result, I believe your proposal is both significant and timely. I am continually impressed with your work and the accomplishments you have been able to achieve in our field. As you know, much of my own research parallels your interests and as a result, I have greatly enjoyed our conversations and more importantly our collaborative efforts over the years.

I have grown particularly excited about this proposal as I believe that our combined work has brought us to a point where we can make a significant impact in the understanding and treatment of lateral ankle sprains. As a result, I enthusiastically write to describe the resources at UNC Chapel Hill that will be available for this proposal. The Sports Medicine and Neuromuscular Research Laboratories are state of the art facilities dedicated to understanding all aspects of human movement and how musculoskeletal injuries negatively impact both movement and quality of life. Within these laboratories, we possess the same major equipment as you do at the University of Kentucky. Further, as a UNC Chapel Hill researcher, I have access to the Biomedical Research Imaging Center (BRIC) on campus. I have already established a working relationship with the BRIC through my current research endeavors and our collaborative efforts during the piloting phase has allowed UNC and UK to develop consistent testing and scanning protocols which will greatly enhance our ability to achieve the proposed aims.

In summary, I look forward to working with you on the proposed investigation and taking a major step forward in understanding the causal mechanisms of CAI.

Sincerely,

Erik A Wikstrom, PhD, ATC
Assistant Professor & Katherine Smith Gunter Fellow
University of North Carolina at Chapel Hill



DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 NORTH PIEDRAS
EL PASO, TX 79920

REPLY TO
ATTENTION OF

October 25, 2016

Dr. Gribble,

This letter is in support of your grant submission "Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation". I strongly support your research proposal and believe the aims of this study will have an immediate impact on military personnel and recovery from and prevention of ankle injuries. I am confident in MAJ Scott Carow's abilities to conduct this study and by collaborating with you on this project hope that his clinical and military experience as a Physical Therapist with the United States Army will be beneficial. As the Soldiers enrolled in this study will be patients undergoing physical rehabilitation I authorize access to this population for recruitment.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Houck", is written over the printed name.

KEVIN M. HOUCK
Lieutenant Colonel, US Army
Chief, Physical Therapy

**Fiscal Year 2016 Investigational New Drug (IND)
or Investigational Device Exemption (IDE)
Documentation Form**

CDMRP Log Number: DM170430

Principal Investigator's (PI's) Name (please print): Phillip Gribble

Title of Application: Addressing neuromuscular deficits for improved outcomes in ankle rehabilitation

I hereby certify that, for the proposed study (select one below):

1. An IND application:

- ☐ Has been submitted and has been accepted by the U.S. Food and Drug Administration (FDA).

IND Number: _____

IND Indication(s): _____

- ☐ Has been submitted to the FDA prior to the grant application submission.

Date of submission: _____

Current status: _____

2. An IDE application:

- ☐ Has been submitted and has been accepted by the FDA.

IDE Number: _____

IDE Indication(s): _____

- ☐ Has been submitted to the FDA prior to the grant application submission.

Date of submission: _____

Current status: _____

3. An IND/IDE has not been submitted.

☐ ☐ An IND/IDE will be submitted within 60 days of award. *Please attach evidence to support that initial preparations are underway including but not limited to a summary of a pre-IND or pre-IDE meeting with the FDA, a pre-IND/pre-IDE meeting request to the FDA, or other communication with the FDA.*

☒ ☐ An IND/IDE is not applicable to the proposed study. *Please attach an explanation and/or documented communication from the FDA or Investigational Review Board of record.*

Signature of PI: **Phillip Gribble** Digitally signed by Phillip Gribble
DN: cn=Phillip Gribble, o=University of Kentucky, ou=Division
of Athletic Training, email=phillip.gribble@uky.edu, c=US
Date: 2016.11.15 09:56:52 -05'00' Date: **11/15/2016**

FDA Applicability

TO: John P Abt, PhD, ATC, FACSM
Associate Professor, University of Kentucky Division of Athletic Training
Director of Sports Medicine Research Institute

FROM: Office of Research Integrity / Chairperson
Medical Institutional Review Board

SUBJECT: IRB assessment of FDA applicability for funding opportunity

DATE: November 11, 2016

On November 11, 2016, the Medical Institutional Review Board (IRB) Executive Chairperson, Terry Malone, EdD, PT, reviewed your proposed activities as outlined in your grant proposals.

The Chairperson determined that the proposals as written do not appear to involve testing of FDA regulated products (i.e., drugs, medical devices, or biologics). There was no indication that data would be collected on or about any standard devices used solely to measure physiologic outcomes.

As such, the proposals would not be under FDA purview and an IND/IDE would not be applicable. Ultimately, significant-risk/nonsignificant risk determinations regarding need for Investigational Device Exemptions (IDE) may only be made by a convened IRB based on a complete research protocol and IRB application.

If you have any questions regarding the IRB Chairperson's determination, or need additional information, please contact the Office of Research Integrity at 859-257-9084.

Cc: Helene Lake-Bullock, PhD, JD, ORI Interim Director

Prepared by: Belinda Smith

J:\Not Human Subjects Research 2016\NOT FDA Determinations\Template FDA letter.doc

see blue.

315 Kinthead Hall | Lexington, KY 40506-0057 | P: 859-257-9428 | F: 859-257-8995 | www.research.uky.edu/ori/

An Equal Opportunity University

Subject: RE: [Non-DoD Source] Re: A-20657.1a, A-20657.1b, and A-20657.1c, Third Administrative Review (Proposal Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)
Date: Tuesday, May 14, 2019 at 4:34:27 PM Eastern Daylight Time
From: Klein, Natalie M CIV USARMY MEDCOM USAMRMC (US)
To: Gribble, Phillip
CC: Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA), Schmearsal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Eaton, Karen M CTR USARMY MEDCOM USAMRMC (USA)

Hi Dr. Gribble,

Brittane left our office, and Karen Eaton (copied) is working with me on the review. I hope to have an update for you soon. Thank you for your patience.

Natalie

Natalie Klein, PhD, CIP
Special Projects Scientist
Human Research Protection Office, Office of Research Protections
US Army Medical Research and Materiel Command
810 Schreider St.
Fort Detrick, Maryland, 21702
Desk 301.619.7804 (DSN 343.7804);
iPhone 240.409.2736 / Fax 301.619.6243
Email: natalie.m.klein.civ@mail.mil

-----Original Message-----

From: Gribble, Phillip [<mailto:phillip.gribble@uky.edu>]
Sent: Tuesday, May 14, 2019 3:28 PM
To: Klein, Natalie M CIV USARMY MEDCOM USAMRMC (US) <natalie.m.klein.civ@mail.mil>
Cc: Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA) <christopher.l.meinberg.civ@mail.mil>; Schmearsal, Larissa A CIV USARMY MEDCOM WBAMC (USA) <larissa.a.schmearsal.civ@mail.mil>
Subject: Re: [Non-DoD Source] Re: A-20657.1a, A-20657.1b, and A-20657.1c, Third Administrative Review (Proposal Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Good afternoon Natalie,

I wanted to follow up from Larissa's email as well as introduce myself. It is my understanding that you may now be handling the HRPO review for our award. I'm hoping everything was in good order on this 3rd Administrative Review and we are anxious to get the project started.

Please let me know if there is anything I can do to assist or if you need anything further.

Thank you,

Phillip

<Caution-

file:///Users/gribble/Library/Containers/com.microsoft.Outlook/Data/Library/Caches/Signatures/signature_1959012791>

Phillip Gribble, PhD, ATC, FNATA

Professor, Director Division of Athletic Training

University of Kentucky

Department of Rehabilitation Sciences, College of Health Sciences

206C Charles T. Wethington Building

Lexington, KY 40536-0200

859-218-0885 < tel:859-218-0885 >

phillip.gribble@uky.edu

On 5/9/19, 11:25 AM, "Schmersal, Larissa A CIV USARMY MEDCOM WBAMC (USA)"

<larissa.a.schmersal.civ@mail.mil> wrote:

CLASSIFICATION: UNCLASSIFIED

Hi, Natalie,

I hope you are doing well!

Dr. Gribble reached out to me today to check in on the status of his HRPO review. I know Brittane is moving on from MPMC, and my understanding was that the updated documents were transferred to you.

Subject: Re: A-20657.1a, .1b, and .1c, Review of Protocol (Proposal Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Thursday, May 23, 2019 at 3:26:26 PM Eastern Daylight Time

From: Gribble, Phillip

To: Eaton, Karen M CTR USARMY MEDCOM USAMRMC (USA)

CC: Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US), kcarter.1@uky.edu, Office of Sponsored Projects Administration, Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA), Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (US), Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (US), Klein, Natalie M CIV USARMY MEDCOM USAMRMC (US), Brown, Joe R., Schmersal, Larissa A CIV USARMY MEDCOM WBAMC (USA)

Attachments: Responses to Recommendations.pdf

Good afternoon Karen,

Please find attached a packet that includes the responses to your queries from the 4th HRPO Administrative Review along with supporting documents. I have addressed all the queries to the best of my ability and have received the necessary approved modifications from the UK IRB.

Please let me know if there are any additional materials or clarifications needed.

I look forward to hearing from you.

Phillip



Phillip Gribble, PhD, ATC, FNATA

Professor, Director Division of Athletic Training

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206C Charles T. Wethington Building

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phillip.gribble@uky.edu

On 5/17/19, 2:35 PM, "Eaton, Karen M CTR USARMY MEDCOM USAMRMC (USA)" <karen.m.eaton.ctr@mail.mil> wrote:

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Review of Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by Phillip Gribble, PhD, University of Kentucky, Lexington, Kentucky, Proposal Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Numbers A-20657.1a (UK site), A-20657.1b (UNC site), and A-20657.1c (WBAMC site)

Dr. Gribble,

The documents and revisions to the protocol per the third administrative HRPO review have been assessed. Below are additional clarifications and requests pertaining to the protocol that require your

attention.

Required Information/Documents.

1. Provide the May 2019 continuing review approval memo issued by the UK IRB.

2. Note that the HRPO can issue a determination on behalf of University College, Dublin as Dr. Delahunt will only be receiving de-identified data. In order for HRPO to issue this determination, one of the following options must be exercised in order to more fully document Dr. Delahunt's role. The options including adding a statement to the UK protocol application that Dr. Delahunt will only be accessing/receiving de-identified data in support of the DoD funded statement of work. This will require review and approval by the UK IRB, after which time, HRPO determination can be issued. If you elect not to modify the UK protocol application, the HRPO can accept a memo from the University College Dublin regarding their role and receipt of de-identified data. Finally, HRPO can review a Material Transfer Agreement that specifies only de-identified data will be shared to University College Dublin.

3. Address if the protocol narrative document has been updated per the recent revisions. Provide the modification application submitted to the IRB for the changes approved on 12 March 2019. It is not clear if this modification approval includes only updates to the consent form or if it includes updates to the protocol as well.

Revisions to be made to the consent form

- Provide documentation that the IRB approved an alteration of consent per 45 CFR 46.116(d), as subjects will not be informed of the randomization procedures in the consent form. Additionally, please provide a point of contact for the UK IRB office in the event HRPO would like to reach out to discuss this issue directly with the IRB.

Please let me know if you have any questions.

Regards,
Karen

Karen M. Eaton, M.S.
Human Subjects Protection Scientist (General Dynamics Health Solutions)
Human Research Protection Office (HRPO)
Office of Research Protections (ORP)
United States Army Medical Research and Materiel Command (USAMRMC) Fort Detrick, Maryland
Phone: 301-619-9268
Fax: 301-619-7803
Karen.m.eaton.ctr@mail.mil

Mailing Address:
Headquarters, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RPH/Karen M. Eaton
810 Schreider Street
Fort Detrick, Maryland 21702-5000

CLASSIFICATION: UNCLASSIFIED

Required Information/Documents.

1. Provide the May 2019 continuing review approval memo issued by the UK IRB.
 - **We have attached the requested memo. The continuation review was actually granted in FEB 19 and extends until FEB 20.**
 - **Based on the required information in #2 below, we completed a modification to the protocol with the UK IRB that reflects the definition of Dr. Delahunt's role. We have attached the approval of this modification from May 23, 2019.**
 - **Copies of the Continuation Review and Modification Review approval memos are provided in this packet.**
2. Note that the HRPO can issue a determination on behalf of University College, Dublin as Dr. Delahunt will only be receiving de-identified data. In order for HRPO to issue this determination, one of the following options must be exercised in order to more fully document Dr. Delahunt's role. The options including adding a statement to the UK protocol application that Dr. Delahunt will only be accessing/receiving de-identified data in support of the DoD funded statement of work. This will require review and approval by the UK IRB, after which time, HRPO determination can be issued. If you elect not to modify the UK protocol application, the HRPO can accept a memo from the University College Dublin regarding their role and receipt of de-identified data. Finally, HRPO can review a Material Transfer Agreement that specifies only de-identified data will be shared to University College Dublin.
 - **We submitted a modification to the previously approved protocol with the UK IRB. Based on their guidance, a definition of Dr. Delahunt's role and the interactions with data were specified in Section 9, Research Description_Resources (Section 9 page 12 of 18; Page 32 of this packet). His role is listed as the Study Consultant.**
 - **The UK IRB has approved the modification with this language included, reflecting the approval of Dr. Delahunt's role. A copy of this updated protocol is provided in the packet.**
3. Address if the protocol narrative document has been updated per the recent revisions. Provide the modification application submitted to the IRB for the changes approved on 12 March 2019. It is not clear if this modification approval includes only updates to the consent form or if it includes updates to the protocol as well.
 - **The protocol narrative document and consent form have been modified only to reflect the changes based on the 3rd and 4th HRPO administrative review requests.**
 - **More specifically, from the 3rd Administrative Review, we have included language specific to that needed to satisfy the components relative to the review at WBAMC IRB. We have communicated with Larissa Schmearsal at WBAMC to verify which revisions were necessary per her review. These revisions were part of the recent continuation review approval granted in FEB 19 (see #1 above).**
 - **From the 4th Administrative review, we have included the specified role of Dr. Delahunt (see #2 above). Additionally, at the request of the UK IRB, we uploaded CITI training completion certificates for non-UK Co-Investigators that had not yet been placed on file. These were all done as one single IRB modification approved on May 23, 2019.**

- **No other modifications were made to the IRB protocol. We have attached the most recent consent form and protocol printed from the UK electronic IRB system. We have discussed the consent form with Jessica Williams in the UK IRB and she has agreed to delay review of the revised consent form until HRPO review is complete and approved.**

Revisions to be made to the consent form

- Provide documentation that the IRB approved an alteration of consent per 45 CFR 46.116(d), as subjects will not be informed of the randomization procedures in the consent form. Additionally, please provide a point of contact for the UK IRB office in the event HRPO would like to reach out to discuss this issue directly with the IRB.

- **I have attached a copy of the email thread leading up to this request and the approval letter received. These took place in MAR 19 as part of a modification review.**
- **The point of contact at the UK IRB office is Jessica Williams (jessica.williams@uky.edu).**



Office of Research Integrity
IRB, RDRC

XP Continuation Review

Approval Ends:
2/6/2020

IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval for Continuation

DATE: 2/7/2019

On 2/7/2019, the Medical Institutional Review Board approved your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

Approval is effective from 2/7/2019 until 2/6/2020 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, the IRB approved consent/assent document(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Review (CR)/Administrative Annual Review (AAR) request which must be completed and submitted to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.



Office of Research Integrity
IRB, RDRC

Modification Review

Approval Ends:
2/6/2020

IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Modification Request

DATE: 5/23/2019

On 5/23/2019, the Medical Institutional Review Board approved your request for modifications in your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

If your modification request necessitated a change in your approved informed consent/assent form(s), the new IRB approved consent/assent form(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]

Note that at Continuation Review, you will be asked to submit a brief summary of any modifications approved by the IRB since initial review or the last continuation review, which may impact subject safety or welfare. Please take this approved modification into consideration when preparing your summary.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

PROTOCOL TYPE

Which IRB

☒ Medical ☐ NonMedical

Protocol Process Type

☐ Exemption
☒ Expedited (Must be risk level 1)
☐ Full

IMPORTANT NOTE: Once you have saved your choices under "Which IRB" and "Protocol Process Type", you will not be able to change your selections. If you select the wrong IRB Type and/or your application is deemed eligible for a different Protocol Process Type, it may be necessary to create a new application.

Please see below for guidance on which selections to make, and/or go to ORI's ["Getting Started"](#) web page. If you still have questions about which IRB or Protocol Process Type to choose, please contact the Office of Research Integrity (ORI) at 859-257-9428 **prior** to saving your selections.

Which IRB

The **Medical IRB** reviews research emanating from the Colleges of Dentistry; Health Sciences; Medicine; Nursing; Pharmacy and Health Sciences; and Public Health.

The **Nonmedical IRB** reviews research originating from the Colleges of Agriculture; Arts & Sciences; Business & Economics; Communications & Information; Design; Education; Engineering; Fine Arts; Law; and Social Work. The Nonmedical IRB does not review studies that involve administration of drugs, testing safety or effectiveness of medical devices, or studies that involve invasive medical procedures, regardless of from what college the application originates.

Which Protocol Process Type

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review;
- by exemption certification;
- by expedited review.

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. For assistance in determining which review process type your IRB application is eligible for, please go to ORI's ["Getting Started"](#) web page.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the [Exemption Categories Tool](#).

EXPEDITED CERTIFICATION

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

- A. Research activities that (1) present no more than [*minimal risk](#) to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and [21 CFR 56.110](#). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. [45 CFR 46.102\(i\)](#)*

Check the appropriate categories that apply to your research project:

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- A. Research on drugs for which an investigational new drug application ([21 CFR Part 312](#)) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- B. Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](#)) is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

*A determination on whether an IDE application is required may be made by the FDA or based on a Non-Significant Risk (NSR) determination by the convened IRB. Unless the study has documentation from FDA indicating that an IDE application is not required, it may not be approved under expedited mechanisms.

** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements- [21 CFR 812.2\(c\)](#)

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP [\[PDF\]](#) for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#) If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- A. Hair and nail clippings in a nondisfiguring manner;
- B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- C. Permanent teeth if routine patient care indicates a need for extraction;
- D. Excreta and external secretions (including sweat);
- E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- F. placenta removed at delivery;
- G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- J. Sputum collected after saline mist nebulization.

☒ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

- A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- B. Weighing or testing sensory acuity;
- C. Magnetic resonance imaging;
- D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☒ 5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101\(b\)\(2\) and \(b\)\(3\)](#). This listing refers only to research that is not exempt.)

PROJECT INFORMATION

Title of Project: (If applicable, use the exact title listed in the grant/contract application). ⓘ

Addressing Neuromuscular Deficits for Improved
Outcomes in Ankle Rehabilitation

Short Title Description

Note: "Short Title" should consist of a couple key words to easily identify your study - these key words (rather than the whole title) will be displayed on the Dashboard in the listing for your study.



Neuromuscular Ankle Rehabilitation

Anticipated Ending Date of Research Project: ⓘ 12/31/2022

Number of human subjects ⓘ 150

Study is/will be open to new subject enrollment or data/specimen collection: ⓘ ☒ Yes ☐ No

PI CONTACT INFORMATION

The Principal Investigator's (PI) contact information is filled in automatically based on who was logged in when the application was created (with LinkBlue ID). If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be the same person listed below.

If you are not the Principal Investigator, do NOT add yourself as study personnel. You may change the PI contact information on an application that is in Researcher edit mode by:

- clicking the "Change Principal Investigator" link below;
- searching for the PI's name using the search feature;
- clicking "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with edit authorization so you can continue editing the application.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to [myUK](#) and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a '[Name Change Form](#)' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the [HR Benefits Office](#) for additional information.

Note: Principal Investigator (PI) role for E-IRB access

The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*). 

[Change Principal Investigator:](#)

First Name: Phillip	Room# & Bldg: 900 South Limestone
Last Name: Gribble	Speed Sort#: 405360200
Middle Name: A	
Department: Health Sciences - Rehabilitati ...	Dept Code: 7N600
PI's Employee/Student ID#: 12060036	Rank:  Associate Professor
PI's Telephone #: 859- 218-0885	Degree: PhD, ATC
PI's e-mail address: phillip.gribble@uky.edu	PI's FAX Number:
PI is R.N. ☐ Yes ☒ No	Trained: Yes
	Date Trained: 4/6/2017

Do you, the PI, have a [significant financial interest](#) related to your responsibilities at the University of Kentucky (that requires disclosure per the [UK administrative regulation 7:2](#))?

☐ Yes ☒ No

RISK LEVEL

Indicate which of the categories listed below accurately describes this protocol

- ☐ (Risk Level 1) Not greater than minimal risk
- ☐ (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individuals subjects
- ☐ (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ☐ (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests [\[45 CFR 46.102\(i\)\]](#)

Download UK's guidance document on assessing the research risk for additional information on risk [\[PDF\]](#) 

SUBJECT DEMOGRAPHICS

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) to

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations

(Please note: The IRB will expect this information to be reported at Continuation Review time):

Enter Numbers Only!		
Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:	0	0
Asian:	4	4
Black/African American:	10	8
Hispanic/Latino:	8	6
Native Hawaiian/Pacific Islander:	0	0
White/Caucasian:	59	51
Other or Unknown:	0	0

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

ADDITIONAL INFORMATION:

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☒ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal

Please visit the [IRB Survival Handbook](#) under the named topic:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults: Link to required [Form](#)

And/Or:

- UKMC Residents or House Officers [see [requirement of GME](#)]

Material

- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☒ Normal Volunteers
- ☒ Military Personnel and/or DoD Civilian Employees
- ☒ Patients
- ☐ Appalachian Population

- Non-English Speaking [see [instructions for recruitment](#) and E-IRB Research Description section on same topic]
- International Citizens [[HTML](#)] (DoD SOP may apply [[PDF](#)])
- Military Personnel and/or DoD Civilian Employees (DoD SOP may apply [[PDF](#)])

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

- ☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

☐ Yes ☒ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: <https://ris.uky.edu/ori/oriforms/formt/Scale.asp>

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

Additional Resources:

- Sample Repository/Registry/Bank Consent ([PDF](#)) ([Word](#))
- [Instructions for Proposed Informed Consent Document](#)
- [Instructions for Proposed Assent Form](#)

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; **DELETE OUTDATED FILES** -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.

Document Types that do NOT get an IRB approval stamp are:

- "Highlighted Changes",
- "Phone Script", and
- "Sponsor's Sample Consent Form".

How to Get the Informed Consent Section Check Mark

1. You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) as a PDF (if open to enrollment).
2. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only check mark the "Stamped Consent Doc(s) Not Needed".
3. After making your selection(s) be sure to scroll to the bottom of this section and **SAVE** your work!



Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☒ Phone Script
- ☒ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☐ Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
Informed Consent/Parental Permission	Form_C_Med_and_HIPAA_v3 SMART.pdf
PhoneScript	Telephone Screening Script_11.7.2018.pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except

for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), **your research activities must fit into one of three regulatory options:**

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk to the subject and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English-* [\[WORD\]](#), *Spanish-* [\[WORD\]](#) The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

Option 1

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

Option 2

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

Option 3

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL

Do you have study personnel who will be assisting with the research?

After selecting 'Yes' or 'No' you must save by hitting the 'Save Study Personnel Information' button. 

☒ Yes ☐ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is being completed to meet the requirements of a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed as such below.
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR, MR) or 'Other Review', and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature, search for applicable personnel first, then click "select" by the listing for the person you want to add as study personnel to your protocol. For each individual selected, be sure to specify responsibility in the project, whether authorized by the principal investigator to obtain informed consent, AND denote who should regularly receive E-IRB notifications.

NOTE: Study personnel are required to receive human research protection (HSP) training before implementing any research procedures (e.g., CITI). For information about mandatory training requirements for study personnel, visit UK's [FAQ's on Mandatory Training web page](#), or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (Jen.Hill@uky.edu) for credit.

Study personnel assisting in research project: 

Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	Removed?	Last Updated	SFI
Abt	John	Co-Investigator	DP	Y	Y	PhD	P	Y	07/31/2018	N	03/09/2018	N
Bain	Katherine	Co-Investigator	SP	Y	N	PT, DPT, ATC, MSAT	P	Y	07/23/2018	N	09/07/2018	N
Beck	Meaghan	Study Coordinator	DP	N	Y	MPA		Y	12/17/2018	N	03/09/2018	N
Cain	Mary	Co-Investigator	SP	Y	N		N	Y	03/03/3000	N	03/15/2019	N
Heebner	Nicholas	Co-Investigator	SP	Y	N	PhD, ATC	P	Y	07/31/2018	N	03/09/2018	N
Helton	Gary	Co-Investigator	SP	Y	N		N	Y	03/03/3000	N	03/15/2019	N
Hoch	Matthew	Co-Investigator	SP	Y	N	PhD	P	Y	08/10/2016	N	05/30/2018	N
Johnson	Nathan	Co-Investigator	SP	Y	N	PhD, PT, DPT	P	Y	05/01/2019	N	03/09/2018	N
Kosik	Kyle	Co-Investigator	SP	Y	N	PhD, ATC	P	Y	08/11/2016	N	03/09/2018	N
Migel	Kimmery	Co-Investigator	SP	Y	N		N	Y	03/03/3000	N	03/15/2019	N
Powell	David	Co-Investigator	SP	Y	N	PhD	P	Y	03/10/2017	N	03/09/2018	N
Roberts	Kathryn	Co-Investigator	SP	Y	N		N	Y	03/03/3000	N	03/15/2019	N
Song	Kyeongtak	Co-Investigator	SP	Y	N		N	Y	03/03/3000	N	03/15/2019	N
Wikstrom	Erik	Co-Investigator	SP	Y	N		N	Y	03/03/3000	N	03/15/2019	N

RESEARCH DESCRIPTION

****!!!!PLEASE READ!!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.

Workaround(s):

- Save your work often to avoid losing data.
- Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

Given the sevenfold increased rate of musculoskeletal injuries in the military and the current rates of Service Members who are medically discharged due to neuromusculoskeletal injuries, there is a clear need to optimize clinical care for these injuries. Clinical prediction rules have long demonstrated the phenomenon that some individuals respond to physical therapy successfully (Responders), while others do not (Non-Responders). For certain injuries, clinicians have abstract characteristics that appear to identify successful Responders to rehabilitation, but a significant gap exists as to what is the underlying mechanism for success in some and failure in others. Patients undergo physical rehabilitation that addresses clinical goals, but given the unacceptable rates of Non-Responders, there is a need to evaluate the standard of care given to determine additions and amplifications needed to create desired long-term success.

Lateral ankle sprains (LASs), the most prevalent neuromusculoskeletal injury in general and physically active populations,¹⁻⁵ are associated with long-term pain, disability and a substantial financial burden.^{6,7} Between 628,000 and 1.01 million LASs are treated annually in US emergency departments, equating to over \$7.5 billion in estimated yearly costs.^{1,4,8} Among military populations, ankle injuries are the most commonly reported injury, representing 13% of the nearly 750,000 musculoskeletal injuries incurred annually, mimicking the prevalence seen in civilian populations.⁹ Neuromusculoskeletal injuries create a substantial manpower time loss in military populations, equating to a \$5.5 billion annual financial burden attributable to treating and returning its warfighters to active duty.¹⁰

Between 50-70% of the people who sustain a LAS, will develop chronic ankle instability (CAI), a condition characterized by ongoing pain, ankle joint instability, injury recurrence, and persistent functional disability.¹¹ Chronicity of symptoms and re-injury has been shown to occur rapidly, with recent work demonstrating the onset of CAI as early as 6-12 months after the initial acute LAS.¹²⁻¹⁶ Further, over 70% of CAI cases have developed early onset post-traumatic ankle joint osteoarthritis (PTOA),¹⁷⁻²⁰ with consequent deteriorations in physical activity and health-related quality of life.²¹⁻²⁴ A smaller percentage of LAS patients, referred to as LAS Copers, breaks the cycle of recurrent injuries and disabilities seen in CAI, exhibiting neuromuscular control and functional levels similar to a population with no history of LAS.^{12,15,25} In the military, there is a shorter service time among those that develop CAI compared to LAS Copers.²⁶ Usual care for ankle instability patients consists of symptom management or activity modification;^{27,28} but given the persistence of CAI and its negative impact on joint and general health, it is clear that the standard of care is inadequate for many.²⁹ Recent systematic reviews^{30,31} suggest that the typical standard of care for LAS may not be comprehensive and robust enough, given the high rate of CAI development and long-term disability seen in the population.

Some researchers have speculated that the root cause for continued pain and disability and loss of function for many individuals who fail to improve is due to central nervous system (CNS) alterations. Recent work by our group has demonstrated deficits in brain white matter structural integrity³², as well as motor excitability outputs^{33,34} in patients with CAI. Additionally, we have observed altered strength³⁵ and movement patterns in the proximal joints of the lower extremity³⁵⁻⁴⁰. We have seen these alterations in structural integrity and motor excitability correlate with functional deficits in CAI patients^{32,33}, which is likely helping to explain the aberrant movement patterns that contribute to instability, altered loading, and potential for long-term consequences seen as decreased physical activity, quality of life and joint health.^{6,7}

One of the more significant consequences of the aberrant patterns associated with CNS alterations is the deterioration of ankle joint cartilage integrity, an early marker of PTOA. Recent work has demonstrated that ankle PTOA is present in young adults with a history of LAS,¹⁸ disputing the notion that ankle PTOA is an age-dependent disorder. The aberrant movement patterns that are present in young CAI patients are likely contributing to this phenomenon by introducing excessive loading to the ankle joint.

While the assumption is that LAS patients will recover without long-term consequence following the rehabilitative standard of care, the high rate of CAI observed in the military and general populations suggests the current standard of care is inadequate. Further, we know that similar aberrant movement patterns and balance deficits are likely to develop 6-12 months following an acute LAS, giving an indication that the CNS changes may be developing rapidly after the initial injury. However, to date, no previous studies have introduced interventions to address the deficits from the time of acute LAS through a one-year follow-up, representing a time period when CAI and the subsequent disability develops.

The long-term negative outcomes associated with LAS patients are emerging,^{6,7} and we know that even with standard of care treatments, LAS patients can develop symptoms of CAI 6-12 months after acute injury.^{12,14-16,41} Recent work by our group demonstrates successful outcomes in CAI patients when sensorimotor techniques are utilized.^{42,43} However, there has yet to be a comprehensive study that employs sensorimotor focused rehabilitation for LAS patients in a prospective study design to diminish the suspected CNS deficits that develop, resulting in better clinical outcomes and ankle joint health and reductions in CAI development. Our preliminary data suggest lingering CNS alterations in CAI patients, which an innovative sensorimotor ankle rehabilitation protocol can address. This rehabilitative approach would optimize the short- and long-term physical performance and resiliency for LAS patients, leading to more LAS Copers and fewer CAI patients.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

Therefore, the purpose of this study is to demonstrate the effectiveness of an innovative sensorimotor rehabilitation protocol compared to a standard of care protocol at improving clinical and novel outcomes, which will associate with lower rates of LAS re-injury and development of CAI during a 12-month follow-up period. The proposed project will focus on three specific aims and is aligned with FY17-18 JPC-8/CRM RP NMSIRRA Focus Areas:

- Lack of short- and long-term evidence for existing support and reintegration strategies, and a need for new evidence-based support and reintegration strategies
- Limited ability to predict, prevent, and mitigate development of secondary health deficits following neuromusculoskeletal injury
- Limited understanding of the management of patient rehabilitation strategies throughout the rehabilitation process following neuromusculoskeletal injury
- Lack of validated metrics that effectively assess initial presentation, rehabilitation, and reintegration following neuromusculoskeletal injury

and Identified Areas of Emphasis:

- Validate optimal dose, timing, frequency, duration, and setting of rehabilitation techniques for Service members with neuromusculoskeletal injuries
- Develop and evaluate metrics to assess initial presentation, rehabilitation, and reintegration of Service members with neuromusculoskeletal injuries
- Identify biomechanical markers of the development and/or progression of secondary musculoskeletal deficits (e.g., osteoarthritis, low back pain, etc.) in Service members with neuromusculoskeletal injuries
- Develop and evaluate innovative rehabilitation techniques for Service members with neuromusculoskeletal injuries
- Develop and evaluate new short- and long-term evidence-based support and reintegration interventions relevant to Service members with neuromusculoskeletal injuries

The purpose of this project is to compare a novel sensorimotor ankle rehabilitation training (SMART) protocol for LAS against a standard of care (SOC) protocol to determine if it is more successful at producing successful one-year outcomes and lower rates of re-injury and improved health. This will address the identified needs for evidence-support and reintegration strategies to improve understanding of the management of patient rehabilitation strategies throughout the rehabilitation process following neuromusculoskeletal injury. The project will validate an innovative rehabilitation approach while providing metrics of success using a variety of clinical and innovative markers. Specifically, in Aims 1 and 2, we will use common clinical outcomes and innovative metrics of central nervous system function to validate the short-term success of the rehabilitation. We will replicate these measures along with measures of re-injury and disability along with MRI of the ankle to indicate ankle joint health at a 12-month follow-up to provide evidence for long-term success. Finally, in our third aim, we will use our outcomes to develop mechanistic models to explain our anticipated successes from the novel sensorimotor rehabilitation outcomes.

Specific Aim #1: Determine if SMART improves clinical outcomes (patient-reported function and quality of life, LAS re-injury rates, postural control, ankle ROM) and ankle joint integrity (articular cartilage turnover) in LAS patients.

Hypothesis 1.1: Compared to the SOC, LAS patients participating in the SMART program will have improved patient-reported function and quality of life, postural control, and ankle ROM at the time of return to full activity.

Hypothesis 1.2: Compared to the SOC, LAS patients participating in the SMART program will have improved patient-reported function and quality of life, postural control, ankle ROM, and lower LAS re-injury rates at the 6-month follow-up.

Hypothesis 1.3: Compared to the SOC, LAS patients participating in the SMART program will have improved patient-reported function and quality of life, postural control, ankle ROM, lower LAS re-injury rates, and less ankle joint cartilage turnover at the 12-month follow-up.

Specific Aim #2: Determine if SMART improves innovative measures of central nervous system function (corticospinal excitability and brain white matter integrity) in LAS patients.

Hypothesis 2.1: Compared to the SOC, LAS patients participating in the SMART program will have improved central nervous system function at the time of return to activity, and at the 6-month and 12-month follow-ups.

Specific Aim #3: Delineate the association between explanatory mechanistic measures (corticospinal excitability and brain white matter integrity) and the hypothesized improvements in clinical and ankle joint integrity in LAS patients receiving SMART.

Hypothesis 3.1: Improved mechanistic measures in these innovative outcomes will help explain the success from SMART on the clinical outcomes and ankle joint integrity at the 12-month follow-up.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is

helpful to IRB members.)

Community-Based Participatory Research: If you are conducting [community-based participatory research \(CBPR\)](#), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance [\[PDF\]](#) or the UK Research Registry Guidance [\[PDF\]](#)

Using a double-blinded, randomized control trial design, we will compare clinical and innovative outcome measures at three time points between cohorts of acute LAS patients that receive a standard of care (SOC) rehabilitation compared to an innovative sensorimotor ankle rehabilitation training (SMART) program to determine if the SMART can reduce the rate of re-injury and the development of CAI during the 12 months following the acute LAS (Figure 7). Using a 2 (Intervention) x 2 (Group) by 3 (Time) mixed model statistical design, we will make comparisons of clinical and innovative outcomes between intervention groups (SMART vs SOC) and those LAS patients that develop CAI and those that do not (LAS Coper) during a 12-month follow-up period after completing the assigned intervention for their acute LAS.

Within one week of completing the designated rehabilitation program and returning to unrestricted physical activity, patients will complete assessments of clinical outcomes (patient-reported outcomes, balance and ROM). Additionally, measures of CNS structural integrity and function and ankle joint cartilage turnover will be assessed. These measures will be repeated at approximately 6 and 12 months after the initial assessment. At the 12-month follow-up, patients will be dichotomized into either a CAI or LAS Coper category based on if there was successful return to physical activity without lingering pain and disability or re-injury.

Interested subjects will contact a member of the research team to complete a telephone screening to determine eligibility to avoid any unneeded screening visits. Subjects eligible will then complete informed consent.

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

Patients will be between the ages of 18-44 and are initiating rehabilitation for a first time acute grade I, II, or III LAS that they have sustained within 72 hours of study enrollment. Patients will be enrolled from orthopaedic departments, emergency departments, and outpatient rehabilitation clinics at UK and UNC, as well as Fort Bliss/William Beaumont Army Medical Center. Participants will be diagnosed by a physician, medic, athletic trainer, physical therapist, or other providing medical coverage in operational environments as having sustained a LAS and referred to the study personnel at each site to initiate rehabilitation. After confirming the diagnosis of LAS by study personnel and obtaining voluntary written consent, the study site coordinator will randomly assign the participant into one of two intervention groups described below to begin supervised rehabilitation with a member of the study personnel (physical therapist or athletic trainer). Patients will consent to receiving the assigned treatment as well as participation in assessment of the outcomes at the time they are released from supervised rehabilitation back to full physical activity, and 6 months and 12 months after this return to activity. Severity of LAS (Grade I, II, or III) and length of rehabilitation will be noted and used as a covariate in the statistical analysis.

The study investigators have previously completed separate RCTs at their home institutions involving participants with ankle instability (see preliminary data). Collectively, our research team has amassed data on more than 700 ankle instability participants. This demonstrates adequate access to the targeted patient population for this proposed project and extensive experience in key areas of

clinical trial management, including multi-site recruitment, retention, blinded assessment and analysis techniques that have positioned these new investigators with the requisite essential skills to conduct this multi-site RCT. The university settings represent flagship state institutions with large medical centers and >30,000 individuals in each of these university community. Along with Fort Bliss/William Beaumont Army Medical Center as military clinics and military treatment facilities with a large military population available, the recruitment needed for this study will be easily attained.

Sample size

To the authors' knowledge, no published literature exists combining our proposed dependent variables and interventions for our targeted population. Therefore, we have estimated our sample size based on previously published work related to the study design and selected outcomes. 12-15, 18, 32-34, 49-52, 59, 68, 76, 90 In order to observe group differences between the CAI and LAS Coper groups we would have first utilized minimally clinically important difference (MCID) in the outcomes. However, as MCID have not been established for our selected outcomes, we will utilize sample sizes that mimic that of the largest of the sample sizes from the previously published literature in this area, which was 82 LAS patients.¹⁴ Allowing for an average attrition rate across the sites of up to 45%, we will enroll 150 LAS patients, recruited equally (50 per site) at each site.

Consented LAS patients will be assigned randomly to one of two intervention groups, a standard of care (SOC) or a sensorimotor ankle rehabilitation training (SMART) protocol. Balanced group membership with random assignment will be achieved by counterbalancing. Upon consenting, group membership will be revealed by opening a sealed envelope with group assignment enclosed.

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Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's [IRB Survival Handbook web page](#) and the PI Guide to Identification and Recruitment of Human Subjects for Research [\[PDF\]](#).

For UK and UNC

Men and women between the ages of 18 and 44 years, representative of the racial and ethnic makeup of greater Lexington or Chapel Hill areas will be recruited through general advertisements and word of mouth. Health care facilities on both campuses will be given approved research flyers to distribute to patients with identified acute lateral ankle sprains. Additionally, the University of Kentucky Center for Clinical and Translational Science and the University of North Carolina Clinical and Translational Research Center have extensive marketing and recruitment programs. Recruitment support includes volunteer databases (allowing investigators to contact eligible subjects), recruitment specialists, online resources, and strategic placement of flyer and other recruitment material around campus. Interested subjects will contact a member of the research team to schedule a telephone screening to determine eligibility. No identifiable information will be collected during this contact. Eligible patients will then be scheduled for testing.

For William Beaumont Army Medical Center (WBAMC)

Men and women between the ages of 18 and 44 years, representative of the racial and ethnic makeup of El Paso, TX. The study will recruit any patients seen at WBAMC, including military and civilian populations. Participation in this study will be announced to the military soldiers and civilian patients via flyers posted throughout the main WBAMC and physical therapy facility. Additionally, word of mouth announcements of the study opportunity will be provided by the brigade physical therapists on post at Fort Bliss. Interested subjects will contact a member of the research team to schedule a telephone screening to determine eligibility. No identifiable information will be collected during this contact. Eligible patients will then be scheduled for testing.

At all sites, interested respondents will contact the study site's research coordinator who then holds a no obligation conversation about the study details and risks. The research coordinator will clearly explain the research design, procedures, and goals. If interested, the potential participant will be screened over the telephone to avoid any unneeded screening visits. Each participant must meet inclusion/exclusion criteria based on medical health history, medications, and lifestyle and exercise habits. Qualifying participants will then come in for a face-to-face interview. The research coordinator will review and have each participant sign the consent form. Established procedures allow us to develop relationships with each participant, while guaranteeing a fully informed willingness to volunteer. The investigators collectively have conducted similar studies with civilians and Conventional and Special Operations Forces for the last decade and have a record of recruiting over 4000 participants for laboratory-based clinical trials and clinical studies. Using similar recruitment strategies, the investigators do not anticipate recruitment difficulties and are cognizant to the special consideration required of recruiting military personnel.

The principal investigator will monitor confidentiality and data monthly to ensure accuracy and recruitment of subjects. Weekly meetings, with the co-investigators, will be held to verify compliance and testing procedures. These meetings will monitor recruitment, retention, data, adverse events, and breaches in confidentiality.

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Advertising: Specify if any advertising will be performed. If yes, please see ["IRB Application Instructions - Advertisements"](#) for

instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's [IRB Survival Handbook](#) web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [\[PDF\]](#). If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by [UK Public Relations \(PR\)](#) to ensure compliance with UK graphic standards, and equal opportunity language. [i](#)

Participation in this study will be announced to patients via flyers posted throughout WBAMC and UK and UNC HealthCare facilities.

Attachments

Attach Type	File Name
Advertising	Research Flyer_Approved.pdf
Advertising	Recruitment Slide_DOD_UNC.pdf
Advertising	Research Flyer Template_WBAMC.pdf

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [\[PDF\]](#) for guidance), prisoners (see Summary of Prisoner Regulations [\[PDF\]](#) for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [\[PDF\]](#) for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals

If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [\[PDF\]](#).

Informed Consent for Research Involving Non-English Speaking Subjects

If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see [IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture](#).

Research Repositories

If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [\[PDF\]](#)

Interested subjects will contact a member of the research team to complete a telephone screening to determine eligibility to avoid any unneeded screening visits.

All subjects will first consent to participation and then verify no change in eligibility status since the telephone screening process. The informed consent interview will be administered by a member of the research team. The subject will be provided the opportunity to ask any questions related to the research study and procedures prior to signing the informed consent form. The informed consent process will be completed outside the Chain of Command (Officers, Enlisted, Non-Commissioned Officers).

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Interventions: SMART vs SOC

Enrolled participants will be randomly assigned to either a standard of care (SOC) or a novel rehabilitation protocol, Sensorimotor Ankle Rehabilitation Training (SMART). The SMART protocol will be used to improve clinical and central nervous system (CNS) outcomes in LAS patients beyond what is achieved in the typical SOC interventions. SMART will incorporate novel sensorimotor tasks with elements of SOC to achieve more robust improvement goals, which we believe will associate with a lower incidence of repeated ankle instability and subsequent re-injury rate during a 12-month follow-up period.

The SOC protocol will include restoration of ankle joint range of motion, strength and functional movement. This has been developed in part from the protocols currently utilized at Fort Bliss/William Beaumont Army Medical Center, under the direction of MAJ Scott Carrow. The SMART protocol will utilize the elements of the SOC, and will also include "Sensorimotor Improvements" and other specific additions that will focus on sensory inputs, motor outputs, and integration of the sensory and motor pathways. The SMART protocol additions were created from the expertise of our research team, which includes members of the Executive Committee of the International Ankle Consortium, along with contemporary theory and recent published evidence and recommendations.^{30,31,42,43,61,62} This includes techniques such as plantar cutaneous massage to stimulate sensory inputs^{42,43}, ankle joint mobilizations to stimulate sensory inputs and improve ankle range of motion^{42,43}, gluteal muscle strengthening to target under-utilized motor pathways that have been shown to have deficits in ankle instability patients³⁵, and finally an advanced progression protocol based on an individual's movement proficiency which was designed to and does improve integration of sensory and motor pathways^{42,43,61}. The advanced progression protocol will also be used because not all patients progress at the same pace in clinical practice. This protocol is based on milestone achievements (e.g. completing a given level of difficulty without movement errors) rather than a standardized timeline of progression (e.g. complete 10 repetitions and advance).³¹

The intervention is divided into three phases: 1) Initial Management, 2) Post-acute, and 3) Return to Function/Activity. In the pages

that follow, we provide an overview of the clinical goals and interventions that will be used to meet those goals specific to the SOC and SMART protocols in each of these phases. These will include a mixture of supervised intervention sessions in our designated facilities at each site, as well as prescribed intervention tasks to be performed at home.⁶² Participants will be given exercise logs to record their home progressions. Patients must complete at least 80% of supervised and unsupervised sessions to remain in the study.

Members of our research personnel will be conducting the SMART and SOC protocols at our testing facilities. These personnel will be either licensed physical therapists and/or athletic trainers. The participants will be blinded to group membership, informed that the study is intended to examine the outcomes of intervention, but will not be informed of the alternative intervention group constitution. The site PI at each site, blinded to intervention group membership, will determine completion and readiness to return to activity/terminate rehabilitation. Therefore, this will be a double-blinded, randomized controlled trial. The protocols are presented below in Tables 1-3, with major differences/additions in the SMART protocol relative to the SOC highlighted in gray in the tables.

Measures and Outcomes

Within this mixed model with prospective cohort creation, we will be able to demonstrate that our SMART protocol reduces the prevalence of clinical and innovative outcomes associated with CAI and long-term disability following LAS. The measurement tools are as follows:

Patient Reported Outcomes

Self-reported Ankle Function and Disability

Self-reported ankle region function and disability of the ankle will be assessed using three validated instruments, as recommended by the International Ankle Consortium.^{11,44,63} the Ankle Instability Instrument⁶⁴, the Identification of Functional Ankle Instability (IdFAI)⁶⁵ and Foot and Ankle Ability Measure (FAAM)⁶⁶

Quality of Life, Physical Activity and Pain

We will assess quality of life using the Short Form 8 physical (SF8P) and mental (SF8M) component instruments, and physical activity using the Tegner scale. Self-reported pain in the ankle will be assessed from questions embedded within the Cumberland Ankle Instability Tool (CAIT) and overall self-reported body pain will be assessed through a visual analog scale.

Ankle Re-injury Rates

At the 6 and 12-month follow-ups, participants will be asked to report any new LAS incidents to the same previously injured ankle. LAS injury will be defined as an acute traumatic injury to the lateral ligament complex of the ankle joint as a result of excessive inversion of the rear foot or a combined plantar flexion and adduction of the foot, resulting in some initial deficits of function and disability.⁶ Any LAS and/or episodes of giving way to the opposite limb during these time periods will also be recorded for future analysis.

Dynamic Balance

Dynamic balance will be assessed using the Star Excursion Balance Test (SEBT).⁶⁷ The SEBT requires the patient to remain balanced on a testing limb at the end of a measuring tape secured to the floor while reaching in different directions with the opposite limb in an effort to make a maximum reach, tap on the ground with the toes, and return back to the start position without compromising the base of support. The reach distances are normalized to the participant's leg length, measured from the anterior superior iliac spine to the base of the medial malleolus of the tibia, and reported as a percentage score.⁶⁷ Our research team has extensive experience with this measurement applied to CAI populations, and it has strong interrater reliability with utility for multi-site application.^{12,37,48,67-71} Based on work by the research team, we will utilize three of the reaching directions (Anterior, Posteromedial, and Posterolateral), using the normalized reach distances.⁶⁷ Dr. Gribble's work has established guidelines, which are now internationally adopted for administering the SEBT⁶⁷ and which have established strong multi-site interrater reliability⁷⁰, giving us confidence that this outcome may be used reliably to collect dynamic postural control data across all sites.

Range of Motion

The weight-bearing lunge test (WBLT) is a valid and reliable clinical test of ankle dorsiflexion ROM.^{72,73} The test will be conducted bilaterally in accordance with previously utilized procedures.^{72,73} A tape measure will be fixed to the floor, perpendicular to a wall. The participant will be asked to face the wall, placing the hallux and heel of test limb in line on the tape measure. The participant will be asked to lunge forward, keeping the foot flat against the ground, and touch the anterior aspect of the knee to the wall. The participant may place their hands on the wall and non-test limb on the floor for support. If the participant successfully touches their knee to the wall, the distance from the hallux to the wall is recorded in centimeters. The goal of the test is to contact the anterior knee to the wall with the hallux at the furthest distance possible, indicating a greater degree of dorsiflexion ROM. Up to five trials can be utilized to determine maximum performance. Differences in WBLT scores between injured and uninjured limb will indicate the magnitude of dorsiflexion ROM deficit.

Central Nervous System Activation

Central nervous system activation will be assessed at the corticospinal level using transcranial magnetic stimulation and spinal reflex pathway levels using H-reflex testing.

Transcranial Magnetic Stimulation (TMS)

Patients that meet the inclusion for TMS as outlined in Protection of Human Subjects (section 1) will participate in TMS testing of the fibularis longus muscle. Methods will be consistent with those previously implemented by the PI in participants with CAI.⁴⁸⁻⁵¹ A Magstim 200 (Magstim Company, Wales, UK) will be used to produce a magnetic stimulus (max 2.0 Tesla) over the motor cortex contralateral to the test limb. Testing will be performed over the area generating the greatest motor evoked potential (MEP) while participants perform 20% ankle eversion contractions in an isokinetic dynamometer. Active motor threshold (AMT) will be determined

as the lowest stimulator intensity required to elicit an MEP peak-to-peak amplitude 100 μ V or greater in at least four of 8 trials. A higher AMT indicates decreased excitability, as a greater stimulus intensity is required to elicit an MEP of at least 100 μ V in at least 4 of 8 trials. Eight stimuli will be delivered at 120%, 130%, and 140% of AMT, and peak-to-peak MEP amplitudes will be recorded for each trial. The cortical silent period (CSP) will be measured as the distance from the end of the MEP to a return of the mean EMG signal plus two times the standard deviation of the baseline (pre-stimulus) EMG signal.⁷⁴ A longer CSP indicates a greater corticospinal inhibition within the fibularis longus.

Spinal reflex testing

Patients that meet the inclusion for spinal reflex testing as outlined in Protection of Human Subjects (section 1) will participate in spinal reflex testing of the fibularis longus muscle. Methods will be consistent with those used previously by the PI in CAI participants.^{48,49,51} While lying supine, a stimulating electrode will be positioned over the sciatic nerve in the popliteal space. Peak-to-peak Hoffmann reflexes (H-reflex) will be measured and the stimulus intensity increased by increments of two volts until a maximal H-reflex is observed. Three H-reflexes will be recorded, averaged, and normalized to the maximal M-response, representing the ratio of the motor neuron pool reflexively activated to the amount of the motor neuron pool available (H:M ratio). Maximal M-responses will be determined following identification of the H-reflex by continuing to increase the stimulus intensity until a maximal M-wave amplitude is elicited. Higher H-reflex values and H:M ratios indicate greater spinal reflexive excitability.

White Matter (WM) Microstructure

WM microstructure will be assessed in the superior cerebellar peduncle and corticospinal tracts (Figure 8). DTI data will be collected on 3-Tesla Siemens TIM scanners with a 32-channel head coil at each testing site using previously reported methods by Dr. Johnson.^{52,54} Pre-processing and analysis of the FA data will follow a series of steps previously described in his work.^{52,54} Briefly, DTI data will be preprocessed and analyzed using the Functional MRI of the Brain (FMRIB) software library (FSL v5.0.9). Each diffusion-weighted volume will be corrected for motion and residual eddy current distortion using a 12-parameter affine alignment to the corresponding b0 image, via FMRIB's Linear Image Registration Tool. Brain masks will then be generated from each b0 image using FMRIB's brain extraction tool (BET v2.1) to exclude non-brain voxels from all subsequent processing. Next, FMRIB's Diffusion Toolbox (FDT v2.0) will be used to fit the diffusion tensor and calculate eigenvalues for fractional anisotropy (FA). Registration of FA images into MNI152 space will follow a series of procedures described in detail in our previous work.^{52,54} All MNI-transformed FA images will be averaged to create a mean FA image used to generate a common WM tract skeleton. An FA value of 0.2 will be used to threshold the skeleton in order to minimize partial voluming effects after warping across subjects. Next, each participant's spatially normalized FA image will be projected onto the FA skeleton in order to account for residual misalignments between participants after the initial nonlinear registration. A region of interest approach will be implemented to extract FA values from the superior cerebellar peduncle and corticospinal tract systems. The Johns Hopkins University ICBM-DTI 81 WM labels and WM tractography atlases will be used to isolate each tract. The FA values range from 0.0-1.0, indicating if the structures of the tract are more isotropic or anisotropic. Values closer to 0 indicate reduced density, and therefore more diffusion of water in the neural tracts, which associates with a loss of structural integrity (Figure 9).

Ankle Joint Cartilage Turnover

T1rho MRI Relaxation Time Analysis

The early progression to osteoarthritis following injury is marked by depletion of proteoglycans within the cartilage, an increase in cartilage water content, and disruption of collagen fibril network.^{75,76} Cartilage T1rho MRI relaxation times are sensitive to early changes in proteoglycan content of the cartilage.^{77,78} There is a strong association between longer T1rho relaxation times and altered physical properties of cartilage tissue,⁷⁹ as well as proteoglycan loss.⁸⁰⁻⁸³ T1rho will be collected on Siemens TIM Trio 3T scanners at each site using a 4-channel Siemens large flex coil to quantify changes in the proteoglycan density of the cartilage matrix.^{84,85} We will use a T1rho prepared 3D FLASH sequence to estimate T1rho. In this sequence, a 500 Hz spin lock power is used. Five different spin lock durations (TSL) will be used: TSL=40, 30, 20, 10, 0 ms. T1rho can then be obtained via the following equation: $S(TSL) = S0 \exp(-TSL/T1rho)$. For the above equation S(TSL) is signal, TSL is the length of the spin-lock time, S0exp is a constant, and T1rho is the T1 relaxation time in the rotating frame. Estimation of T1rho relaxation times is performed using a modified version of the T1rho MATLAB-based analysis.

Cartilage Segmentation for Post-Processing

Talar cartilage will be manually segmented using anatomical images from a Proton Density Space (PD space) scanning sequence (ITK-Snap Software, GNU General Public License). All T1rho images of the same structures will be converted from the time dimension into three-dimensional images using ImageJ Software (National Institutes of Health). All three-dimensional T1rho data will be processed using custom-made Matlab code (Mathworks, Inc., Natick, MA, USA) to determine voxel-by-voxel relaxation times. T1rho data will be overlaid onto the anatomical PD space image to determine volumetric and T1rho outcomes for specific areas of the talus. T1rho relaxation time data from the talus will be divided into anterior, middle and posterior sections for analysis (Figure 5).

Statistical Analysis

Specific Aim #1: Determine if SMART improves clinical outcomes (patient-reported function and quality of life, LAS re-injury rates, postural control, ankle ROM) and ankle joint integrity (articular cartilage turnover) in LAS patients.

Specific Aim #2: Determine if SMART improves innovative measures of central nervous system function (corticospinal excitability and brain white matter integrity) in LAS patients.

The primary comparison we will make in these two aims is how does the SMART improve short-term and long-term clinical outcomes, ankle joint integrity CNS function relative to the SOC. This means we will compare those Intervention groups at each Time point.

Additionally, using a prospective cohort design will be able to dichotomize all participants into either the CAI or LAS Coper Group at the end of the 12-month follow-up, based on the re-injury rates and ankle-specific disability questionnaires. This will allow us to track these subgroups during all three time points to examine how the assigned intervention influenced their development of long-term disability from the beginning to the end of the study. Therefore, for each dependent variable in these specific aims, we will employ a three-way, mixed model ANOVA model (Intervention by Time by Group). In the event of statistically significant interactions, we will employ Tukey's post hoc testing. Statistical significance will be set at $P < 0.05$. Multiple covariates such as age, gender, body mass,

physical activity and severity of ankle injury will be considered in these models. Statistical significance will be set at $P < 0.05$ for all analyses.

Specific Aim #3: Delineate the association between explanatory mechanistic measures (corticospinal excitability and brain white matter integrity) and the hypothesized improvements in clinical and ankle joint integrity in LAS patients receiving SMART. To determine the strength of associations between the clinical and innovative measures, we will employ Pearson Product Moment correlations. The following criteria will be used to interpret correlation coefficients (r): 0.00-0.29 = negligible correlation, 0.30-0.49 = low correlation, 0.50-0.69 = moderate correlation, 0.70-0.89 = high correlation, 0.90-1.00 = very high correlation.⁸⁶ To determine differences in correlation coefficients between the CAI and LAS Coper groups, Fisher's r -to- z transformations will be employed.

Attachments

Attach Type	File Name
ResearchProcedures	Pages from ProjectNarrative and Attachment 12.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

All data and questionnaires will be stored and managed in the University of Kentucky's Research Electronic Data Capture (REDCap), the secure, web-based application designed exclusively to support data capture for research studies. Data will be collected in the native programs, as appropriate, and exported to REDCap.

Attachments

Attach Type	File Name
DataCollection	Data Collection Forms.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see [FDA Guidance](#)). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see [IRB Application Instructions - Off-Site Research](#) web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

Facilities and Resources

Sports Medicine Research Institute

The Sports Medicine Research Institute (SMRI) is a 9000 square foot state-of-the-art facility located in the University of Kentucky's Nutter Training Facility and comprised of a research laboratory, academic/administrative offices, and conferencing space. It is a multidisciplinary research facility dedicated to injury prevention, performance, treatment, and rehabilitation, specializing in musculoskeletal, neurobehavioral, and physiological/metabolic health. The SMRI is supported by a team consisting of thirteen core faculty, staff, and graduate students, and 44 affiliated faculty across the University.

Laboratory Facility

The SMRI is outfitted with biomechanical, physiological, musculoskeletal, and neurocognitive equipment. The biomechanics laboratory includes a 14 camera 3D motion analysis system, dual force plate system, multi-axial and virtual reality stability device, accelerometers, and inertial measurement unit system. The exercise physiology laboratory includes desktop and portable metabolic units, electromagnetic cycle ergometer, multiple treadmills, and wearable technology. The neurobehavioral laboratory includes visual acuity hardware/software, visual motor and neurocognitive rehabilitation and sports training device, and neurocognitive software. The musculoskeletal laboratory includes isokinetic dynamometry, handheld dynamometer, therapeutic exercise equipment, and diagnostic

ultrasound. SMRI's dedicated lab space is connected to the UK Athletic Training Facility. The SMRI is located within the athletics facilities portion of campus. Within the same building as the SMRI are the coaches and team meeting rooms, athletic training room, nutrition room, and sports performance training facility for track and field, baseball, swimming and diving, golf, and tennis. The SMRI is within five to fifteen-minutes walking distance from all UK Athletic facilities on campus including, football, basketball, soccer, and softball. The SMRI's proximity and integration into athletics provides easy access to the student athletes, coaches and administrators on campus. The SMRI currently assists on an as-needed basis for rehabilitation, injury, and performance consultations for our athletic teams and student athletes on campus. This relationship with the individual teams and their coaching and medical staff will be a significant aid in facilitating recruitment and retention of research subjects for this proposed project.

Clinical

The SMRI is outfitted with two clinical examination rooms for physicians to evaluate patients as part of their regular clinical practice and research enrollment. The SMRI also has sufficient space and therapeutic exercise equipment for physical therapy or other rehabilitation services.

Computer

Multiple computers are available for data collection, processing and analysis, with data redundancy completed by peripherals and the internal server/network for the SMRI. The computers are latest generation Intel quad core i7 processor, with a minimum of 8GB RAM and 256GB SSD. Systems are configured with Windows Pro OS (7 or 10) and various Office, statistics, and programming software. All graduate students are provided workstations within the laboratory. All personnel are provided with full support of computers and information technology to enhance productivity.

Offices

Dr. Gribble has a 100-square foot office in the College of Health Sciences, within close proximity to SMRI. His office is equipped with a dedicated telephone line, personal computer, printer and filing cabinets to ensure confidentiality of records. Dr. Gribble also has a dedicate workspace in SMRI. Drs. Abt and Heebner have 150-square foot offices at SMRI that are fully equipped and conducive to team meetings. The research coordinator's office is adjacent to Dr. Abt's office. SMRI is staffed with an administrative staff support person who provides phone coverage and administrative support during regular business hours. When not on-site together, the investigative team can meet via Zoom teleconferencing in any UK investigator office or in the SMRI state-of-the-art conference room.

Video-Teleconferencing

Each faculty has access to Zoom video conferencing and web conferencing service. This technology is widely used by UK investigators and allows for immediate and scheduled communication with unlimited participants across multiple platforms. Zoom unifies cloud video conferencing, simple online meetings, group messaging, and a software-defined conference room solution into one easy-to-use platform. Security features include work email single sign-on, Secure Socket Layer encryption, AES 128-bits encryption, HTTPS access, role-based access control, and admin feature controls. Zoom will be used by the investigators for all video teleconference/teleconference meetings between existing investigators and development of new collaborations.

Other Resources:

Institutional Faculty Resources. As a University of Kentucky faculty member, the PI and his co-investigators have access to robust research-support services, including multiple core facilities, shared resources, and outstanding clinical research expertise. The services most integral to this project include:

REDCap Project and REDCap Survey. UK is a member of the Research Electronic Data Capture (REDCap) Consortium, a coalition of institutions that supports a secure web application designed to support data capture for research studies. The application allows users to build and manage online surveys and databases quickly and securely. The core supports REDCap Project and REDCap Survey by providing training and design support to CCTS investigators. REDCap Project allows researchers to easily collect data for research studies ranging from simple laboratory-based studies with limited data collection and participants to complex multi-site clinical trials with multiple encounters per participant. Data collection forms and surveys are easy to create and modify and are available through a simple web-based interface that provides strong security and audit trails. Authorized users can download data collection forms and surveys into several formats for further analysis. The UK REDCap instance, launched in 2009, has over 2,000 production projects and over 2,000 users.

Participant Recruitment Services. To support studies involving human subjects, the UK Center for Clinical and Translational Science (CCTS) provides wide-ranging participant recruitment services (PSR) such as consultation and strategic support for development of advertising campaigns; planning and creation of flyers, brochures, educational materials, posters, and postcards; and development of web, social media, video, and camera-ready resources. Services also include assistance with recruitment language for IRB submission, tools to capture enrollment metrics, and representation at community outreach events. PSR assistance is supported by various digital and software tools including the i2b2 tool to access the CCTS clinical data warehouse in order to estimate a specific patient population, the ResearchMatch registry funded by the CTSA as a recruitment tool, and the Kentucky Women's Health Registry.

Office of Research Integrity. The UK Office of Research Integrity (ORI), a unit reporting to the Office of the Vice President for Research, plays a central role in the institution's fully accredited Human Research Protection Program (HRPP). The ORI promotes research within the current ethical, regulatory, and legal framework by supporting investigators, staff, and students with human research protections, regulatory oversight, privacy requirements, and data retention and ownership. The UK Human Research Protection Program (HRPP) achieved full accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in June 2007 after a three-year evaluation process. The UK HRPP was re-accredited and awarded five-year cycles for accreditation in 2010 and 2015. Achieving accreditation demonstrates UK's commitment to the highest ethical standards in the conduct of human research.

The professional team of over 20 staff members collectively provide key administrative support to six federally mandated review

boards: four Medical Institutional Review Boards (IRBs), one Nonmedical IRB, and the Radioactive Drug Research Committee. Specific areas of administrative responsibility include protocol review, ethics/regulatory training and advising, quality improvement and efficiency initiatives, allegation and compliance reporting, and research compliance policy development. In addition, designated ORI staff facilitate IRB review of off-site and collaborative research and coordinate IRB reliance agreements for select multi-site research. ORI administrators serve as liaisons with other institutional administrative units with responsibilities for human research protection and research compliance. A designated Research Compliance Officer within the ORI, who is unaffiliated with any specific research protocol, provides a confidential channel for all research participants to discuss problems, concerns, and questions; obtain information; or offer input. This team will play an integral role in this multi-site study.

The University of Kentucky Research Foundation (UKRF). UKRF serves as the university's agent in the receipt of all external grants and contracts, intellectual property income and other designated income; oversees the protection, development, and commercialization of intellectual properties; and manages special cooperative agreements. The Office of Sponsored Projects Administration (OSPA), a unit within the Office of the Vice President for Research, serves UKRF in the procurement, review, approval, and submission of proposals. OSPA ensures compliance with the terms and conditions of grants and contracts, including the submission of progress, final, and other appropriate reports, excluding financial reports. OSPA also provides general grant, contract, and agreement administration with project sponsors. University Financial Services (UFS) provides post-award grant accounting, including financial reporting, invoicing, and collection of receipts in accordance with federal, state, and sponsor guidelines. UFS also oversees time and effort reporting functions.

College of Health Sciences Resources: The UK College of Health Sciences, the administrative home of the SMRI, offers investigators robust administrative and research support services.

Administrative/financial oversight. The College of Health Sciences works closely with OSPA and UFS to establish, administer, and close sponsored awards. A College Grants Officer (CGO) is employed by OSPA and assigned to the College. The CGO serves as the liaison between OSPA and the College. The CGO provides financial grant reports and meets monthly with the project director to review expenditures and plan budget adjustments. The CGO serves as the liaison between the project and OSPA to ensure the program remains in compliance with university and federal policy. CHS's Office of Finance and Administration supports the College's academic, research, and service efforts in managing financial resources. This professional staff of six full-time employees is responsible for personnel and financial management for the College, including financial reporting, facilities management, purchasing, payroll, and grant management. As a public, land grant university, UK's business processes are governed by a comprehensive set of Administrative regulations (uky.edu/regs/ar.htm) and a detailed Business Procedures Manual (uky.edu/ufs/business-procedures-manual).

Office of Research. The college has a dedicated Office of Research wholly dedicated to support faculty investigators as they seek and secure intramural and extramural funding. The Office of Research is staffed with the Associate Dean for Research, the Director of Extramural Support, The College Grants Office and an administrative support specialist. This office identifies appropriate funding opportunities, offers proposal development support, and serves as a liaison between the faculty investigator and various university departments and colleges. The Office of Research works closely with individual faculty on all pre-award and post-award issues. The Office of Research offers competitive pilot grants annually to assist with the collection of preliminary data to better position faculty for extramural support. Additionally, the Office of Research hosts a monthly (academic year) grantsmanship seminar. This seminar provides faculty and doctoral students the opportunity to share their proposed research ideas and receive critical input from other investigators.

Financial Resources. The College of Health Sciences invests in and rewards faculty research efforts. The university's Facilities and Administrative (F & A) rate is 53% for on-campus research. A portion of the F & A funds generated by extramural research is returned directly to the faculty investigator to support his or her laboratory (graduate research assistants, supplies, equipment maintenance, etc.). The University is supported with state budget dollars with salary lines dedicated to faculty positions. When a regular-title series faculty investigator is able to off-set their salary costs through sponsored research, a portion of the salary savings is returned directly to the faculty for investment in research and other scholarly supports. If a faculty member offsets 25% of their salary costs in a fiscal year, a portion of those funds are returned to the faculty in the form of a personal bonus.

Professional Development. The College of Health Sciences is committed to growing young faculty into independent faculty investigators. Faculty development and mentoring are important responsibilities jointly shared by College faculty and administration. The College provides a structure for formal faculty mentoring with oversight by the CHS Associate Dean for Academic and Faculty Affairs. To facilitate 1:1 mentoring, the Department Chair, in consultation with the Division Director, identify appropriate mentoring faculty for each new faculty member. With the agreement of the CHS senior faculty member and new faculty member, the mentor-mentee relationship is established for one year. The mentor and mentee may choose to continue the relationship beyond the expected one-year commitment. The content and structure of the mentorship is individualized based on the needs and preferences of the pair.

Meetings with the Department Chair about Distribution of Effort allocation, Faculty Performance Review, and 2- and 4- year reviews provide faculty members with additional opportunities to assess skills and progress and to discuss faculty development strategies. Department Chairs and faculty provide suggestions to the Associate Dean regarding faculty development needs, and these form the basis for periodic workshops and activities available to all CHS faculty. In addition to these activities, periodic Grantsmanship sessions are also available. Faculty are encouraged to attend university-sponsored faculty development opportunities throughout the year. They also are provided with funding and release time to attend and participate in professional meetings and faculty development activities.

Equipment
Sports Medicine Research Institute

Major Equipment

The SMRI is outfitted with a variety of biomechanical, musculoskeletal, and neurocognitive equipment. The neurobehavioral laboratory includes an iPad (Model A1822, Apple Inc, Cupertino, CA) use for neurocognitive assessments including the NIH Toolbox for assessment of Neurological and Behavior Function application and a dedicated network-wired desktop computer (Lenovo THINK Station, IBM Corp, Armonk, NY) and the REDCap electronic data capture tool application (supported by NIH/NCATS UL1 TR000445) used for demographic surveys and standardized questionnaires. The biomechanics laboratory space includes a motion analysis system (Vicon, Centennial, CO) with integrated force plate system (model 6090, Bertec Corp, Columbus OH) and portable 16 channel wireless inertial measurement unit system (IM Trigno sensors, Delsys Inc, Natick, MA). Integrated data collection utilizes Vicon Nexus software (Vicon, Centennial, CO) running in Microsoft Windows 10 operating system (Windows Corp, Redmond, WA) on a Dell Precision Tower 5810 (Dell Inc, Round Rock, TX). In addition to data collection instrumentation the SMRI is equipped with 11 networked desktop computer systems (Lenovo THINK stations and HP Z1 stations) at researcher workstations with access to Matlab (Mathworks, Natick, MA) data processing software, SPSS (IBM Corp, Armonk, NY) statistical software, and an entire suite of Microsoft software packages through Office 365 (Windows Corp, Redmond, WA). The computers are latest generation Intel quad core i7 processor, with a minimum of 8GB RAM and 256GB SSD.

Other University of Kentucky Resources

Each faculty has access to Zoom video conferencing and web conferencing service. This technology has been used by investigators for the several years and allows for immediate and scheduled communication with unlimited participants across multiple platforms. Zoom unifies cloud video conferencing, simple online meetings, group messaging, and a software-defined conference room solution into one easy-to-use platform. Security features include work email single sign-on, Secure Socket Layer encryption, AES 128-bits encryption, HTTPS access, role-based access control, and admin feature controls. Zoom will be used by the investigators for all video teleconference/teleconference meetings between existing investigators and development of new collaborations. Zoom allows for true remote access and relies only on internet connectivity through cellular or wireless networks.

Multi-Site Communication

Weekly video-teleconference/teleconference meetings will be held with key personnel at the University of Kentucky, University of North Carolina, and WBAMC. These meetings will discuss subject recruitment, data quality, adverse events, confidentiality, subject complaints, and compliance relative to IRB procedures and test protocols. These meetings will also monitor project specific timelines and progress while addressing logistical implementation and impediments to successful completion of the identified aims. The study will also undergo a yearly review by the institutional review board. We do not anticipate any problems, but should anything occur it will immediately be reported to the Institutional Review Board, and the appropriate steps will be taken as per Institutional Review Board policies. The principal investigator will continually monitor the project for confidentiality and safety and consider the benefit relative to the risks. As needed during the quarterly meetings with the research team safety and data monitoring procedures will be reviewed. The principal investigator will review confidentiality, safety, and efficacy and in consultation with its Institutional Review Board, make decisions concerning stoppage of the study if needed. Data collection, transmission, storage, processing, analysis, and sharing procedures will be embedded within the IRB protocols of participating consortium institutions. This regular communication will be crucial in facilitating optimal oversight of clinical sites at UK, UNC, and WBAMC and translations of studies' progress and outcomes to be put into clinical practice or developed further in future research projects. Quarterly site visits will occur with the investigators to ensure data quality control and data collection procedures.

The University of Kentucky will seek a reliance agreement with the other institutions and will be the master IRB of record for any human subjects approvals.

Study Consultant

Dr. Eamonn Delahunt, a faculty member at University College Dublin in Dublin, Ireland will serve as a paid consultant on the project as part of the DOD funding. Dr. Delahunt is an international expert on ankle instability and injury. He, Dr. Wikstrom and Dr. Gribble have published extensively and serve together in the leadership of the International Ankle Consortium. Dr. Delahunt will be available to consult on the interpretation of results and assist with the writing of any resulting manuscripts. Dr. Delahunt will not have access to any raw data or de-identified data. The PI, Dr. Gribble, will share aggregate results of data that has already been processed and analyzed statistically. Dr. Delahunt will be available for phone calls and video conference calls to discuss the statistical results and interpretation as needed.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Foreseeable Risks

The procedures outlined for measuring rehabilitation outcomes proposed are considered safe. The PI and the Co-PI each have over 10 years of experience with performing the proposed measures without incidence of injury. There are no serious risks to participants that are associated with participating in this research. The potential risks for participants in the current study are minimal, and include the following:

- Participants could develop minor, local, transient skin irritations from electrodes used for the corticospinal and spinal reflex excitability measures.
- Participants could develop minor, transient muscle soreness from the SOC or the SMART protocols and the proposed outcome measures.
- Participants may experience mild discomfort at the site of magnetic stimulation and transient headaches.
- While seizures are the major risk for transcranial magnetic stimulation (TMS), the risk of seizures is less than 1 in 10,000.
- Participants may feel restless or uncomfortable when lying in the MRI scanner.
- Participants could experience claustrophobia due to their presence in the MRI scanner.
- The MRI scanner produces loud noise, and all participants are required to wear ear protection provided by the experimenter.
- There are always possibilities that unknown side effects may occur during or following testing.

As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and we will follow thorough procedures to maintain confidentiality.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

All participants will be recruited from the university and local communities in the cities of each study site through partnerships, referrals, flyers, and advertisements. All recruitment efforts will be in compliance with HIPAA regulations. The Co-PI's will oversee recruitment procedures at their study site. Participants may contact the PI's on their own volition after seeing flyers and recruitment materials. Clinicians (physicians, physical therapists, athletic trainers, physiotherapists, etc) may alert patients with ankle sprain history of the study. They will screen the patients for the presence of any conditions that would make the patient ineligible for the study (see exclusion criteria above). The clinicians will only refer patients that they believe are qualified for the study and express an interest in participating. Interested patients will be provided with additional detailed information regarding the study by the Investigative Team. Oral and written information will be provided that explains to the patient in simple terms: 1) the criteria for participation, 2) the purpose of the research and the procedures involved, 3) the patient's right to withdraw at any time without penalty, 4) potential risks and benefits to the patient, 5) assurance of anonymity, and 6) terms of remuneration. If the potential patient meets the acceptance criteria and is interested in participating, the information just described will be reviewed, questions will be answered, and the patient will be requested to sign the consent form.

All protocols and techniques to be used will be approved by the Institution Review Board and the Scientific Advisory Committees as applicable to each study site prior to initiation of the study. Informed written consent will be obtained from a member of the study team who has been trained according to institutional guidelines. Volunteers will meet with a study representative in a private and quiet room and will be permitted ample time to read the document in an unhurried setting. The study representative will be present to answer questions regarding the study or procedures, should they arise. Once the volunteer has read over the document, the study representative will review the entire document with the patient to be sure that the procedures and time commitments are understood. The volunteer's comprehension and autonomy will be assessed by asking patients to explain in their own words what the study is about. The patient will initial the bottom of each page once this has been done. The patient will receive a copy of the signed and dated consent document. The study representative will then review the HIPAA Authorization form and explain what protected information will be collected, who will have access to it, and what steps will be taken to protect this information. The volunteers will initial the bottom of each page once this has been done, and will receive a copy of the signed and dated HIPAA Authorization form.

Confidentiality of all medical records is strictly maintained by established procedures. Volunteers will be identified in computer files only by a coded patient ID that is unique to the study and distinct from any medical record numbers. Only the research staff will have access to these codes. All hard copies of data and backup disks of computer files related to this study will be stored in a locked cabinet located in the study coordinator's office. The office is locked when the coordinator is not present.

The study personnel have extensive experience in the conduct of all aspects of the proposed investigation. The following special precautions will be taken. Study personnel are all trained in CPR and Emergency Response techniques and hold certifications for this skills (i.e. American Red Cross). Appropriately maintained emergency equipment (i.e. AED's) is accessible in all facilities. To minimize the risk for muscle strains or ligament sprains during testing, patients will be given adequate warm-ups and practice attempts. To minimize the risks with treatment, specific guidelines for advancing exercise have been developed as described in the Research Design and Methods. In order to minimize the risk associated with the TMS testing (transient headache, scalp soreness, or seizure), all patients will be carefully screened for eligibility using the following TMS exclusion criteria from the National Institute of Neurological Disorders will minimize any risks: 1) personal or familial history of epilepsy or seizures; 2) history of migraine headaches; 3) ocular foreign body, increased intracranial pressure, open head injury or significant closed head injury; 4) cochlear implants; 5) implanted brain stimulators, aneurysm clips or other metal in the head (except mouth); 6) implanted medication pumps, pacemakers or intracardiac lines; 7) current medication with tricyclic anti-depressants, neuroleptic agents or other drugs that lower seizure threshold; 8) history of diagnosed major psychiatric disorder; 9) history of illicit drug use; 10) current alcohol abuse or currently withdrawing from alcohol abuse; and 11) history of heart disease. All patient information will be kept confidential, and patients will be referred to number codes.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc...), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [\[PDF\]](#).

The patients benefit immediately from the educational experience surrounding frequent interaction with the investigators who are highly interested in addressing functional limitations following LAS. In addition, there are possible long-term benefits for improvements in function and general health for patients receiving progressive rehabilitation. Finally, all LAS patients enrolled will receive free rehabilitation during the study enrollment. The LAS patients enrolled in the SOC group will be offered access to the SMART intervention program after completion of the study enrollment at the 12 month follow up. As the risks associated with the

proposed measures in this study are low, this study has a high benefit to risk ratio.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

NA

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Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):

If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [\[PDF\]](#).

All information collected will be de-identified.

Confidentiality: Specify where the data/specimens will be stored and how the researcher will protect both the data and/or specimens with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality); and procedures employed when sharing material or data, (e.g., honest broker (if applicable), written agreement with recipient not to re-identify). If you plan to procure, store, and/or share material (tissue/specimens/data) expressly for use in current or future research, describe measures that you will take to secure and safeguard confidentiality and privacy.

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the Study Closure SOP [\[PDF\]](#). If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK.

NIH-funded genomic research: The National Institutes of Health (NIH) [Genomic Data Sharing \(GDS\) Policy](#) sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Please note: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [\[PDF\]](#).

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [\[PDF\]](#). The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

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There is an extremely small risk of loss of confidentiality. The investigators will make every effort to maintain each and every participant's confidentiality. While the information gained during this study is not typically considered sensitive, injury information from an athletic population may be considered sensitive. The investigators will record all information in the database, but it will not be linked to your name in a database. To reduce the risk of loss of confidentiality, all collected data will be kept in a locked cabinet in the principal investigator's office, or on a password protected computer. Only the investigators in this study will have access to the data

that is collected. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and we will follow thorough procedures to maintain confidentiality.

Confidentiality of all medical records is strictly maintained by established procedures. Volunteers will be identified in computer files only by a coded patient ID that is unique to the study and distinct from any medical record numbers. Only the research staff will have access to these codes. All hard copies of data and backup disks of computer files related to this study will be stored in a locked cabinet located in the study coordinator's office. The office is locked when the coordinator is not present.

Any information about the subjects obtained from this research will be kept as confidential (private) as possible. The identity of the subjects enrolled under this project will be coded rather than listed by name. A unique identifier (UK001..., UNC001..., and WBAMC001...) will be created for each aim with hierarchical delineation of aim for which the specific research subject is enrolled. The subject identifiers will allow for the data to be queried and to address specific research questions that are dependent on aim or subject specificity. Prior to the initiation of data collection, the Research Associate will create the unique identifiers. All records related to involvement in this research study and the information linking identified codes with the subject's identity will be stored separately (different shares) from the research records on a secured HIPAA compliant University of Kentucky network server. Access to the linking file will be limited to the Principal Investigator. Hard-copy paper forms that contain identifiable information, such as consent forms, will be kept locally at UK, UNC, and WBAMC, in a separate locked filing cabinet from all other study material. The only people with key access to the filing cabinet will be the site Research Associates and site investigators. When the results of the research are published or discussed in conferences, no information will be included that would reveal individual subject identity. Individual study investigators will only be provided de-identified data. Access to the data will be limited to the clinical coordinator and exported from the database as requested. The restricted mechanism will be established to prevent improper handling, accidental deletion or corruption of data, or inadvertent release of identifiable data.

Data will be maintained for a period of seven years after the completion of the study and then destroyed using software designed to sanitize electronic storage devices. Also at this time any paper records that include identifiable information, such as consent forms, will be destroyed.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Non-military personnel will be compensated \$100 for completing all aspects of the study. According to DOD policy, military personnel will not be compensated for participation in this study.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There will be no costs involved for participating in this study.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). [Click here for additional guidance on developing a Data and Safety Monitoring Plan.](#)

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, [click here for additional guidance](#) for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review. 

The primary investigator will monitor confidentiality and data bi-monthly to ensure accuracy and recruitment of subjects. Weekly meetings, with the co-investigators, will be held to verify compliance and testing procedures. These meetings will monitor recruitment, retention, data, adverse events, and breaches in confidentiality. All hard copy records related to involvement in this research study will be stored in a locked file cabinet at UK, UNC, and WBAMC. An electronic repository is used to store data and is maintained on a secured network server. This data will be house on a University of Kentucky HIPAA-compliant. Data access will be limited to those investigators listed on the project. Data will be maintained for a period of seven years and then destroyed using software designed to sanitize electronic storage devices.

Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Complaints about the study, you can contact the investigator, Phillip Gribble at 859-218-0885, or by email phillip.gribble@uky.edu. The subjects will be encouraged to ask questions at any time during the consenting process to determine if he would like to participate and throughout the study to determine continued participation. Subjects having any questions or concerns about this study or rights as a research subject may contact the principal investigator or the University of Kentucky's Office of Research Integrity at 859-257-9428 or toll free at 1-866-400-9428.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

☐ Yes ☒ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the IRB Application Instructions on [Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture](#).

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first.**)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the [International Compilation of Human Research Standards](#)

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc...)?**

☐ Yes ☒ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [\[PDF\]](#).

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online [IRB Survival Handbook](#) to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [\[PDF\]](#), and visit the [Office for Human Research Protections web site](#) for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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- 1) involves testing a Nonsignificant Risk (NSR) Device, or
- 2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

☐ Yes ☒ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the PI assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [\[PDF\]](#), IDE regulatory requirements for SR device trials [\[PDF\]](#), and abbreviated regulatory requirements for NSR device trials [\[PDF\]](#). For detailed descriptions see [FDA Responsibilities for Device Study Sponsors](#) or [FDA Responsibilities for IND Drug Study Sponsor-Investigators](#).

- Describe your (the PI's) experience/knowledge/training (if any) in serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if you have transferred any sponsor obligations to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see [Sponsor-Investigator FAQs](#)). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the PI completed the mandatory PI-sponsor training prior to this submission?

☐ Yes ☒ No

If you (the PI) have completed equivalent sponsor-investigator training, you may submit documentation of the content for the IRB's consideration.

[Attachments](#)

HIPAA

Is HIPAA applicable? ☐ Yes ☒ No

(Visit ORI's [Health Insurance Portability and Accountability Act \(HIPAA\) web page](#) to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s): 

☐ HIPAA De-identification Certification Form

☐ HIPAA Waiver of Authorization

Attachments

STUDY DRUG INFORMATION

☐ Yes ☒ No

If yes, complete the questions below. Additional [study drug guidance](#).

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

☐ Yes ☒ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐

Held By:

Investigator: ☐

Held By:

Other: ☐

Held By:

☐ Checkmark this if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND).

- [FDA's Expanded Access Program Information \(e.g., treatment IND\)](#)
- Guidance and definitions: "[Expanded Access SOP](#)" (PDF).

Please also complete and attach the [Study Drug Form \(PDF\)](#) (required):



Attachments

STUDY DEVICE INFORMATION

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's [Use of Any Device Being Tested in Research web page](#).

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

☐ Yes ☐ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer "no" above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE) or Humanitarian Device Exemption (HDE) application? See UK [HUD SOP](#) (PDF) for guidance.

☐ Yes ☐ No

If Yes, list IDE or HDE #(s) and complete the following:

IDE/HDE Submitted/Held by:

Sponsor: ☐

Held By:

Investigator: ☐

Held By:

Other: ☐

Held By:

☐ Check if this is a Treatment or Compassionate Use IDE under the Food and Drug Administration (FDA) Early Expanded Access program.

- [FDA's Early Expanded Access Program Information](#)
- Guidance and definitions: "[Medical Device Clinical Investigations, Compassionate Use, and Treatment IDE SOP](#)" (PDF)

Does the intended use of any device used in this study meet the regulatory [definition](#) of Significant Risk (SR) device?

☐ Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential

for serious risk to the health, safety, or welfare of a subject.

☒ No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Please also complete and attach the [Study Device Form \(PDF\)](#) (required):



Attachments

RESEARCH SITES

In order for this section to be considered complete, you must click "SAVE" after ensuring all responses are accurate.

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☒ UK Classroom(s)/Lab(s)
- ☐ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's [IRB Application Instructions - Off-site Research](#) web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

List all other non-UK owned/operated locations where the research will be conducted:*

*A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the [IRB Application Instructions - Off-Site Research](#) web page for more information.

The University of North Carolina at Chapel Hill - Sport Medicine Research Laboratory
William Beaumont Army Medical Center - Department of Physical Therapy

Attachments

Attach Type	File Name
-Individual Investigator Agreement	Letters of Support_non-UK site.pdf
-IRB Authorization Agreement	IAIR WBAMC-Univ of Kentucky Research Foundation 16 Mar 2018.pdf

B) Is this a multi-site study for which you are the lead investigator or UK is the lead site? ☒ Yes ☐ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☐ Academic Degree/Required Research
- ☐ Aging Research
- ☐ Alcohol Abuse Research
- ☐ Cancer Research
- ☐ Certificate of Confidentiality
- ☐ CCTS-Center for Clinical & Translational Science
- ☐ Clinical Research
- ☒ Clinical Trial
- ☒ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
- ☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
- ☐ Clinical Trial Placebo Controlled Trial
- ☐ Clinical Trial UK Only
- ☐ Collection of Biological Specimens
- ☐ Collection of Biological Specimens for Banking
- ☐ Community-Based Participatory Research
- ☐ Data & Safety Monitoring Board
- ☒ Data & Safety Monitoring Plan
- ☐ Deception
- ☐ Drug/Substance Abuse Research
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Genetic Research
- ☐ Gene Transfer
- ☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
- ☐ International Research
- ☐ Internet Research
- ☐ Planned Emergency Research Involving Waiver of Informed Consent
- ☐ Pluripotent Stem Cell Research
- ☐ Recombinant DNA
- ☒ Survey Research
- ☐ Transplants
- ☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
- ☐ Vaccine Trials

Click applicable listing(s) for additional requirements and/or information:

- [Cancer Research \(MCC PRMC\)](#)
- [Certificate of Confidentiality](#) (look up "Confidentiality/Privacy...")
- [CCTS \(Center for Clinical and Translational Science\)](#)
- [Clinical Research](#) (look up "What is the definition of....")
- [Clinical Trial](#) (look up "What is the definition of....")

Determine if research meets [NIH definition of clinical trial](#);

*Reminder: Ensure compliance with [clinicaltrials.gov](#) registration requirements for applicable clinical trials and [Good Clinical Practice \(GCP\) training](#) requirements.

- [Collection of Biological Specimens for Banking](#) (look up "Specimen/Tissue Collection...")
- [Collection of Biological Specimens](#) (look up "Specimen/Tissue Collection...")
- [Community-Based Participatory Research](#) (look up "Community-Engaged...")
- [Data & Safety Monitoring Board](#) (DSMB)

*For Medical IRB: [Service Request Form](#) for CCTS DSMB

- [Data & Safety Monitoring Plan](#)
- [Deception*](#)

*For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- [Emergency Use \(Single Patient\) \[attach Emergency Use Checklist\]](#) (PDF)
- [Genetic Research](#) (look up "Specimen/Tissue Collection...")
- [Gene Transfer](#)
- [HIV/AIDS Research](#) (look up "Reportable Diseases/Conditions")
- [Screening for Reportable Diseases \[E2.0000\]](#) (PDF)
- [International Research](#) (look up "International & Non-English Speaking")
- [Planned Emergency Research Involving Waiver of Informed Consent*](#)

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- [Use of radioactive material, ionizing radiation or x-rays for research](#)

FUNDING/SUPPORT

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply. ⓘ

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☐ (HHS) Dept. of Health & Human Services
- ☐ (NIH) National Institutes of Health
- ☐ (CDC) Centers for Disease Control & Prevention
- ☐ (HRSA) Health Resources and Services Administration
- ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Department of Defense

Click applicable listing(s) for additional requirements and/or information:

- [\(HHS\) Dept. of Health & Human Services](#)
- [\(NIH\) National Institutes of Health](#)
- [\(CDC\) Centers for Disease Control & Prevention](#)
- [\(HRSA\) Health Resources & Services Administration](#)
- [\(SAMHSA\) Substance Abuse & Mental Health Services Administration](#)
- Industry (Other than Pharmaceutical Companies) [[IRB Fee Info](#)]
- [National Science Foundation](#)
- [\(DoEd\) U.S. Department of Education](#)
- [\(DoJ\) Department of Justice or Bureau of Prisons](#)
- [\(DoE\) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist](#)
- [\(EPA\) Environmental Protection Agency](#)

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

US Army Medical Research and Materiel Command (USAMRMC)
US Army Medical Research Acquisition Activity (USAMRAA)

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.

If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP [\[PDF\]](#) and DoD Summary [\[PDF\]](#) for details)

☒ Yes ☐ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Attach Type	File Name
Funding_ProcessDODSOP	DoD SOP Attachments.pdf

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? *[If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.]*

☐ Yes ☒ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC)--Attach [required IBC materials](#)
- Radiation Safety Committee (RSC)-- For applicability, see [instructions](#) and/or upload form [\[WORD\]](#) [\[PDF\]](#)
- Radioactive Drug Research Committee (RDRC)--[information](#)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per [instructions](#)
- See requirement of [Office of Medical Education \(OME\)](#)
- See requirement of [Graduate Medical Education Committee \(GME\)](#)

Attachments

**** If you are proposing a study involving cancer research, be sure to have "Cancer Research" marked in the E-IRB "Research Attributes" section.** If your study involves cancer research, ORI will provide a copy of your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The [MCC PRMC](#) is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

Do you want specific information inserted into your approval letter? ☐ Yes ☒ No

Approval Letter Details (e.g., serial #):

Submission Description: If you wish to have specific details included in your approval letter (e.g., serial #, internal tracking identifier, etc...), type in the box below exactly what you wish to see on the approval letter. What you type will automatically appear at the top of all approval letters, identical to how you typed it, until it is changed by you (Hint: don't include instructions or questions to ORI staff as those will appear in your approval letter). **If these details need to be changed as a result of revisions, continuation review, or modifications to the application, you are responsible for updating the content of the field below accordingly.**

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

NOTE: [Instructions for Dept. of Health & Human Services \(DHHS\)-approved protocol](#)

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

[To view what materials are currently attached to your application, go to "Application Links" in the menu bar on the left and click "All Attachments".]

Attachments

Attach Type	File Name
AdditionInfoConsiderations	E-IRB 44172 Email Trail MR 3.11.19 ORI and PI.pdf
AdditionInfoConsiderations	18-1538_UNC_relyon_Univ_Kentucky_SmartIRB_LOA_exd_7-11-18.pdf
AdditionInfoConsiderations	Cain_HSP.pdf
AdditionInfoConsiderations	Helton_HSP.pdf
AdditionInfoConsiderations	Migel_HSP.pdf
AdditionInfoConsiderations	Song_HSP.pdf
AdditionInfoConsiderations	Wikstrom_HSP.pdf
AdditionInfoConsiderations	Roberts_HSP.pdf
AdditionInfoConsiderations	Responses to UK IRB Query 5-22-19.docx
AdditionInfoConsiderations	Migel_HSP_UNC.pdf

SIGNATURES (ASSURANCES)

On all IRB applications there is a requirement for additional assurances by a Department Chairperson (or equivalent) [hereafter referred to as "Department Authorization" (DA)], and when applicable, a Faculty Advisor (FA) (or equivalent), which signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. Note: the individual assigned as DA *should not* also be listed in the Study Personnel section, the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, download the guidance document "[What does the Department Chairperson's Assurance Statement on the IRB application mean?](#)" 

Required Signatures:



First Name	Last Name	Role	Department	Date Signed	
Janice	Kuperstein	Department Authorization	Health Sciences - Rehabilitati	04/20/2018 06:18 PM	View/Sign
Phillip	Gribble	Principal Investigator	Health Sciences - Rehabilitati	04/19/2018 12:38 PM	View/Sign

Department Authorization

☒ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator is knowledgeable of the additional regulatory requirements of the sponsor and can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☒ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the

categories specified in the Protocol Type: Exemption Categories section.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

SUBMISSION INFORMATION

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed; otherwise your submission for IRB review and approval will not be able to be sent to the Office of Research Integrity/IRB.

Please remember to update, when applicable, the Approval Letter Details text box under the Additional Information section to ensure verbiage you want on your approval letter is accurate.

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and a message will be forthcoming to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Modification Request Information

Select One:

- ☐ This modification does not increase risk to study participants.
- ☐ This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

- ☐ Yes ☐ No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

- ☐ Yes ☐ No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

Added non-UK study personnel from testing sites (University of North Carolina and William Beaumont Army Medical Center) and associated HSP completion certificates.
 Added a LOA form for reliance on UK IRB from the University of North Carolina IRB
 Added to the end of "Research Description_Resources" a description of the role that a consultant, Dr. Delahunt, will provide.
 We have not added consent forms from local IRB of our testing sites. These will be added once we receive DOD approval of the UK consent form.

Your protocol has been submitted.

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
🔗	ApprovalLetter	ApprovalLetter.pdf		0.058	klars2	5/23/2019 11:17:39 AM
🔗	Stamped Consent Form	Form_C_Med_and_HIPAA_v3 SMART.pdf		0.125	klars2	5/23/2019 11:17:38 AM
🔗	AdditionInfoConsiderations	Migel_HSP UNC.pdf	Migel_HSP_2	0.112	pagr224	5/22/2019 4:36:13 PM
🔗	AdditionInfoConsiderations	Responses to UK IRB Query 5-22-19.docx	Responses to Queries 5-22-19	0.012	pagr224	5/22/2019 4:35:23 PM
🔗	AdditionInfoConsiderations	Roberts_HSP.pdf	Roberts_HSP	0.404	pagr224	5/21/2019 8:51:35 AM
🔗	AdditionInfoConsiderations	Wikstrom_HSP.pdf	Wikstrom_HSP	0.403	pagr224	5/21/2019 8:46:33 AM
🔗	AdditionInfoConsiderations	Song_HSP.pdf	Song_HSP	0.153	pagr224	5/21/2019 8:46:21 AM
🔗	AdditionInfoConsiderations	Migel_HSP.pdf	Migel_HSP	0.404	pagr224	5/21/2019 8:46:11 AM
🔗	AdditionInfoConsiderations	Helton_HSP.pdf	Helton_HSP	0.404	pagr224	5/21/2019 8:45:57 AM
🔗	AdditionInfoConsiderations	Cain_HSP.pdf	Cain_HSP	0.403	pagr224	5/21/2019 8:45:44 AM
🔗	AdditionInfoConsiderations	18-1538 UNC relyon Univ Kentucky SmartIRB LOA_exd_7-11-18.pdf	LOA for IRB Reliance UNC	0.090	pagr224	3/15/2019 1:00:31 PM
🔗	AdditionInfoConsiderations	E-IRB 44172 Email Trail MR 3.11.19 ORI and PI.pdf	Email Trail on MR 3.11.19 ORI and PI	0.161	klars2	3/11/2019 2:09:54 PM
🔗	PhoneScript	Telephone Screening Script_11.7.2018.pdf		0.141	mcbe237	11/7/2018 3:44:23 PM
🔗	Advertising	Research Flyer Template_WBAMC.pdf	WBAMC Flyer	0.163	mcbe237	8/22/2018 9:36:55 AM
🔗	Advertising	Recruitment Slide_DOD UNC.pdf	UNC Approved Flyer	0.423	mcbe237	8/20/2018 9:19:06 AM
🔗	Informed ConsentParental Permission	Form_C_Med_and_HIPAA_v3 SMART.pdf		0.081	pagr224	8/9/2018 3:36:12 PM
🔗	Funding_ProcessDODSOP	DoD SOP Attachments.pdf		0.189	mcbe237	4/23/2018 8:11:13 AM
🔗	DataCollection	Data Collection Forms.pdf		0.806	mcbe237	4/19/2018 11:49:35 AM
🔗	Advertising	Research Flyer_Approved.pdf		0.187	mcbe237	4/16/2018 12:29:34 PM
🔗	-IRB Authorization Agreement	IAIR WBAMC-Univ of Kentucky Research Foundation 16 Mar 2018.pdf	DoD Institutional Agreement	0.963	mcbe237	3/27/2018 1:20:17 PM
🔗	-Individual Investigator Agreement	Letters of Support_non-UK site.pdf		0.385	mcbe237	3/12/2018 2:22:07 PM

	ResearchProcedures	Pages from ProjectNarrative and Attachment 12.pdf	Intervention Tables	0.069	mcbe237	3/12/2018 1:33:40 PM

Protocol Changes

Protocol Number: 44172

Research Description Resources changed by pagr224 on 5/22/2019 11:36:07 AM

Facilities and Resources ¶

Sports Medicine Research Institute ¶

The Sports Medicine Research Institute (SMRI) is a 9000 square foot state-of-the-art facility located in the University of Kentucky's Nutter Training Facility and comprised of a research laboratory, academic/administrative offices, and conferencing space. It is a multidisciplinary research facility dedicated to injury prevention, performance, treatment, and rehabilitation, specializing in musculoskeletal, neurobehavioral, and physiological/metabolic health. The SMRI is supported by a team consisting of thirteen core faculty, staff, ¶

and graduate students, and 44 affiliated faculty across the University. ¶

¶

Laboratory Facility ¶

The SMRI is outfitted with biomechanical, physiological, musculoskeletal, and neurocognitive equipment. The biomechanics laboratory includes a 14 camera 3D motion analysis system, dual force plate system, multi-axial and virtual reality stability device, accelerometers, and inertial measurement unit system. The exercise physiology laboratory includes desktop and portable metabolic units, electromagnetic cycle ergometer, multiple treadmills, and wearable technology. The neurobehavioral laboratory includes visual acuity hardware/software, visual motor and neurocognitive rehabilitation and sports training device, and neurocognitive software. The musculoskeletal laboratory includes isokinetic dynamometry, handheld dynamometer, therapeutic exercise equipment, and diagnostic ultrasound. SMRI's dedicated lab space is connected to the UK Athletic Training Facility. The SMRI is located within the athletics facilities portion of campus. Within the same building as the SMRI are the coaches and team meeting rooms, athletic training room, nutrition room, and sports performance training facility for track and field, baseball, swimming and diving, golf, and tennis. The SMRI is within five to fifteen-minutes walking distance from all UK Athletic facilities on campus including, football, basketball, soccer, and softball. The SMRI's proximity and integration into athletics provides easy access to the student athletes, coaches and administrators on campus. The SMRI currently assists on an as-needed basis for rehabilitation, injury, and performance consultations for our athletic teams and student athletes on campus. This relationship with the individual teams and their coaching and medical staff will be a significant aid in facilitating recruitment and retention of research subjects for this proposed project. ¶

Clinical ¶

¶

The SMRI is outfitted with two clinical examination rooms for physicians to evaluate patients as part of their regular clinical practice and research enrollment. The SMRI also has sufficient space and therapeutic exercise equipment for physical therapy or other rehabilitation services. ¶

¶

Computer ¶

Multiple computers are available for data collection, processing and analysis, with data redundancy completed by peripherals and the internal server/network for the SMRI. The computers are latest generation Intel quad core i7 processor, with a minimum of 8GB RAM and 256GB SSD. Systems are configured with Windows Pro OS (7 or 10) and various Office, statistics, and programming software. All graduate students are provided workstations within the laboratory. All personnel are provided with full support of computers and information technology to enhance productivity. ¶

Offices ¶

¶

Dr. Gribble has a 100-square foot office in the College of Health Sciences, within close proximity to SMRI. His office is equipped with a dedicated telephone line, personal computer, printer and filing cabinets to ensure confidentiality of records. Dr. Gribble also has a dedicated workspace in SMRI. Drs. Abt and Heebner have 150-square foot offices at SMRI that are fully equipped and conducive to team meetings. The research coordinator's office is adjacent to Dr. Abt's office. SMRI is staffed with an administrative staff support person who provides phone coverage and administrative support during regular business hours. When not on-site together, the investigative team can meet via Zoom teleconferencing in any UK investigator office or in the SMRI state-of-the-art conference room. ¶

¶

Video-Teleconferencing ¶

Each faculty has access to Zoom video conferencing and web conferencing service. This technology is widely used by UK investigators and allows for immediate and scheduled communication with unlimited participants across multiple platforms. Zoom unifies cloud video conferencing, simple online meetings, group messaging, and a software-defined conference room solution into one easy-to-use platform. Security features include work email single sign-on, Secure Socket Layer encryption, AES 128-bits encryption, HTTPS access, role-based access control, and admin feature controls. Zoom will be used by the investigators for all video teleconference/teleconference meetings between existing investigators and development of new collaborations. ¶

¶

Other Resources: ¶

Institutional Faculty Resources. As a University of Kentucky faculty member, the PI and his co-investigators have access to robust

research-support services, including multiple core facilities, shared resources, and outstanding clinical research expertise. The services most integral to this project include: ¶

REDCap Project and REDCap Survey. UK is a member of the Research Electronic Data Capture (REDCap) Consortium, a coalition of institutions that supports a secure web application designed to support data capture for research studies. The application allows users to build and manage online surveys and databases quickly and securely. The core supports REDCap Project and REDCap Survey by providing training and design support to CCTS investigators. REDCap Project allows researchers to easily collect data for research studies ranging from simple laboratory-based studies with limited data collection and participants to complex multi-site clinical trials with multiple encounters per participant. Data collection forms and surveys are easy to create and modify and are available through a simple web-based interface that provides strong security and audit trails. Authorized users can download data collection forms and surveys into several formats for further analysis. The UK REDCap instance, launched in 2009, has over 2,000 production projects and over 2,000 users. ¶

Participant Recruitment Services. To support studies involving human subjects, the UK Center for Clinical and Translational Science (CCTS) provides wide-ranging participant recruitment services (PSR) such as consultation and strategic support for development of advertising campaigns; planning and creation of flyers, brochures, educational materials, posters, and postcards; and development of web, social media, video, and camera-ready resources. Services also include assistance with recruitment language for IRB submission, tools to capture enrollment metrics, and representation at community outreach events. PSR assistance is supported by various digital and software tools including the i2b2 tool to access the CCTS clinical data warehouse in order to estimate a specific patient population, the ResearchMatch registry funded by the CTSA as a recruitment tool, and the Kentucky Women's Health Registry. ¶

Office of Research Integrity. The UK Office of Research Integrity (ORI), a unit reporting to the Office of the Vice President for Research, plays a central role in the institution's fully accredited Human Research Protection Program (HRPP). The ORI promotes research within the current ethical, regulatory, and legal framework by supporting investigators, staff, and students with human research protections, regulatory oversight, privacy requirements, and data retention and ownership. The UK Human Research Protection Program (HRPP) achieved full accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in June 2007 after a three-year evaluation process. The UK HRPP was re-accredited and awarded five-year cycles for accreditation in 2010 and 2015. Achieving accreditation demonstrates UK's commitment to the highest ethical standards in the conduct of human research. ¶

The professional team of over 20 staff members collectively provide key administrative support to six federally mandated review boards: four Medical Institutional Review Boards (IRBs), one Nonmedical IRB, and the Radioactive Drug Research Committee. Specific areas of administrative responsibility include protocol review, ethics/regulatory training and advising, quality improvement and efficiency initiatives, allegation and compliance reporting, and research compliance policy development. In addition, designated ORI staff facilitate IRB review of off-site and collaborative research and coordinate IRB reliance agreements for select multi-site research. ORI administrators serve as liaisons with other institutional administrative units with responsibilities for human research protection and research compliance. A designated Research Compliance Officer within the ORI, who is unaffiliated with any specific research protocol, provides a confidential channel for all research participants to discuss problems, concerns, and questions; obtain information; or offer input. This team will play an integral role in this multi-site study. ¶

The University of Kentucky Research Foundation (UKRF). UKRF serves as the university's agent in the receipt of all external grants and contracts, intellectual property income and other designated income; oversees the protection, development, and commercialization of intellectual properties; and manages special cooperative agreements. The Office of Sponsored Projects Administration (OSPA), a unit within the Office of the Vice President for Research, serves UKRF in the procurement, review, approval, and submission of proposals. OSPA ensures compliance with the terms and conditions of grants and contracts, including the submission of progress, final, and other appropriate reports, excluding financial reports. OSPA also provides general grant, contract, and agreement administration with project sponsors. University Financial Services (UFS) provides post-award grant accounting, including financial reporting, invoicing, and collection of receipts in accordance with federal, state, and sponsor guidelines. UFS also oversees time and effort reporting functions. ¶

College of Health Sciences Resources: The UK College of Health Sciences, the administrative home of the SMRI, offers investigators robust administrative and research support services. ¶

Administrative/financial oversight. The College of Health Sciences works closely with OSPA and UFS to establish, administer, and close sponsored awards. A College Grants Officer (CGO) is employed by OSPA and assigned to the College. The CGO serves as the liaison between OSPA and the College. The CGO provides financial grant reports and meets monthly with the project director to review expenditures and plan budget adjustments. The CGO serves as the liaison between the project and OSPA to ensure the program remains in compliance with university and federal policy. CHS's Office of Finance and Administration supports the College's academic, research, and service efforts in managing financial resources. This professional staff of six full-time employees is responsible for personnel and financial management for the College, including financial reporting, facilities management, purchasing, payroll, and grant management. As a public, land grant university, UK's business processes are governed by a comprehensive set of Administrative regulations (uky.edu/regs/ar.htm) and a detailed Business Procedures Manual (uky.edu/ufs/business-procedures-manual). ¶



Office of Research. The college has a dedicated Office of Research wholly dedicated to support faculty investigators as they seek and secure intramural and extramural funding. The Office of Research is staffed with the Associate Dean for Research, the Director of Extramural Support, The College Grants Office and an administrative support specialist. This office identifies appropriate funding opportunities, offers proposal development support, and serves as a liaison between the faculty investigator and various university departments and colleges. The Office of Research works closely with individual faculty on all pre-award and post-award issues. The Office of Research offers competitive pilot grants annually to assist with the collection of preliminary data to better position faculty for extramural support. Additionally, the Office of Research hosts a monthly (academic year) grantsmanship seminar. This seminar provides faculty and doctoral students the opportunity to share their proposed research ideas and receive critical input from other investigators. ¶



Financial Resources. The College of Health Sciences invests in and rewards faculty research efforts. The university's Facilities and Administrative (F & A) rate is 53% for on-campus research. A portion of the F & A funds generated by extramural research is returned directly to the faculty investigator to support his or her laboratory (graduate research assistants, supplies, equipment maintenance, etc.). The University is supported with state budget dollars with salary lines dedicated to faculty positions. When a regular-title series faculty investigator is able to off-set their salary costs through sponsored research, a portion of the salary savings is returned directly to the faculty for investment in research and other scholarly supports. If a faculty member offsets 25% of their salary costs in a fiscal year, a portion of those funds are returned to the faculty in the form of a personal bonus. ¶



Professional Development. The College of Health Sciences is committed to growing young faculty into independent faculty investigators. Faculty development and mentoring are important responsibilities jointly shared by College faculty and administration. The College provides a structure for formal faculty mentoring with oversight by the CHS Associate Dean for Academic and Faculty Affairs. To facilitate 1:1 mentoring, the Department Chair, in consultation with the Division Director, identify appropriate mentoring faculty for each new faculty member. With the agreement of the CHS senior faculty member and new faculty member, the mentor-mentee relationship is established for one year. The mentor and mentee may choose to continue the relationship beyond the expected one-year commitment. The content and structure of the mentorship is individualized based on the needs and preferences of the pair. ¶

Meetings with the Department Chair about Distribution of Effort allocation, Faculty Performance Review, and 2- and 4- year reviews provide faculty members with additional opportunities to assess skills and progress and to discuss faculty development strategies. Department Chairs and faculty provide suggestions to the Associate Dean regarding faculty development needs, and these form the basis for periodic workshops and activities available to all CHS faculty. In addition to these activities, periodic Grantsmanship sessions are also available. Faculty are encouraged to attend university-sponsored faculty development opportunities throughout the year. They also are provided with funding and release time to attend and participate in professional meetings and faculty development activities. ¶



Equipment ¶

Sports Medicine Research Institute ¶



Major Equipment ¶

The SMRI is outfitted with a variety of biomechanical, musculoskeletal, and neurocognitive equipment. The neurobehavioral laboratory includes an iPad (Model A1822, Apple Inc, Cupertino, CA) use for neurocognitive assessments including the NIH Toolbox for assessment of Neurological and Behavior Function application and a dedicated network-wired desktop computer (Lenovo THINK Station, IBM Corp, Armonk, NY) and the REDCap electronic data capture tool application (supported by NIH/NCATS UL1 TR000445) used for demographic surveys and standardized questionnaires. The biomechanics laboratory space includes a motion analysis system (Vicon, Centennial, CO) with integrated force plate system (model 6090, Bertec Corp, Columbus OH) and portable 16 channel wireless inertial measurement unit system (IM Trigno sensors, Delsys Inc, Natick, MA). Integrated data collection utilizes Vicon Nexus software (Vicon, Centennial, CO) running in Microsoft Windows 10 operating system (Windows Corp, Redmond, WA) on a Dell Precision Tower 5810 (Dell Inc, Round Rock, TX). In addition to data collection instrumentation the SMRI is equipped with 11 networked desktop computer systems (Lenovo THINK stations and HP Z1 stations) at researcher workstations with access to Matlab (Mathworks, Natick, MA) data processing software, SPSS (IBM Corp, Armonk, NY) statistical software, and an entire suite of Microsoft software packages through Office 365 (Windows Corp, Redmond, WA). The computers are latest generation Intel quad core i7 processor, with a minimum of 8GB RAM and 256GB SSD. ¶



Other University of Kentucky Resources ¶

Each faculty has access to Zoom video conferencing and web conferencing service. This technology has been used by investigators for the several years and allows for immediate and scheduled communication with unlimited participants across multiple platforms. Zoom unifies cloud video conferencing, simple online meetings, group messaging, and a software-defined conference room solution into one easy-to-use platform. Security features include work email single sign-on, Secure Socket Layer encryption, AES 128-bits encryption, HTTPS access, role-based access control, and admin feature controls. Zoom will be used by the investigators for all video teleconference/teleconference meetings between existing investigators and development of new collaborations. Zoom allows for true remote access and relies only on internet connectivity through cellular or wireless networks. ¶



Multi-Site Communication ¶

Weekly video-teleconference/teleconference meetings will be held with key personnel at the University of Kentucky, University of North Carolina, and WBAMC. These meetings will discuss subject recruitment, data quality, adverse events, confidentiality, subject complaints, and compliance relative to IRB procedures and test protocols. These meetings will also monitor project specific timelines and progress while addressing logistical implementation and impediments to successful completion of the identified aims. The study will also undergo a yearly review by the institutional review board. We do not anticipate any problems, but should anything occur it will immediately be reported to the Institutional Review Board, and the appropriate steps will be taken as per Institutional Review Board policies. The principal investigator will continually monitor the project for confidentiality and safety and consider the benefit relative to the risks. As needed during the quarterly meetings with the research team safety and data monitoring procedures will be reviewed. The principal investigator will review confidentiality, safety, and efficacy and in consultation with its Institutional Review Board, make decisions concerning stoppage of the study if needed. Data collection, transmission, storage, processing, analysis, and sharing procedures will be embedded within the IRB protocols of participating consortium institutions. This regular communication will be crucial in facilitating optimal oversight of clinical sites at UK, UNC, and WBAMC and translations of studies' progress and outcomes to be put into clinical practice or developed further in future research projects. Quarterly site visits will occur with the investigators to ensure data quality control and data collection procedures. ¶

The University of Kentucky will seek a reliance agreement with the other institutions and will be the master IRB of record for any human subjects approvals. ¶

¶

Study Consultant ¶

Dr. Eamonn Delahunt, a faculty member at University College Dublin in Dublin, Ireland will serve as a paid consultant on the project as part of the DOD funding. Dr. Delahunt is an international expert on ankle instability and injury. He, Dr. Wikstrom and Dr. Gribble have published extensively and serve together in the leadership of the International Ankle Consortium. Dr. Delahunt will be available to consult on the interpretation of results and assist with the writing of any resulting manuscripts. Dr. Delahunt will not have access to any raw data or de-identified data. The PI, Dr. Gribble, will share aggregate results of data that has already been processed and analyzed statistically. Dr. Delahunt will be available for phone calls and video conference calls to discuss the statistical results and interpretation as needed.

Study Personnel Changes:

N958	
Name	Wikstrom, Erik
Email	ewikstro@email.unc.edu
Role 1	SP
Role 2	Co-Investigator
Is Contact	N
Room	
Dept Code	
Dept Desc	
SFI	N
Is PIRN	

N960	
Name	Helton, Gary
Email	gary.l.helton8.mil@mail.mil
Role 1	SP
Role 2	Co-Investigator
Is Contact	N
Room	
Dept Code	
Dept Desc	
SFI	N
Is PIRN	

N961	
Name	Migel, Kimmery
Email	kmigel@live.unc.edu
Role 1	SP
Role 2	Co-Investigator
Is Contact	N
Room	
Dept Code	
Dept Desc	
SFI	N
Is PIRN	

N962	
Name	Cain, Mary
Email	mscain@email.unc.edu
Role 1	SP
Role 2	Co-Investigator
Is Contact	N

N963	
Name	Song, Kyeongtak
Email	ktsong@email.unc.edu
Role 1	SP
Role 2	Co-Investigator
Is Contact	N

N964	
Name	Roberts, Kathryn
Email	kbuehrle.kb@gmail.com
Role 1	SP
Role 2	Co-Investigator
Is Contact	N

Room	
Dept Code	
Dept Desc	
SFI	N
Is PIRN	

Room	
Dept Code	
Dept Desc	
SFI	N
Is PIRN	

Room	
Dept Code	
Dept Desc	
SFI	N
Is PIRN	

Study Personnel Comment by Karen Larson - ORI to IRB/PI on 3/18/2019 2:38:11 PM

3.18.19- Please refer to Email from Jessica Williams of 3.15.19- "You'll want to attach the CITI/HSP training documentation under "additional information" after you've added your non-UK study personnel."

Study Personnel Comment by Karen Larson - ORI to PI on 5/22/2019 12:44:01 PM

5.22.19- For Kimmery, Miguel please upload HSP training course. Biomedical Responsible Conduct of Research course is not HSP training.

Study Personnel Comment by Karen Larson - ORI to PI on 5/22/2019 2:22:09 PM

5.22.19 Where is Kathryn Roberts employed? What is her role in the study?

Study Personnel Comment by Karen Larson - ORI to IRB/PI on 5/23/2019 8:49:44 AM

5.22.19- From PI email: For Kimmery Migel and the requested HSP document, I spoke to Dr. Wikstrom today and he said she is having surgery today and would not be able to respond. He provided a letter from the Office of Research at UNC that verifies Ms. Migel has completed her training. The letter was used for a recent NIH submission. I hope this will work? Otherwise, it might be sometime into next week before I can get a response from Ms. Migel.

Study Personnel Comment by Karen Larson - ORI to IRB/PI on 5/23/2019 8:50:16 AM

5.22.19- From Jessica Williams email reply: This should work if there is a letter from UNC's office of research in E-IRB. This will certainly work until we can get Ms. Miguel's documentation next week. I'm copying John Roberts from UNC to see if he has some documentation he can provide. Karen, please go ahead and send this on to the IRB so that we can get this mod approved.

Study Personnel Comment by Karen Larson - ORI to IRB/PI on 5/23/2019 9:13:37 AM

5.22.19- PI Reply about Kathryn Roberts: She is employed through Geneva Foundation (sub-award on the DOD grant) and is working at William Beaumont Army Medical Center (WBAMC) as Clinical Research Coordinator. MAJ Helton (site PI at WBAMC) is supervising her directly on site. Per Jessica email 5.23.19 Kathryn is covered under WBAMC agreement.



ADDRESSING NEUROMUSCULAR DEFICITS FOR IMPROVED OUTCOMES IN ANKLE REHABILITATION

You are being invited to take part in a research study about successful outcomes following lateral ankle sprain rehabilitation. You are being invited to take part in this research study because you have sustained a lateral ankle sprain as diagnosed by a health care provider. This is a joint study between the University of Kentucky, the University of North Carolina at Chapel Hill, and William Beaumont Army Medical Center (WBAMC).

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to examine the effects of rehabilitation on short and long-term outcomes following lateral ankle sprain.

By doing this study, we hope to learn how the initial treatment of lateral ankle sprain affects future return to full activity, function, and pain.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this research study you will have the opportunity to engage in unique opportunity to engage in unique performance measures that will be tracked as you progress through a prescribed ankle rehabilitation program under the guidance of a health care professional, and during a follow-up period of 12 months after you have completed rehabilitation for your ankle sprain. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not participate in this study if you have had a lower extremity fracture or surgery, previous history of ankle sprain to either limb, and acute lower extremity or head trauma in the 3 months prior to testing.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You may choose not to participate in this study, and your care will not be affected in any way. There is no alternative research study to participating in this study. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study at each site. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Phillip Gribble at 859-218-0885 or phillip.gribble@uky.edu. (UK), Eric Wikstrom at 919-962-2260 or ewikstro@email.unc.edu (UNC), MAJ Gary Helton at 915-742-1511 or gary.l.helton8.mil@mail.mil (WBAMC).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify for this study if you have had a lower extremity fracture or surgery, previous history of ankle sprain to either limb, and acute lower extremity or head trauma in the 3 months prior to testing.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

If you are enrolling at the University of Kentucky, the research procedures will be conducted at the University of Kentucky Sports Medicine Research Institute (UK-SMRI), Musculoskeletal Laboratory (MSL), Magnetic Resonance Imaging and Spectroscopy Center (MRISC) and in your home.

If you are enrolling at the University of North Carolina, the research procedures will be conducted at the Sports Medicine Research Laboratory and UNC Health Care.

If you are enrolling at WBAMC, the research procedures will be conducted at the Department of Physical Therapy and the Department of Radiology for testing procedures.

For all sites: The initial in-person visit will take approximately 20 minutes to be consented and complete some surveys. You will be required to report for supervised rehabilitation sessions (about 3-4 times week) for up to eight weeks. Each of these rehabilitation sessions will last approximately 45 minutes. Additionally, you will be given some rehabilitation exercises to perform at home. You will be required to come to your campus sites for three testing sessions: at the completion of your rehab, six months after rehab, and 12 months after rehab. Each of these testing sessions will last approximately 120 minutes.

WHAT WILL YOU BE ASKED TO DO?

Rehabilitation Intervention

You will be asked to complete a supervised rehabilitation program that will focus on improving your strength, range of motion, balance, and physical function. You will report to a designated facility for sessions 3-4 times per week under the supervision of a licensed physical therapist and/or athletic trainer. He or she will guide through sessions lasting approximately 20-30 minutes. Additionally, you will be given hard copy printouts of some additional rehabilitation exercises you will be asked to complete in your home on the days that you do not come to our facilities for supervised sessions. You will be asked to keep records of your completed home rehabilitation sessions. These rehabilitation sessions will commence begin within 48 hours after you agree to participate in this study, and will continue for up to 8 weeks, depending on the severity of your ankle sprain.

Laboratory Measurements

We will take several measurements in our facilities on our campus to track your progress of your recovery from your ankle sprain. This battery of measurements will be repeated at multiple time points. The first visit will take place within a few days after you agree to enroll in this study, and will serve as your baseline. A second scheduled session will take place within a few days after your final rehabilitation session and will indicate your status when you are ready to return to full activity. A third session will be scheduled approximately 6 months after you return to activity to serve as a follow-up. A fourth and final session will be scheduled approximately 12 months after you return to activity to serve as a final follow-up.

The tasks and tests that will be used in these testing sessions include:

Self-Reported Questionnaires:

You will be asked to complete multiple self-report surveys. These surveys will ask you about how you feel about your overall health and physical activity, as well as the health of your ankles. This survey will be assessed at the initial encounter, as well as when you return to full activity, six months, and 12 months following the initial injury. The survey will be emailed to you for the follow up periods.

Dynamic Balance:

By balancing on one leg we will be able to assess your dynamic postural control. You will be positioned in the center of a grid resembling a “Y” that is outlined by three standard metric tape measures secured to the ground. You will be instructed to place your hands on your hips and stand on one leg. Next, you will reach as far as you can with your opposite leg while maintaining your balance and keeping your heel flat on the ground. Four practice trials for each direction will be provided and then three test trials for each direction will be recorded. Failed trials will be repeated until three successful trials are recorded for data analysis.

Ankle Range of Motion:

We will test how far you are able to comfortably move your ankle in a standing and in a seated position. During the standing position you will face a wall and place your hands on the wall to help maintain balance. Your feet will be placed in a tandem position (one foot in front of the other) over a secured tape measure. You will be asked to lunge as far as you feel comfortable until the front of your knee touches the wall and keeping your heel on the ground. During the seated position, you will sit on the edge of a treatment table and you will be asked to pull your toes up towards your head as far as you feel comfortable.

Maximal Ankle Muscle Response:

This test provides an estimate of how well nerves in the lower legs function. This test is conducted while you are lying down. You will be asked to relax your musculature. Two electromyography (EMG) electrodes (stickers) will be placed over your lower leg muscle (the soleus) on the testing leg and the medial malleolus on the non-testing leg. These electrodes do not do anything to you; they simply record your normal muscle electrical activity. The areas of the EMG electrodes will be shaved, gently scraped with fine sandpaper, and cleaned with isopropyl alcohol wipes. This is done to help the electrodes get the best reading possible of the muscles under that skin area. An electrode that provides a stimulus will be taped on the backside of your knee. Several reflex measurements will be taken while you are lying down.

These measurements include several brief (1-millisecond) electrical stimuli in order to make the nerve respond reflexively. The intensity of each stimulus will vary depending on the reflex being elicited. You will feel the stimuli similar to static electricity felt as you touch a doorknob after walking across carpet.

Neural Excitability:

This testing provides us important information regarding how your brain is sending messages to muscles controlling your ankle. You will be asked to sit in a chair that resembles a car seat. You will have a seat belt applied so that you do not move your body as you attempt to contract your lower leg muscles as hard as you can. Specifically, you will be asked to move your ankle like you are pushing down on a gas pedal as hard as you can and hold it for five seconds. You will then be asked to pull your ankle towards you as hard as you can. We will position a coil over your head and adjust the position of the coil until it is in the ideal spot to deliver a stimulus to the muscles we are studying. We will ask you to wear a swim cap and ear plugs. A brief magnetic stimulus will then be produced which will sound like a “click.” You may feel a brief muscle contraction in the muscles of your ankle. You will be asked to flex certain lower leg muscles at a small to moderate intensity while we provide a series of brief magnetic stimuli to your head. Sets of 8 stimuli will be delivered. The intensity of the stimuli will be varied up and down with each set until the researchers find the lowest intensity possible that makes your muscle contract 4 out of 8 times during a set. Stickers (electrodes) will be placed on the skin overlying the muscles of your legs (the soleus and tibialis anterior muscles). These electrodes record the activity of your muscles. This process will take approximately 20 minutes.

Brain Structure and Ankle Joint Structure Using MRI

You will be taken to the MRI scanner in the Magnetic Resonance Imaging and Spectroscopy Center by the experimenter. In the interest of your individual safety, the safety of others, and to prevent damage to the equipment itself, you will be asked to remove all jewelry, body piercings, hair accessories, belts, wallets, credit cards, and loose change and leave these items with the experimenter. You will also fill out a short questionnaire asking about the presence of metal in your body. You will then be instructed about specific MRI procedures, which include the need to remain still while in the scanner, the need to remain attentive and awake during the study, and how we will communicate with you while you are in the MRI scanner. The experimenter will then place you on the bed of the MRI scanner and will take a few minutes to make sure you are positioned correctly and are comfortable. You are then placed into the MRI scanner, the experimenter goes to the control room and communicates with you via an intercom system.

We will take scans of your brain and of your ankle. The MRI scans will start with a scan of your brain. You will be asked to lay flat on your back on a table that will slide into the scanner. We will place a coil around your head neck that resembles a neck brace. Once you indicate you are comfortable, the table will slide into the scanner and the procedures will begin. After the brain scan is complete, the table will slide you out of the scanner and the neck coil will be removed. You will be asked to reposition yourself on the table so that your feet are now facing the scanner. A flexible coil will be wrapped around your foot and lower leg comfortably, and then the table will slide into the scanner again to complete the scan of your ankle.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

When participating in any research study, you may encounter some risks. Although the risk for taking part in this study is very low, you may experience one or more of the following:

1. Because you are performing balance tests, there is a slight chance of falling and or losing your balance during the testing. However, you will be given instruction on how to perform the task and as much practice as you need to become comfortable with the task. Finally, an investigator will be standing nearby in the unlikely event that you need assistance.
2. You may experience minor muscle soreness or tiredness for one to three days following the study as you would after exercising strenuously or doing a new activity for the first time. You will be given the rest periods between test trials in order to minimize this risk.
3. You might experience minor discomfort from noise associated with the magnetic stimulation pulse (less likely risk). To minimize this risk, you will be offered ear plugs to wear during testing. Hearing loss has also been reported, but only in patients given multiple repetitive magnetic stimulation to treat disorders such as depression. You will not be receiving repetitive magnetic stimulation.
4. You may experience mild, temporary skin irritation from the electrodes and markers, although this is a very unlikely risk.
5. You may experience a mild headache following magnetic stimulation and lasting a few hours after testing although these risks are very unlikely risks.
6. In individuals with a history of seizures, there is a slight possibility of causing a seizure with the magnetic stimulation; therefore, you must tell us prior to testing if you have ever had a seizure so we can exclude you from the study.
7. Magnetic stimulation of the brain is safe; however, it may have short or long-term risks associated with it that are not presently known or suspected. If you become pregnant, the particular procedures involved in the study may involve risks to the embryo or fetus that are currently unknown.
8. If during the MRI an incidental finding is seen, we will provide you a recommendation for possible follow-up with your physician.

The risks of participating in the MRI study are outlined in the table below.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Claustrophobia	It occasionally occurs	Can be treated	Yes, participant is removed from the magnet
Loud noise	It is expected to occur	Not serious	Yes, participants wear ear protection

There is a slight chance of falling and or losing balance of participants during a balance assessment, or feeling tired while walking. In addition to the risks listed below, you may experience a previously unknown risk or side effect.

There is an extremely small risk of loss of confidentiality. The investigators will make every effort to maintain each and every participant's confidentiality. While the information gained during this study is not typically considered sensitive, injury information from an athletic population may be considered sensitive. The investigators will record all information in the database, but it will not be linked to your name in a database. To reduce the risk of loss of confidentiality, all collected data will be kept in a locked cabinet in the principal investigator's office, or on a password protected computer. Only the investigators in this study will have access to the data that is collected. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help certified athletic trainers, physical therapists, and sports medicine physicians to better treat ankle injuries across the population.

WHAT WILL IT COST YOU TO PARTICIPATE?

There will be no cost involved in participating in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

Officials of the Department of Defense, the University of Kentucky, and U.S. Army Medical Research and Materiel Command may look at or copy pertinent portions of records that identify you.

REDCap, a secure, web-based program, will be used to capture and store data at the University of Kentucky. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to the server.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition*;
- authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.
- For WBAMC: Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep all names and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

First, we will give everyone a code number and remove their names from all data collection documents. All information that is collected will be kept in a locked cabinet in an investigator's office. All electronic data will be password protected.

Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky, University of North Carolina, WBAMC, and the Department of Defense.

The information that we obtain from you may be included in future studies for other types of comparisons. However, the information used will have no identifiable link to your personal identification.

Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still in route to us.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

For patients enrolled at WBAMC, you may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. Whether or not you withdrawal your participation in this research study will have no effect on your current or future relationship with the US Army, Department of Defense, or military status. Whether or not you withdraw, your participation in this research study will have no effect on your current or future medical care within the military.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Phillip Gribble at 859-218-0885 immediately.

Dr. Phillip Gribble and the local principal investigator will work together to determine what type of treatment, if any, is best for you at that time.

For patients enrolled at UK or UNC: It is important for you to understand that the University of Kentucky, University of North Carolina, or WBAMC do not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, neither the University of Kentucky nor the University of North Carolina will pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be

- your responsibility
- or**
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or**
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be costly.

For patients enrolled at WBAMC:

If you think that you have a research-related injury, notify your Principal Investigator immediately: MAJ Gary Helton at 915-742-1511.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

For all participants: You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

The Department of Defense is providing funding in support of this study.

For non-military personnel, you will receive \$100 payment for completing all aspects of the study. For military personnel, per DOD guidelines you will not be paid for your participation in this study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. Because the investigators will not have access to information that identifies you, the research findings will generally not be provided to you.

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Dr. Phillip Gribble; 900 South Limestone, 206C Wethington Building, University of Kentucky, Lexington, KY 40536-0200.

WHAT ELSE DO YOU NEED TO KNOW?

A description of this clinical trial will be available on [ClinicalTrials.gov](https://clinicaltrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION OR SPECIMEN(S):

Identifiable information such as your name, medical record number, or date of birth may be removed from the information or samples collected in this study. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information (Date of birth, age, gender, race, ethnicity, occupation)
- Last four digits of social security number
- Military identification number
- Contact information

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- WBAMC Human Research Protection Office Representatives
- Officials at the Department of Defense and U.S. Army Medical Research and Materiel Command

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky, the University of North Carolina, or WBAMC;
- Current or future payments to the University of Kentucky, the University of North Carolina, or WBAMC;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Phillip Gribble, phillip.gribble@uky.edu, Room 206C Wethington Building, 900 South Limestone Street, Lexington, Kentucky 40536-0200 to inform him of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information. The use and sharing of your information has no time limit.
- Your health information is being used for this study only and is not requested for future research studies.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent
- Authorization to Use or Disclose Your Identifiable Health Information

You will receive a copy of this consent form after it has been signed.

Signature of research subject <i>or, if applicable, research subject's legal representative</i>	Date
Printed name of research subject	
Printed name of [authorized] person obtaining informed consent and HIPAA authorization <i>(if HIPAA applies)</i>	Date
Signature of Principal Investigator or Sub/Co-Investigator	

Subject: A-20657.1c, Amendment Approval Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Friday, September 6, 2019 at 10:21:06 AM Eastern Daylight Time

From: Englar, Nancy E CIV USARMY MEDCOM USAMRMC (USA)

To: Golden, Andrew P CPT USARMY MEDCOM WBAMC (USA)

CC: 'kcarter.1@uky.edu', Office of Sponsored Projects Administration, Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US), Gribble, Phillip, Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA), Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (US), Schmersal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (USA), Englar, Nancy E CIV USARMY MEDCOM USAMRMC (USA), Gibbs, Katelyn D CTR USARMY MEDCOM USAMRMC (USA)

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Amendment for the Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by CPT Andrew P. Golden, William Beaumont Army Medical Center, El Paso, Texas, in Support of the Proposal, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by Phillip A. Gribble, PhD, University of Kentucky, Lexington, Kentucky, Proposal Log Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Number A-20657.1c

1. The subject protocol received initial approval by the U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) on 5 July 2019.
2. An amendment to this no greater than minimal risk protocol was received by the HRPO on 16 August 2019. The University of Kentucky Institutional Review Board (IRB) approved the amendment on 29 July 2019. William Beaumont Army Medical Center is relying on the review by University of Kentucky IRB.
3. The amendment allows for a change in Principal Investigator from MAJ Gary Helton to CPT Andrew Golden along with several minor non-substantive modifications.
4. The changes proposed in the amendment have been reviewed by the HRPO and found to be acceptable. The HRPO approves the protocol amendment.
5. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil. Failure to comply could result in suspension of funding.
 - a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRDC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in the IRB of Record, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

b. A copy of the IRB continuing review approval letter must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the IRB is due no later than 6 February 2020. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

d. The following study events must be promptly reported to the HRPO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), by facsimile (301-619-7803), or mail to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

(1) All unanticipated problems involving risk to subjects or others.

(2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

(3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

(4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

(5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

(6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

6. Please note: The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

7. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds by notice of official award documentation. It is recommended that you contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

8. The HRPO point of contact for this action is Katelyn Gibbs, BA, Human Subjects Protection Scientist, at 301-619-7839, DSN 343-7839, or katelyn.d.gibbs.ctr@mail.mil.

NANCY E. ENGLAR, MHL, BSN, RN, CIP
Human Subjects Protection Scientist
Human Research Protection Office
Office of Research Protections
U.S. Army Medical Research and Development Command

Note: The official copy of this memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 810 Schreider Street, Fort Detrick, MD 21702-5000. Signed copies will be provided upon request.
CLASSIFICATION: UNCLASSIFIED

Subject: Re: A-20657.1c, Amendment Approval Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Saturday, February 1, 2020 at 8:27:10 AM Eastern Standard Time

From: Gribble, Phillip A.

To: Englar, Nancy E CIV USARMY MEDCOM USAMRMC (USA), Klein, Natalie M CIV USARMY MEDCOM USAMRMC (US), Gibbs, Katelyn D CTR USARMY MEDCOM USAMRMC (USA)

CC: Schmursal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Larson, Karen, Williams, Jessica R., Brown, Joe, Golden, Andrew P CPT USARMY MEDCOM WBAMC (USA)

Attachments: image001.png, 56691_ApprovalLetter_244016.pdf, 56691_Stamped Consent Form_244015.pdf, HIPAA Authorization_27Jan2020[1].docx

Good morning,

This email memo is to serve two purposes:

1. To indicate that we have obtained approval of the continuation review (CR) from the University of Kentucky (UK) IRB of our previously approved protocol. Please find this letter of approval attached.
2. To indicate a substantive change for post-approval HRPO review that accompanies the UK IRB CR.
 - It was discovered during the recent CR that the existing common consent form that was approved for study implementation needed to be modified. We are using a common consent form for all three study sites: UK, University of North Carolina (UNC), and William Beaumont Army Medical Center (WBAMC), with approval from all three site IRBs. In JAN 20, UK IRB alerted me that the previously approved consent form had language related to HIPAA authorization that was not in compliance with UK policies. This HIPAA authorization language was provided to me from Dr. Larissa Schmursal during the HRPO Administrative review and related to HIPAA Authorization required for enrollment of participants at WBAMC. This language was included in a version of the consent form that was reviewed and approved by HRPO in JUL 19 and then provided to UK IRB for approval as the primary IRB in JUL 19 for modification review to the approved protocol.
 - As an oversight, I did not alert UK IRB that this language was added to a revised consent form, and UK IRB did not detect the added language during that review in JUL 19. UK IRB policy is that that UK cannot serve as the HIPAA authorization board for other institutions, and therefore this should not have been included in the approved consent form. However, the protocol and associated consent form were approved and study enrollment commenced in OCT 19. Three participants were enrolled under the approved common consent form with the HIPAA language included before the error was discovered: 1 at UK and 2 at WBAMC.
 - In JAN 20 in the annual CR of the protocol by UK IRB, the oversight error was discovered and UK IRB representative Karen Larson contacted me. Immediately, I contacted study personnel at UK, UNC, and WBAMC that enrollment was suspended until the matter was addressed.
 - Rapid efforts were made between UK IRB and WBAMC IRB officers to rectify the situation during JAN 19. The solution that was discussed was that the HIPAA authorization language would be removed from the common consent form. Subsequently, the consent form was approved by UK IRB and a copy is attached to this email.
 - The plan discussed with Dr. Schmursal moving forward to meet HIPAA compliance requirements for WBAMC is that study investigators at WBAMC will also use an approved HIPAA authorization form during enrollment (see attached) in addition to the approved consent form. This form has been discussed and reviewed by Dr. Schmursal and me. She has indicated approval of the attached HIPAA authorization form that will be used only in participants at WBAMC which will satisfy requirements for this site, but does not affect the enrollment procedures at the other study sites. UK IRB is aware and in support of this plan following discussions between Ms. Williams and Dr. Schmursal.

- Therefore, I submit the CR from UK IRB in approval of the protocol, along with the modified common consent form approved by UK IRB and the HIPAA authorization form supported by WBAMC to address the issues that were discovered and have been discussed between the IRB officers and me. I also understand that Dr. Schmursal had a communication with Dr. Klein to alert her of these circumstances and that this communication from me would be coming.
- Following up to this issue, all 3 previously enrolled participants will be re-consented with the appropriate consent forms and HIPAA authorization forms (as necessary). I will be providing copies of these re-consent documents to UK-IRB officers.
- I believe that we have responded rapidly and efficiently to this oversight and I am grateful to the UK (Larson, Williams, Brown) and WBAMC (Schmursal) IRB officers and staff that have assisted in rectifying these issues.

Please let me know if there are questions or follow-up information needed.

Phillip



Phillip Gribble, PhD, ATC, FNATA

Chair and Professor

University of Kentucky

Department of Athletic Training & Clinical Nutrition, College of Health Sciences

210 Charles T. Wethington Building

Lexington, KY 40536-0200

859-218-0885

phillip.gribble@uky.edu

From: "Englar, Nancy E CIV USARMY MEDCOM USAMRMC (USA)" <nancy.e.englar.civ@mail.mil>

Date: Friday, September 6, 2019 at 10:21 AM

To: "Golden, Andrew P CPT USARMY MEDCOM WBAMC (USA)" <andrew.p.golden3.mil@mail.mil>

Cc: "'kcarter.1@uky.edu'" <kcarter.1@uky.edu>, Office of Sponsored Projects Administration <OSPA@uky.edu>, "Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US)"

<jodi.h.bennett.civ@mail.mil>, "Gribble, Phillip" <phillip.gribble@uky.edu>, "Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA)" <christopher.l.meinberg.civ@mail.mil>, "Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (US)" <darius.j.ghannadian.civ@mail.mil>, "Schmursal, Larissa A CIV USARMY MEDCOM WBAMC (USA)" <larissa.a.schmursal.civ@mail.mil>, "Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (USA)" <kimberly.l.odam.civ@mail.mil>, "Englar, Nancy E CIV USARMY MEDCOM USAMRMC (USA)" <nancy.e.englar.civ@mail.mil>, "Gibbs, Katelyn D CTR USARMY MEDCOM USAMRMC (USA)" <katelyn.d.gibbs.ctr@mail.mil>

Subject: A-20657.1c, Amendment Approval Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Amendment for the Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by CPT Andrew P. Golden, William Beaumont Army Medical Center, El Paso, Texas, in Support of the Proposal, "Addressing Neuromuscular

FL Continuation Review

Approval Ends:
1/15/2021IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval for Continuation

DATE: 1/22/2020

On 1/16/2020, the Medical Institutional Review Board approved your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

Summary of the event: We are the IRB of record for UK, UNC-Chapel Hill, and William Beaumont Army Medical Center (WBAMC). However, since this is DOD-funded, DOD's HRPO has been heavily involved in reviewing the project on their end, so everything has to go through UK's IRB and HRPO. Dr. Gribble combined all consents at the beginning of the study activation, because there was no HIPAA involved. After HRPO reviewed, they added HIPAA/Authorization language into the ICF, as this is apparently required in order for WBAMC to participate in the study (they require HIPAA, but UNC and UK do not). But, when Dr. Gribble submitted the ICF/HIPAA combined (which is not permissible as we cannot be the privacy board for other sites), **this language was not highlighted and therefore was not identified by ORI staff or the IRB.**

The IRB acknowledged the protocol violation for your protocol. The IRB determined the events did not meet the criteria for serious noncompliance or continuing noncompliance on the parts of the Principal Investigator (PI), nor the UK ORI/IRB. The IRB accepted the corrective action plan submitted by the Principal Investigator (PI) and the ORI staff.

The PI's corrective action plan is as follows:

- PI immediately informed the other sites to stop enrolling subjects on prior stamped Consent Forms containing the HIPAA Authorization language that he had sent to them.
- PI immediately informed his DoD contact person/HRPO about this issue.
- PI submitted a detailed memo as to the issue. He verified three subjects had been enrolled using the Consent Form that contained the HIPAA Authorization section in it; two at WBAMC and one at UK.
- PI submitted a revised Consent Form that removed the HIPAA Authorization section. In the future, the PI will require another study personnel, including Dr. Kyle Kosik and Ms. Katie Roberts to review all materials submitted for future Modification Reviews as oversight.
- PI will also look into hiring a Study Coordinator, to replace person who left the position last year.

UK ORI/IRB's corrective action plan is as follows:

- For future studies involving multiple sites, where UK IRB is the IRB of record, separate Consent Forms will be used for each individual site.
- Members of the Reliance Team will be involved in reviewing any changes to Consent Forms submitted as Modification Requests or as part of Continuation Review.

The UK IRB (as the Reviewing IRB of Record) requests the PI to inform the relying sites of the IRB's determinations, which are as follows:

- The UK IRB will not serve as a Privacy Board/HIPAA Board for relying sites. If HIPAA is required by any other relying sites, those sites are responsible for creation of a separate HIPAA Authorization, for their site and implementation of it with prior enrolled subjects and all future subjects.
- The subjects that signed a Consent Form that contained a HIPAA Authorization section, need to be re-consented on the new stamped Consent Form dated 1.16.20.
- At next year's Continuation Review, the PI is to include a memo to the IRB, updating the IRB on the progress of re-consenting the subjects.

Please share this letter with the relying sites.

Approval is effective from 1/16/2020 until 1/15/2021 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, the IRB approved consent/assent document(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of

this period, you will be sent a Continuation Review (CR)/Administrative Annual Review (AAR) request which must be completed and submitted to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.



Consent to Participate in a Research Study

ADDRESSING NEUROMUSCULAR DEFICITS FOR IMPROVED OUTCOMES IN ANKLE REHABILITATION

IRB Approval
1/16/2020
IRB # 44172
IRB3

You are being invited to take part in a research study about successful outcomes following lateral ankle sprain rehabilitation. You are being invited to take part in this research study because you have sustained a lateral ankle sprain as diagnosed by a health care provider. This is a joint study between the University of Kentucky, the University of North Carolina at Chapel Hill, and William Beaumont Army Medical Center (WBAMC).

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to examine the effects of rehabilitation on short and long-term outcomes following lateral ankle sprain.

By doing this study, we hope to learn how the initial treatment of lateral ankle sprain affects future return to full activity, function, and pain.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this research study you will have the opportunity to engage in unique opportunity to engage in unique performance measures that will be tracked as you progress through a prescribed ankle rehabilitation program under the guidance of a health care professional, and during a follow-up period of 12 months after you have completed rehabilitation for your ankle sprain. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not participate in this study if you have had a lower extremity fracture or surgery, previous history of ankle sprain to either limb, and acute lower extremity or head trauma in the 3 months prior to testing.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You may choose not to participate in this study, and your care will not be affected in any way. There is no alternative research study to participating in this study. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study at each site. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Phillip Gribble at 859-218-0885 or phillip.gribble@uky.edu. (UK), Eric Wikstrom at 919-962-2260 or ewikstro@email.unc.edu (UNC), CPT Andrew Golden at 915-742-1339 or andrew.p.golden3.mil@mail.mil (WBAMC).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify for this study if you have had a lower extremity fracture or surgery, previous history of ankle sprain to either limb, and acute lower extremity or head trauma in the 3 months prior to testing.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

If you are enrolling at the University of Kentucky, the research procedures will be conducted at the University of Kentucky Sports Medicine Research Institute (UK-SMRI), Musculoskeletal Laboratory (MSL), Magnetic Resonance Imaging and Spectroscopy Center (MRISC) and in your home.

If you are enrolling at the University of North Carolina, the research procedures will be conducted at the Sports Medicine Research Laboratory and UNC Health Care.

If you are enrolling at WBAMC, the research procedures will be conducted at the Department of Physical Therapy and the Department of Radiology for testing procedures.

For all sites: The initial in-person visit will take approximately 20 minutes to be consented and complete some surveys. You will be required to report for supervised rehabilitation sessions (about 3-4 times week) for up to eight weeks. Each of these rehabilitation sessions will last approximately 45 minutes. Additionally, you will be given some rehabilitation exercises to perform at home. You will be required to come to your campus sites for three testing sessions: at the completion of your rehab, six months after rehab, and 12 months after rehab. Each of these testing sessions will last approximately 120 minutes.

WHAT WILL YOU BE ASKED TO DO?

Rehabilitation Intervention

You will be asked to complete a supervised rehabilitation program that will focus on improving your strength, range of motion, balance, and physical function. You will report to a designated facility for sessions 3-4 times per week under the supervision of a licensed physical therapist and/or athletic trainer. He or she will guide through sessions lasting approximately 20-30 minutes. Additionally, you will be given hard copy printouts of some additional rehabilitation exercises you will be asked to complete in your home on the days that you do not come to our facilities for supervised sessions. You will be asked to keep records of your completed home rehabilitation sessions. These rehabilitation sessions will commence begin within 48 hours after you agree to participate in this study, and will continue for up to 8 weeks, depending on the severity of your ankle sprain.

Laboratory Measurements

We will take several measurements in our facilities on our campus to track your progress of your recovery from your ankle sprain. This battery of measurements will be repeated at multiple time points. The first visit will take place within a few days after you agree to enroll in this study, and will serve as your baseline. A second scheduled session will take place within a few days after your final rehabilitation session and will indicate your status when you are ready to return to full activity. A third session will be scheduled approximately 6 months after you return to activity to serve as a follow-up. A fourth and final session will be scheduled approximately 12 months after you return to activity to serve as a final follow-up.

The tasks and tests that will be used in these testing sessions include:

Self-Reported Questionnaires:

You will be asked to complete multiple self-report surveys. These surveys will ask you about how you feel about your overall health and physical activity, as well as the health of your ankles. This survey will be assessed at the initial encounter, as well as when you return to full activity, six months, and 12 months following the initial injury. The survey will be emailed to you for the follow up periods.

Dynamic Balance:

By balancing on one leg we will be able to assess your dynamic postural control. You will be positioned in the center of a grid resembling a “Y” that is outlined by three standard metric tape measures secured to the ground. You will be instructed to place your hands on your hips and stand on one leg. Next, you will reach as far as you can with your opposite leg while maintaining your balance and keeping your heel flat on the ground. Four practice trials for each direction will be provided and then three test trials for each direction will be recorded. Failed trials will be repeated until three successful trials on the testing leg are recorded for data analysis.

Static Balance:

By balancing on one leg we will be able to assess your static postural control. You will be positioned in the center of a metal plate. You will be instructed to place your hands on your hips and stand on one leg. You will do this test with your eyes open and your eyes closed. After a few practice trials are provided, you will perform three test trials for each eye condition (open and closed). Failed trials will be repeated until a total of six successful trials on the testing leg are recorded for data analysis.

Walking Assessment:

We will measure the movement patterns of how you walk. We will attach several reflective markers using double-sided tape to several spots on your feet, ankles, legs, hips, trunk and shoulders. These markers along with specialized cameras in our laboratory will allow us to create an animation of the way your body moves while you walk. You will wear these markers while you walk across the floor in the laboratory in a straight line for approximately 40 feet at a pace that is your normal, self-selected walking speed. In the middle of the laboratory, there are metal plates flush with the floor that measure the force under your feet while you walk. During your trials, your feet will make contact with these plates, which will feel no different than while you are walking on the floor. After a few practice trials, you will complete 5 walking trials down the straight-line path on the laboratory floor. Failed trials will be repeated until a total of 5 successful trials are completed.

Ankle Range of Motion:

We will test how far you are able to comfortably move your ankle in a standing and in a seated position. During the standing position you will face a wall and place your hands on the wall to help maintain balance. Your feet will be placed in a tandem position (one foot in front of the other) over a secured tape measure. You will be asked to lunge as far as you feel comfortable until the front of your knee touches the wall and keeping your heel on the ground. During the seated position, you will sit on the edge of a treatment table and you will be asked to pull your toes up towards your head as far as you feel comfortable.

Maximal Ankle Muscle Response:

This test provides an estimate of how well nerves in the lower legs function. This test is conducted while you are lying down. You will be asked to relax your musculature. Two electromyography

(EMG) electrodes (stickers) will be placed over your lower leg muscle (the soleus) on the testing leg and the medial malleolus on the non-testing leg. These electrodes do not do anything to you; they simply record your normal muscle electrical activity. The areas of the EMG electrodes will be shaved, gently scraped with fine sandpaper, and cleaned with isopropyl alcohol wipes. This is done to help the electrodes get the best reading possible of the muscles under that skin area. An electrode that provides a stimulus will be taped on the backside of your knee. Several reflex measurements will be taken while you are lying down.

These measurements include several brief (1-millisecond) electrical stimuli in order to make the nerve respond reflexively. The intensity of each stimulus will vary depending on the reflex being elicited. You will feel the stimuli similar to static electricity felt as you touch a doorknob after walking across carpet.

Neural Excitability:

This testing provides us important information regarding how your brain is sending messages to muscles controlling your ankle. You will be asked to sit in a chair that resembles a car seat. You will have a seat belt applied so that you do not move your body as you attempt to contract your lower leg muscles as hard as you can. Specifically, you will be asked to move your ankle like you are pushing down on a gas pedal as hard as you can and hold it for five seconds. You will then be asked to pull your ankle towards you as hard as you can. We will position a coil over your head and adjust the position of the coil until it is in the ideal spot to deliver a stimulus to the muscles we are studying. We will ask you to wear a swim cap and ear plugs. A brief magnetic stimulus will then be produced which will sound like a "click." You may feel a brief muscle contraction in the muscles of your ankle. You will be asked to flex certain lower leg muscles at a small to moderate intensity while we provide a series of brief magnetic stimuli to your head. Sets of 8 stimuli will be delivered. The intensity of the stimuli will be varied up and down with each set until the researchers find the lowest intensity possible that makes your muscle contract 4 out of 8 times during a set. Stickers (electrodes) will be placed on the skin overlying the muscles of your legs (the soleus and tibialis anterior muscles). These electrodes record the activity of your muscles. This process will take approximately 20 minutes.

Brain Structure and Ankle Joint Structure Using MRI

You will be taken to the MRI scanner in the Magnetic Resonance Imaging and Spectroscopy Center by the experimenter. In the interest of your individual safety, the safety of others, and to prevent damage to the equipment itself, you will be asked to remove all jewelry, body piercings, hair accessories, belts, wallets, credit cards, and loose change and leave these items with the experimenter. You will also fill out a short questionnaire asking about the presence of metal in your body. You will then be instructed about specific MRI procedures, which include the need to remain still while in the scanner, the need to remain attentive and awake during the study, and how we will communicate with you while you are in the MRI scanner. The experimenter will then place you on the bed of the MRI scanner and will take a few minutes to make sure you are positioned correctly and are comfortable. You are then placed into the MRI scanner, the experimenter goes to the control room and communicates with you via an intercom system.

We will take scans of your brain and of your ankle. The MRI scans will start with a scan of your brain. You will be asked to lay flat on your back on a table that will slide into the scanner. We will place a coil around your head/neck that resembles a neck brace. Once you indicate you are comfortable, the table will slide into the scanner and the procedures will begin. After the brain scan is complete, the table will slide you out of the scanner and the neck coil will be removed. You will be asked to reposition yourself on the table so that your feet are now facing the scanner. A flexible

coil will be wrapped around your foot and lower leg comfortably, and then the table will slide into the scanner again to complete the scan of your ankle.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

When participating in any research study, you may encounter some risks. Although the risk for taking part in this study is very low, you may experience one or more of the following:

1. Because you are performing balance tests, there is a slight chance of falling and or losing your balance during the testing. However, you will be given instruction on how to perform the task and as much practice as you need to become comfortable with the task. Finally, an investigator will be standing nearby in the unlikely event that you need assistance.
2. You may experience minor muscle soreness or tiredness for one to three days following the study as you would after exercising strenuously or doing a new activity for the first time. You will be given the rest periods between test trials in order to minimize this risk.
3. You might experience minor discomfort from noise associated with the magnetic stimulation pulse (less likely risk). To minimize this risk, you will be offered ear plugs to wear during testing. Hearing loss has also been reported, but only in patients given multiple repetitive magnetic stimulation to treat disorders such as depression. You will not be receiving repetitive magnetic stimulation.
4. You may experience mild, temporary skin irritation from the electrodes and markers, although this is a very unlikely risk.
5. You may experience a mild headache following magnetic stimulation and lasting a few hours after testing although these risks are very unlikely risks.
6. In individuals with a history of seizures, there is a slight possibility of causing a seizure with the magnetic stimulation; therefore, you must tell us prior to testing if you have ever had a seizure so we can exclude you from the study.
7. Magnetic stimulation of the brain is safe; however, it may have short or long-term risks associated with it that are not presently known or suspected. If you become pregnant, the particular procedures involved in the study may involve risks to the embryo or fetus that are currently unknown.
8. If during the MRI an incidental finding is seen, we will provide you a recommendation for possible follow-up with your physician.

The risks of participating in the MRI study are outlined in the table below.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Claustrophobia	It occasionally occurs	Can be treated	Yes, participant is removed from the magnet
Loud noise	It is expected to occur	Not serious	Yes, participants wear ear protection

There is a slight chance of falling and or losing balance of participants during a balance assessment, or feeling tired while walking. In addition to the risks listed below, you may experience a previously unknown risk or side effect.

There is an extremely small risk of loss of confidentiality. The investigators will make every effort to maintain each and every participant's confidentiality. While the information gained during this study is not typically considered sensitive, injury information from an athletic population may be considered sensitive. The investigators will record all information in the database, but it will not be linked to your name in a database. To reduce the risk of loss of confidentiality, all collected data will be kept in a locked cabinet in the principal investigator's office, or on a password protected

computer. Only the investigators in this study will have access to the data that is collected. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help certified athletic trainers, physical therapists, and sports medicine physicians to better treat ankle injuries across the population.

WHAT WILL IT COST YOU TO PARTICIPATE?

There will be no cost involved in participating in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

Officials of the Department of Defense, the University of Kentucky, and U.S. Army Medical Research and Materiel Command may look at or copy pertinent portions of records that identify you.

REDCap, a secure, web-based program, will be used to capture and store data at the University of Kentucky. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to the server.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition*;
- authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.
- For WBAMC: Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep all names and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

First, we will give everyone a code number and remove their names from all data collection documents. All information that is collected will be kept in a locked cabinet in an investigator's office. All electronic data will be password protected.

Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky, University of North Carolina, WBAMC, and the Department of Defense.

The information that we obtain from you may be included in future studies for other types of comparisons.

However, the information used will have no identifiable link to your personal identification.

Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still in route to us.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

For patients enrolled at WBAMC, you may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. Whether or not you withdrawal your participation in this research study will have no effect on your current or future relationship with the US Army, Department of Defense, or military status. Whether or not you withdraw, your participation in this research study will have no effect on your current or future medical care within the military.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Phillip Gribble at 859-218-0885 immediately.

Dr. Phillip Gribble and the local principal investigator will work together to determine what type of treatment, if any, is best for you at that time.

For patients enrolled at UK or UNC: It is important for you to understand that the University of Kentucky, University of North Carolina, or WBAMC do not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, neither the University of Kentucky nor the University of North Carolina will pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be

- your responsibility
- or**
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or**
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be costly.

For patients enrolled at WBAMC:

If you think that you have a research-related injury, notify your Principal Investigator immediately: CPT Andrew Golden at 915-742-1339.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

For all participants: You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

The Department of Defense is providing funding in support of this study.

For non-military personnel, you will receive \$100 payment for completing all aspects of the study. For military personnel, per DOD guidelines you will not be paid for your participation in this study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. Because the investigators will not have access to information that identifies you, the research findings will generally not be provided to you.

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Dr. Phillip Gribble; 900 South Limestone, 206C Wethington Building, University of Kentucky, Lexington, KY 40536-0200.

WHAT ELSE DO YOU NEED TO KNOW?

A description of this clinical trial will be available on [ClinicalTrials.gov](https://clinicaltrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION OR SPECIMEN(S):

Identifiable information such as your name, medical record number, or date of birth may be removed from the information or samples collected in this study. After removal, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research subject <i>or, if applicable, research subject's legal representative</i>	Date
Printed name of research subject	
Printed name of [authorized] person obtaining informed consent	Date
Signature of Principal Investigator or Sub/Co-Investigator	

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Protocol #

Principal Investigator (PI) Name and Rank: CPT Andrew Golden

Corps and Service/Organization: William Beaumont Army Medical Center

Title of Research Study: Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

I. Purpose of this Document

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

We are requesting the use and disclosure of your health information to study how the initial treatment of lateral ankle sprain affects future activity, function, and pain.

Please note: Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty. We will keep private all research records that identify you to the extent allowed by law.

A. What health information will be used or disclosed about you?

Protected health information (PHI) required for the study will include: results of physical examinations, medical history, lab tests, or certain health information indicating or relating to your ankle injury may be used by researchers in the future, but will not be linked to identifying information. Treatment visits regarding your injury will be tracked in your medical record (AHLTA).

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep all names and other identifying information private.

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Protocol #

B. Who will be authorized to use or disclose (release) your health information?

Members of the research staff at William Beaumont Army Medical Center (Kathryn Roberts, MS, ATC and Andrew Golden, DPT) will have access to your health information for the purposes of treatment of your injury and the study. De-identified information will be shared with the approved research team at University of Kentucky.

C. Who may receive your health information?

Officials of the Department of Defense, the University of Kentucky, and U.S. Army Medical Research and Materiel Command may look at or copy pertinent portions of records that identify you. Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky Institutional Review Board, the WBAMC Human Research Protections Office, and the Department of Defense.

REDCap, a secure, web-based program, will be used to capture and store data at the University of Kentucky. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to the server.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is

D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not receive research-related treatment.

The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

Yes, your health information is requested for future research studies as specified below:

The information that we obtain from you may be included in future studies for other types of comparisons. However, the information used will have no identifiable link to your personal identification.

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

☐ I give permission to use my health information for future research studies

☐ I do not give permission to use my health information for future research studies

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Protocol #

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

You may revoke your Authorization by sending a written request to : CPT Andrew Golden, DPT, Mendoza Soldier Family Care Center, Physical Therapy, 11335 SSG Sims St., Fort Bliss, Texas 79918

H. Does this Authorization expire?

No, it does not expire

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

Protocol #

Signature of Research Participant or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

Participant Signature

Date

Participant Printed Name

If the personal representative signs on a participant's behalf, then the personal representative must provide verification of their authority under applicable state law.

Personal Representative Signature

Date

Personal Representative Printed Name

Description of the Personal Representative's
Authority

Subject: A-20657.1a, A-20657.1b, and A-20657.1c, Continuing Review Acceptance and Amendment Approval Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Wednesday, March 11, 2020 at 11:11:42 AM Eastern Daylight Time

From: Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (USA)

To: Gribble, Phillip A., Wikstrom, Erik A., Golden, Andrew P CPT USARMY MEDCOM WBAMC (USA)

CC: 'kcarter.1@uky.edu', Office of Sponsored Projects Administration, Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (USA), Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA), Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (USA), Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (USA), Schmursal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Kline, Andrea J CIV USARMY MEDCOM USAMRMC (USA), McLean, Allison L (Allie) CTR (USA), Larson, Karen, Brown, Joe

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Continuing Review Acceptance and Amendment Approval for the Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by Phillip A. Gribble, PhD, University of Kentucky (UK), Lexington, Kentucky, Erik Wikstrom, PhD, University of North Carolina (UNC), Chapel Hill, North Carolina, and CAPT Andrew P. Golden, William Beaumont Army Medical Center (WBAMC), El Paso, Texas, Proposal Log Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Numbers A-20657.1a (UK Site), A-20657.1b (UNC Chapel Hill Site), and A-20657.1c (WBAMC Site)

1. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the subject protocol on 5 July 2019.
2. The HRPO received a continuing review report for the subject protocol on 1 February 2020. The UNC, Chapel Hill and the WBAMC are relying on the review provided by the UK Institutional Review Board (IRB). The UK IRB approved continuation of the protocol on 16 January 2020; this approval will expire on 15 January 2021.
3. The submitted continuing review report and supporting documentation have been reviewed by the HRPO and found to be in compliance with Federal, DOD, and U.S. Army human subjects protection requirements. The report and supporting documents are accepted.
4. The HRPO received an amendment on 1 February 2020. The amendment revises the common consent form to remove HIPAA language and approves a standalone HIPAA authorization form for the WBAMC site only. The amendment was approved by the UK IRB on 16 January 2020.
5. The protocol change proposed in the amendment has been reviewed by the HRPO and found to be acceptable. The protocol amendment is approved.
6. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil. Failure to comply could result in suspension of funding.

a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRDC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in the IRB of Record, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

b. A copy of the IRB continuing review approval letter must be submitted to the HRPO as soon as possible after receipt of approval. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

d. The following study events must be promptly reported to the HRPO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), by facsimile (301-619-7803), or mail to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

(1) All unanticipated problems involving risk to subjects or others.

(2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

(3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

(4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

(5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

(6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

7. Please note: The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.