AWARD NUMBER: W81XWH-22-1-0532

TITLE: Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)

PRINCIPAL INVESTIGATOR: Neal Glaviano

CONTRACTING ORGANIZATION: University of Connecticut, Storrs, CT

REPORT DATE: July 2023

TYPE OF REPORT: Annual

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

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Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)

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W81XWH-22-1-0532

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Glaviano, Neal; DiStefano, Lindsay; Mangum, Lauren; Bazett-Jones, David; Toland, Michael; Boling, Michelle

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Connecticut
2095 Hillside Rd. U-1110
Storrs, CT 06269

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The primary purpose of this study will compare the effects of a 6-week strength exercises to a combination of strength and power exercises in individuals with patellofemoral pain. The proposed study will evaluate pain, self-reported function, and recurrence rates during a two-year follow-up after the intervention. Our hypothesis is that the combination of strength and power exercises will have greater improvements than the strength only group. The secondary purpose will evaluate changes in hip rate of torque development and single leg squat kinematics. The study is a multi-site randomized controlled trial being conducted at the University of Connecticut, University of Central Florida, and University of Toledo.

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	32	19b. TELEPHONE NUMBER *(include area code)*

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1. Introduction

Patellofemoral pain (PFP) is a common knee injury that accounts for 9.7-571.4 cases per 1000 person-years in the military. PFP presents as chronic knee pain during walking, running, jumping, squatting, and stair ambulation, placing a significant impact on activities of daily living and occupational military requirements. Current treatment programs target hip and thigh muscle weakness; however, programs do not target muscle power, which is the ability to generate force as quickly as possible. Recently evidence has emerged that hip muscle power has a greater difference between those with and without PFP than more standard strength measurements, suggesting power should be targeted with rehabilitation programs. Targeting power might improve rehabilitation outcomes in those with PFP. Long-term outcomes are suboptimal following current PFP treatment interventions, with over 90% of patients experiencing pain and dysfunction 5-18 years after diagnosis. Currently, no rehabilitation programs that target hip muscle power have evaluated long-term outcomes in a PFP population. This study will compare the effects of standard of care (SOC) intervention to a SOC that includes power-based exercises (Strength Training Rehabilitation Incorporating Power Exercises [STRIPE]) intervention in patients with patellofemoral pain (PFP). This study will evaluate rehabilitation strategies for PFP, with the focus on enabling return to duty within one year of injury.

2. Keywords

Patellofemoral pain, rehabilitation, hip, power

3. Accomplishments

SOW Goals	**Timeline**	**Achieved**
Major Task 1: Adapt standard of care and standard of care protocol with power-based exercises for patellofemoral pain	**Months**	**Y/N**
Coordinate with Sites for MOA	1-3	**Y**
Coordinate with Sites for material transfer agreements (MTAs) and clinical trial agreements (CTAs) submission	1-3	**Y**
Coordinate with Sites for nondisclosure agreements (NDAs).	1-3	**Y**
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 Connecticut IRB review	1-6	**Y**
Coordinate with Sites for USAMRDC review (ORP/HRPO)	1-6	**Y**
Clinicaltrial.gov registration	6	**Y**
Submit amendments, adverse events and protocol deviations as needed	As Needed	**Y**
Coordinate with Sites for annual IRB report for continuing review	Annually	**Y**
Milestone Achieved: Local IRB approval at UConn, UCF and UToledo	3	**Y**
Milestone Achieved: HRPO approval for all protocols and local IRB approval through University of Connecticut.	6	**Y**

Major Task 2: Train Study Staff for Clinical Trial		
Subtask 1: Facilitate and Coordinate with Sites for training, supervision and fidelity checks as needed for attrition		
Coordinate with Sites for training Independent Evaluators to maintain 100% concordance	1-3	**Y**
Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of clinical trial	3-4	**Y**
Subtask 2: Assess *inter-rater and intra-rater* reliability of all measures of interest across sites	4-6	**Y**
Milestone Achieved: Establish inter-rater and intra-rater reliability of all members of the study team	5-6	**Y**
Subtask 3. Publish study protocol with reliability data	6-9	**Y**
Milestone Achieved: Publish study protocol in peer-reviewed journal	6-9	**Y**
Major Task 3: Participant Recruitment, Therapy, Participant Evaluation		
Subtask 1: Study 1, Randomized Controlled Trial		
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-8	**Y**
Finalize assessment measurements	1-4	**Y**
Randomization for all three sites	5-6	**Y**
Milestone Achieved: 1st participant consented, screened and enrolled	7	**Y**
Milestone Achieved: Study 1 begins	7-24	**Y**
Begin subject recruitment	7-24	**Y**
Participants complete assigned 6-week treatment regimen N=88	7-24	**Y**
Complete immediately follow-up assessments after completion of the standard of care or standard of care with power-based exercises.	9-26	**Y**
Milestone Achieved: Report findings from immediate post-intervention follow-up assessments	26-28	**N**
Major Task 4: Randomized Controlled Trial Long-Term Follow-Up		
Subtask 1: Conduct 6-Month Follow-Up Study		
Collect long-term follow-up at 6-months	15-30	**Y**
Milestone Achieved: Collect 6-month follow-up data	15-30	**N**
Subtask 2: Conduct 12-Month Follow-Up Study		
Collect long-term follow-up at 12-months	21-36	**N**
Milestone Achieved: Collect 12-month follow-up data	21-36	**N**
Subtask 3: Conduct 18-Month Follow-Up Study		
Collect long-term follow-up at 18-months	27-42	**N**

Milestone Achieved: Collect 18-month follow-up data	27-42	**N**
Subtask 4: Conduct 24-Month Follow-Up Study		
Collect long-term follow-up at 24-months	33-48	**N**
Milestone Achieved: Collect 24-month follow-up data	33-48	**N**
Milestone Achieved: Report findings from overall studies	44-48	**N**
Major Task 5: Data Analysis		
Subtask 1: Coordinate with Sites & Data Core for monitoring data collection rates and data quality	31-48	**N**
Perform all analyses according to specifications, share output and finding with all investigators	40-48	**N**
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD)	36-48	**N**
Milestone Achieved: Report results from data analyses	36-48	**N**

SUMMARY

Human Subject Protections

We received initial IRB approval from the University of Connecticut on 18 APR 2022 with reliance agreements from the University of Central Florida and University of Toledo on 14 JUL 2022. The University of Connecticut IRB approved site-specific consent forms for the University of Central Florida and University of Toledo on 30 JUN 2022. We received initial HRPO approval for the University of Connecticut on 20 MAY 2022, University of Central Florida on 11 AUG 2022, and University of Toledo on 11 AUG 2022. IRB was approved from the University of Connecticut on 24 FEB 2023 and a continuing review acknowledgement memorandum was sent to the PI from HRPO on 07 MAR 2023. Specific details about human subject protection status are outlined below in section (a) Human Use Regulatory Protocol

Personnel

Drs. Glaviano, Mangum, and Bazett-Jones have doctoral students at each site serve as the intervention member. The doctoral students are trained in the STRIPE study and actively conduct the intervention to enrolled participants. Dr. DiStefano has accepted a new position as Associate Vice President for Research Development at the University of Connecticut. She is now a 12-month employee so her summer effort will be converted to academic effort; however, there will be no changes in work or current budget.

SOP Procedure, Training, Protocol Manuscript

Dr. Mangum and Dr. Bazett-Jones visited Dr. Glaviano at the University of Connecticut on 11 AUG 2022 - 12 AUG 2022. The team completed a review of the study, including finalizing inclusion / exclusion criteria, eligibility evaluation, testing procedures, intervention training and study timelines. Additionally, the team conducted reliability testing for the rate of torque development outcome measures during the visit, which were integrated into the protocol manuscript. Drs. Glaviano, Mangum and Bazett-Jones conducted a quarterly meeting on 28 OCT 2022, 27 JAN 2023, and 28 APR 2023. The team reviewed the study testing procedures, recruitment, eligibility criteria, and data collection. Additional communication occurred during the third quarter with a focus on recruitment strategies for the University of Toledo site due to slower enrollment. The meetings have been successful with an increase in enrollment at the University of Toledo site. The doctoral students in the study also met to review the STRIPE protocol, techniques for conducing remote intervention, recruitment approaches, and maintain open communication for the two sites that have a single doctoral student (University of Central Florida and University of Toledo) and the UConn team. The protocol manuscript with reliability data has been published online in BMJ Open Sport & Exercise Medicine, http://dx.doi.org/10.1136/bmjsem-2022-001482 .

Recruitment and Enrollment
We have successfully enrolled participants at each site, twenty-two participants at the University of Connecticut, fourteen participants at the University of Central Florida, and eight at the University of Toledo. Twenty participants at the University of Connecticut have completed the intervention and immediate post-intervention and two participants withdrew from the study. Six participants at the University of Connecticut site have been sent the 6-month follow-up assessment, with five participants completing all required sections. Eleven participants have completed the intervention and immediate post-intervention at the University of Central Florida and three participants are actively participating in the intervention. Four participants at the University of Central Florida site have been sent the 6-month follow-up assessment and all four have completed all required sections. Six participants at the University of Toledo have completed the intervention and immediate post-intervention data collection and two are currently participating in the intervention. Three participants at the University of Toledo site have been sent the 6-month follow-up assessment, with two participants completing all required sections The PI from each site is tracking the immediate post-intervention date for future post-intervention data collections.

ClinicalTrial.gov Registration
The study was successfully registered on ClinicalTrials.gov (3 JUN2022). The study has been assigned to NCT number: NCT05403944.

(a) ***Human Use Regulatory Protocols***

TOTAL PROTOCOLS: 1

PROTOCOL (1 of 1 total):

Protocol [HRPO Assigned Number]: OHRO Log Number E0321.1a-c

Title: Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)

Target required for clinical significance: 88 participants

Target approved for clinical significance: 88 participants

SUBMITTED TO AND APPROVED BY:

• Approval of human subjects has been granted by the University of Connecticut on 18 APR 2022. Reliance agreements were agreed upon all three sites for the University of Connecticut to serve as the primary IRB for all sites. Reliance agreements were completed between the University of Connecticut and both the University of Central Florida and the University of Toledo on 14 JUL 2022. The University of Connecticut IRB approved site-specific consent forms for University of Central Florida and University of Toledo on 30 JUN 2022.

• The Initial HRPO documents were submitted to the University of Connecticut site on 18 APR 2022. Notification of receipt and initiation of review was received by Katelyn Murter at USAMRDC ORP on 28 APR 2022. Initial HRPO Administrative Review was received on 17 MAY 2022. Responses and supporting documents were returned to Katelyn Murter on 17 May 2022. Notification of receipt and review was received from Katelyn Murter on 17 May 2022. HRPO approval was granted on 20 MAY 2022 from Jessica Mendoza of the USAMRDC ORP.

• Initial HRPO documents for the University of Central Florida site was submitted on 13 JUL 2022. Notification of receipt and initiation of review was received by Katelyn Murter at USAMRDC OCP on 19 JUL 2022. Initial Administrative Review was received on 28 JUL 2022. Responses and supporting documents were returned to Katelyn Murter on 4

AUG 2022. HRPO approval was granted on 11 AUG 2022 from Jessica Mendoza of the USAMRDC ORP.

• Initial HRPO documents for the University of Toledo site was submitted on 3 AUG 2022. Notification of receipt and initiation of review was received by Katelyn Murter at USAMRDC OCP on 4 AUG 2022. HRPO approval was granted on 11 AUG 2022 from Jessica Mendoza of the USAMRDC ORP

• The University of Connecticut IRB requires all federally funded studies to gain reapproval once a year. The PI submitted all documentation to the University of Connecticut IRB and the study was reapproval on 24 Feb 2023. Documentation were submitted to HRPO on 28 Feb 2023 and a continuing review acknowledgement memorandum was sent to the PI on 07 Mar 2023 from Megan Hedges.

STATUS

(i) Number of subjects recruited/original planned target: 75/No Limit
Number of subjects screened/original planned target: 75/No Limit
Number of patients enrolled/original planned target: 44/88
Number of patients completed intervention/original planned target: 37/88
Number of patients completed 6-month assessment/original planned target: 11/88
Number of patients completed 12-month assessment/original planned target: 0/88
Number of patients completed 18-month assessment/original planned target: 0/88
Number of patients completed 24-month assessment/original planned target: 0/88

We have screened out 31 participants who were interested in the study but did not meet inclusion criteria, either through initial email exchange or during the orthopedic evaluation with the study team.

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
Nothing to report

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
Nothing to report

Plan for Next Reporting Period
We will continue to conduct fidelity assessments with the STRIPE team and conduct our quarterly meetings to track progress. We have been successful with recruitment goals being met during the first year of the study and aim to finish the enrollment of all participants in year two. Additionally, we will continue to collect follow-up assessments at both the 6-month, 12-month, and 18-month time periods during the second year of the study. We will continue to work on developing publications with the baseline data with a focus on submitting to high-impact journals.

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 slow enrollment of participants at the University of Toledo site between 18 DEC 2022 to 31 MAR 2023. The study PI met with the University of Toledo PI to discuss additional recruitment strategies, which have been successful with a total of 8 participants enrolled (6 completed intervention) at the site. Additionally, the University of Central Florda site has enrolled a total of 14 participants, which exceeds their initial first year goal of 11. We believe the modifications in our initial plan have been successful and allow us to be at our first-year enrollment goals.

Changes in Expenditures
There are no changes to the expenditures of this study.

Changes in Use of Care of Human Subjects
Nothing to report

6. Products

Publications, Conference Papers, and Presentations
The protocol manuscript with reliability data, entitled “Strength Training Rehabilitation Incorporating Power Exercises (STRIPE) for Individuals with Patellofemoral Pain: A Randomized Controlled Trial Protocol” was accepted and has been published online at the BMJ Open Sport & Exercise Medicine. The article is accessible at: http://dx.doi.org/10.1136/bmjsem-2022-001482

We have submitted a manuscript entitled “Influence of Self-Perceived Disability on Squatting Kinematics in Individuals with Patellofemoral Pain” to *Clinical Biomechanics*. We received confirmation that the manuscript was under review on 26 JUN 23 and was assigned manuscript number CLBI-D-23-00336.

Websites or Other Internet Sites
Nothing to report

Technologies or Techniques
Nothing to report

Invention, Patent Applications, and/or licenses
Nothing to report

Other Products
Nothing to report

7. Participants & Other Collaborating Organizations

Individuals work on Project

Name:	**Neal Glaviano**
Project on Role:	Principal Investigator
Nearest person month worked:	2
Contribution to Project:	Provide scientific oversight to the project across UConn, UCF and UToledo. Assumes responsibility

	for the scientific integrity of the project by working closely with site-PIs and graduate students. Ensure compliance within the appropriate timelines as outlined in the award notification.
Funding Support:	N/A
Name:	**L. Colby Mangum**
Project on Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Site PI at UCF, oversight to all activities at UCF, maintains communication with PI.
Funding Support:	N/A
Name:	**David Bazett-Jones**
Project on Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Site PI at UToledo, oversight to all activities at UToledo, maintains communication with PI.
Funding Support:	N/A

Changes in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period

PENDING
Neal Glaviano
Title: Quantitative Assessment of Patellofemoral Joint Stress
Role: PI
Level of Effort: 1.45 calendar
Performance Period: 07/01/2023-06/30/2025
Supporting agency: National Institutes of Health NIAMS
Level of funding:
Specific aims/tasks: Compare patellofemoral joint stress during gait pre- and post-rehabilitation of the STRIPE program *and* identify if changes in patellofemoral joint stress during a gait assessment predicts pain six months post-intervention.
Brief description of the project's goals: To compare a patellofemoral joint stress in individuals with and without patellofemoral pain and to determine if a change in patellofemoral joint stress predicts future pain.
Overlap: This proposal is an ancillary grant designed to support currently funded federal studies. The proposal will use the same participants and intervention of the STRIPE study but would evaluate new aims that would be collected during an additional data collection session.

NEW - PENDING
Michael Toland
Title: Literacy Everywhere: Designing Supports for Early Literacy and Awareness for Families Experiencing Housing Instability and Early Care Professionals Who Work With Them
Time commitments:
Role: Co-I (PI: Kate Delaney)
Supporting agency: Ohio Department Education
Address: TBD
Contracting/Grants Officer: TBD
Performance Period: 09/01/23-09/30/24
Level of funding:
Goals: Create a responsive system of support for families with young children (0 to 5) experiencing housing instability and/or homelessness that is centered on early literacy practices and connecting families with community and state-wide assistance. A secondary goal is to empower early childhood care professionals with knowledge and resources to address needs of families at risk for or experiencing housing insecurity.

Aims: Work with pilot sites to test prototypes and materials that can then be used for a state-wide awareness campaign that targets families at risk of housing instability and homelessness, while simultaneously addressing early literacy and learning needs of their young children. A toolkit for early childhood care professionals will also be developed through an iterative design process, field-tested, and revised to be accessible and useful.
Overlap: There is also no budgetary overlap with the proposed proposal

Title: Bold Beginnings for Higher Education
Time commitments: 0.45 (years1-5) calendar
Role: Co-I (PI: Laurie Dinnebeil
Supporting agency: Department of Education: Personnel Development to Improve Services and Results for Children with Disabilities Program
Address: TBD
Contracting/Grants Officer: TBD
Performance Period: 01/01/24-12/31/29
Level of funding:
Goals: The goal of BBHE is to enhance the quality of the EC curriculum and field experiences at each of four CCs in Ohio so associate-degreed ECEs are better prepared to meet the needs of diverse young children with disabilities and their families.
Aims: Implement the Blueprint to support revisions to the EC curriculum at each of four community colleges to reflect explicit and intentional emphasis on evidence-based practices that support diverse children with disabilities and their families in coursework and field experiences. Work with partnering CCs to enhance program practices related to recruitment and support of students from underrepresented groups, develop effective articulation agreements between community colleges and their regional 4-year IHEs, and explore the possibility of developing bachelor's degree programs in ECE.
Overlap: There is also no budgetary overlap with the proposed proposal

Title: Early Childhood Reading Proficiency Initiative Evaluation
Time commitments:
Role: Evaluator (PI: Bob Savage)
Supporting agency: Department of Education (Subaward from Toledo Tomorrow)
Address: TBD
Contracting/Grants Officer: TBD
Performance Period: 08/01/23-07/31/25
Level of funding:
Goals: Conduct an evaluation of the early childhood reading proficiency initative being conducted by Toledo Tomorrow.
Aims: Conduct formative evaluation during the first year of the project in which the Early Childhood Reading Proficiency Initiative will be convening school and nonprofit partners. Conduct formative evaluation during the implementation of initial pilot project. Conduct summative assessment of the effectiveness of initial pilot project and follow-up study.
Overlap: There is also no budgetary overlap with the proposed proposal

Title: COMPASS Across Settings (CAST) for Integrating School, Home, and Community Services and Improving Transition Outcomes for Students with ASD
Time commitments: 0.43 calendar (years2-4)
Role: Co-I (PI: Lisa Ruble)
Supporting agency: Institute of Education Sciences; Subaward from Ball State University
Address: TBD
Contracting/Grants Officer: TBD
Performance Period: 08/01/23-07/31/27
Level of funding:
Goals: Develop and evaluate COMPASS Across Settings (CAST) with home, community, and school services for alignment of goals and intervention strategies on student postsecondary outcomes.
Aims: Develop and evaluate COMPASS Across Settings (CAST) with home, community, and school services for alignment of goals and intervention strategies on student postsecondary outcomes.
Overlap: There is also no budgetary overlap with the proposed proposal

Title: Examining the effectiveness of critical thinking instruction among children in an art education program at an art museum
Time commitments: 0 calendar (year1)
Role: Co-I (PI: Falynn Thompson)
Supporting agency: Toledo Museum of Art
Address: PO Box 1013, Toledo, OH 43697
Contracting/Grants Officer: Mike Deetsch
Performance Period: 01/01/2023-06/30/2023
Level of funding:
Goals: Examine the effectiveness of a critical thinking technique among children in an art education program at a local museum of art.
Aims: Compare students critical thinking across experimental and business as usual education programming.
Overlap: There is also no budgetary overlap with the proposed proposal

Title: Efficacy of a Narrative Comprehension Intervention for Elementary School Children at Risk for Attention-Deficit Hyperactivity Disorder
Time commitments: 0.45 calendar (year 1)
Role: Co-I (PI: Betty Lorch)
Supporting agency: US Department of Education –Institute of Education Sciences, Cognition and Student Learning - Goal 3, Grant Number: R305A160318; Subaward from University of Kentucky
Address: TBD
Address: Pending
Contracting/Grants Officer: Pending
Performance period: 10/01/2022-06/30/2023
Level of funding:
Goals: To formally evaluate the impact of the supplemental afterschool narrative structure (NS) intervention on the narrative comprehension of children at-risk for ADHD relative to two counterfactuals.
Aims: To test the differential effects of NS versus reciprocal teaching (RT) and problem solving (PS) on comprehension self-efficacy and on proximal and distal measures of narrative comprehension?
Overlap: No scientific or budgetary overlap with the proposed proposal
Note. Initial work done at prior institution (University of Kentucky). Because of COVID-19 the project and initial subaward request was put on pause during 2020-2021. A subaward was submitted to PI at prior institution for year 4 work.

8. Special Reporting Requirements

Collaborative Awards
Nothing to report

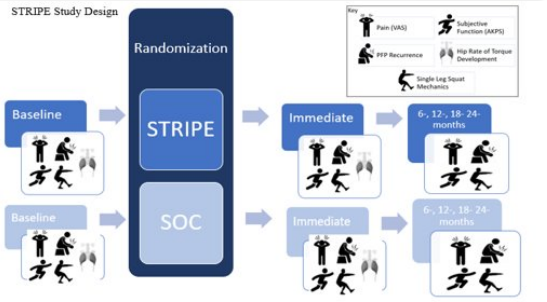
Quad Chart

Optimizing Clinical Outcomes for Patients with Patellofemoral pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)
W81XWH-22-1-0532

PI: Glaviano **Org:** University of Connecticut, University of Central Florida, and University of Toledo **Award Amount:** $1,499,995

Study Aims
- 1) Compare the effect of STRIPE on pain compared to a standard of care rehabilitation program in individuals with PFP.
- 2) Compare effect of STRIPE on subjective function compared to a SOC rehabilitation program in individuals with PFP.
- 3) Compare effect of STRIPE on PFP recurrence rates compared to a SOC rehabilitation program
- 4) Compare effect of STRIPE on secondary outcomes (hip abduction and extension RTD and single leg squat kinematics) to a SOC rehabilitation program.

Approach
We will recruit 88 participants with PFP across three locations. Participants will be randomized into two 6-week (3 sessions a week) interventions, a strength training rehabilitation program (standard of care), or a strength training rehabilitation program incorporating power exercises (STRIPE). Pain, knee-related function, recurrence rates and hip muscle function will be assessed before and after a 6-week intervention, in addition to follow-up assessments at 6-, 12-, 18-, and 24-months post intervention.



Accomplishment: IRB and HRPO approval, conducted reliability study, submitted protocol manuscript, completed all training, and enrolled first participant

Timeline and Cost

Activities CY	22	23	24	25
Task 1 & 2: Prepare document and train staff				
Task 3: Enroll participants and administer interventions				
Task 4: Long-term Follow-Up				
Task 5: Data Analysis				
Estimated Budget ($K)	**$402**	**$355**	**$361**	**$382**

Updated: (24 Oct 22)

Goals/Milestones
CY22 Goal – Preparation and initiating data collection
☐Prepare study documents and gain approval
☐Train staff across data collection sites
☐Recruit and enroll participants
CY23 Goals – System validation
☐Recruit and enroll participants
☐Complete all interventions
CY24 Goal – Follow-up testing
☐ Collect 6- and 12-month follow-up
CY25 Goal – Follow-up testing
☐ Collect 18- and 24-month follow-up
Comments/Challenges/Issues/Concerns
- No comments, challenges, issues, or concerns at this point.

Budget Expenditure to Date
Projected Expenditure: $1,499,995
Actual Expenditure: $1,499,995

9. Appendices

A. Letter - 18 APR 2022 from UConn IRB to Dr. Neal Glaviano Re: approval of STRIPE IRB for the University of Connecticut site. (Page 15)

B. Email - 20 MAY 2022 from Ms. Jessica Mendoza to Dr. Neal Glaviano Re: HRPO approval of University of Connecticut site (Page 18)

C. Letter 03 AUG 2023 from UConn IRB to Dr. Neal Glaviano Re: approval of STRIPE IRB for the University of Central Florida site. (Page 20)

D. Letter - 03 AUG 2022 from UConn IRB to Dr. Neal Glaviano Re: approval of STRIPE IRB for the University of Toledo site. (Page 22)

E. Email - 11 AUG 2022 from Ms. Jessica Mendoza to Dr. Neal Glaviano Re: HRPO approval of University of Central Florida site (Page 24)

F. Email - 11 AUG 2022 from Ms. Jessica Mendoza to Dr. Neal Glaviano Re: HRPO approval of University of Toledo site (Page 27)

G. Letter - 24 FEB 2023 from UConn IRB to Dr. Neal Glaviano Re: approval of continuation of the STRIPE IRB for the University of Connecticut, University of Central Florida, and University of Toledo (Page 29)

H. Email 07 MAR 2023 from Ms. Megan Hedges to Dr. Neal Glaviano Re: OHRO continuing review acknowledgment memorandum (Page 31)

UCONN
UNIVERSITY OF CONNECTICUT

DATE: April 18, 2022

TO: Neal Glaviano, Ph.D.
Kinesiology

FROM: Rachel Tambling, Ph.D., LCSW
Chair, Institutional Review Board
FWA# 00007125

RE: Protocol #: HR22-0038, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)"
Please refer to the Protocol# in all future correspondence with the IRB.
Funding Source: Department of Defense
Approval Period: From: April 15, 2022 Valid Through: March 30, 2023
"Expiration Date"

At its meeting of March 31, 2022, the Institutional Review Board (IRB) reviewed the above-referenced research study and determined that modifications were required to secure approval. Those requirements have been met, and the IRB granted approval of the study on April 18, 2022.

Enclosed is the validated consent form, which is valid through March 30, 2023. **A copy of the approved, validated consent form (with the validation text) must be used to consent each subject.**

Please take note of the following:

- The IRB determined that this study is minimal risk.
- The IRB reviewed this DoD-funded study in compliance with the Department of Defense Instruction 3216.02.
- Register this study as a clinical trial at clinicaltrials.gov. Please review the requirements at https://ovpr.uconn.edu/services/rics/clinical-trials/. For assistance with ClinicalTrials.gov, contact Ellen Ciesielski.
- UConn's IRB will serve as the single IRB (sIRB) of record. At this time this review only reflects the primary site (UConn Storrs). the HRPP UConn-Storrs office will reach out to you with additional steps to add each site through subsequent modifications.

All investigators at the University of Connecticut are responsible for complying with the attached IRB "Responsibilities of Research Investigators."

Office of the Vice President for Research
Research Compliance Services
438 WHITNEY ROAD EXTENSION, UNIT 1246
STORRS, CT 06269-1246
PHONE 860.486.8802
FAX 860.486.1044
compliance.uconn.edu

Research Compliance Services would like to remind Principal Investigators (PIs) that institutions receiving federal funding from the National Institutes of Health (NIH) and the National Science Foundation (NSF), must certify that a plan is in place for providing the appropriate training and oversight in the Responsible Conduct of Research (RCR) to all students and postdoctoral researchers who participate in NSF or NIH funded research (renewals or new applications) regardless if they are directly paid or are otherwise supported by the funding. Currently, the policy does not pertain to faculty members. However, everyone is strongly encouraged to take the course. PIs are responsible for ensuring that each undergraduate student, graduate student and postdoctoral researcher who participates in their NSF or NIH funded research completes the training during the course of their participation in the project. Sponsored Program Services will track the completion of RCR training. A description of the plan is available on the website of the Vice President for Research, https://ovpr.uconn.edu/services/rics/responsible-conduct-of-research/.

Please note that for investigator-initiated research with external funding, IRB approval encompasses only those aims and procedures in the grant proposal that are also written into the research protocol. If there are any aims or procedures described in the grant proposal that are not also described in the research protocol (for example, when implementation of aim two is dependent on outcomes of aim one), a request for modification to the research protocol, or a request for a new study approval, must be submitted to the IRB before any such aims or procedures are implemented.

Re-approval: It is the investigator's responsibility to apply for re-approval of ongoing research at **least once yearly**, or more often if specified by the IRB. The Re-approval/Completion Form (IRB-2) and other applicable re-approval materials must be submitted **six weeks** in advance of the expiration date noted above.

Modifications: If you wish to change any aspect of this study, such as the procedures, the consent forms, the investigators, or funding source, please submit the changes in writing to the IRB using the Amendment Review Form (IRB-3). All modifications must be reviewed and approved by the IRB prior to initiation.

Audit: All protocols approved by the IRB may be audited by the Research Compliance Monitor.

Please keep this letter with your copy of the approved protocol.

Attachments:

1. Validated Consent Form
2. Validated Photo/Video Release
3. Validated Data Security Assessment Form
4. Validated Recruitment Material
5. Validated Appendix A
6. Validated IRB-1 Application and Study Protocol Forms

7. “Responsibilities of Research Investigators”

Glaviano, Neal

From: Jessica Mendoza <jessica.l.mendoza19.civ@mail.mil>
Sent: Friday, May 20, 2022 9:37 AM
To: Glaviano, Neal
Cc: Kimberly Odam; Andrea Kline; Tracey Harris; Katelyn Murter; Megan Hedges; Jessica Mendoza; Kenneth Furdella; Lisa Sawyer
Subject: E03213.1a - HRPO Approval Memorandum (Proposal Number OR210126, Award Number Pending)

Message sent from a system outside of UConn.

SUBJECT: Initial Approval for the Protocol, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Neal Glaviano, Ph.D., University of Connecticut, in Support of the Proposal, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Neal Glaviano, Ph.D., University of Connecticut, Storrs, Connecticut, Proposal Log Number OR210126, Award Number Pending, HRPO Log Number E03213.1a

1. The subject protocol was approved by the University of Connecticut (UConn) Institutional Review Board (IRB) on 18 April 2022. The U.S. Army Medical Research and Development Command (USAMRDC),Office of Research Protections (ORP), Human Research Protection Office (HRPO) reviewed the protocol and found that it complies with applicable DOD, U.S. Army, and USAMRDC human subjects protection requirements.

2. This no greater than minimal risk study is approved for the enrollment of 88 subjects across all sites, with 44 participants to be enrolled at UConn. This approval is for the UConn site only; the University of Central Florida and University of Toledo require separate HRPO review and approval prior to implementation of the study at those sites.

3. The Principal Investigator has a duty and responsibility to foster open and honest communication with research subjects. The USAMRDC strongly encourages the Principal Investigator to provide subjects with a copy of the research protocol, if requested, with proprietary and personal information redacted as needed.

4. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to usarmy.detrick.medcom-USAMRDC.other.hrpo-cr-documents@mail.mil. **Failure to comply could result in suspension or termination 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 (Note: HRPO review and approval of institution is required), 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 30 March 2023. 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: MCMR-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.

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.

5. **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.

6. 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.

7. The HRPO point of contact for this study is Mrs. Katelyn Murter, Human Subjects Protection Scientist, at 301-619-7839/katelyn.d.murter.ctr@mail.mil.

8. The HRPO point of contact for post-approval oversight is Ms. Megan Hedges, Human Subjects Protection Scientist, at 301-619-6972/megan.e.hedges2.ctr@mail.mil.

Ms. Jessica Mendoza, BA, BSN
Chief, Chem-Bio Research Review
Human Research Protection Office
Office of Research Protections
U.S. Army Medical Research and Development Command
Email: jessica.l.mendoza19.civ@mail.mil

UCONN
UNIVERSITY OF CONNECTICUT

DATE: August 3, 2022

TO: Neal Glaviano, Ph.D.
Kinesiology

FROM: RCS IRB Office/nf
Institutional Review Board
FWA# 00007125

RE: Protocol #: HR22-0038, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)"
Please refer to the Protocol# in all future correspondence with the IRB.

The request for approval of an amendment received June 24, 2022 for the above-referenced protocol was approved by the Institutional Review Board (IRB) on June 30, 2022. This amendment is eligible for expedited review under 45 CFR 46.110(b)(2): minor changes in previously approved research during the period (of one year or less) for which approval is authorized. The amendment includes:

1. The IRB approval of the addition of the University of Central Florida as a research site which will rely on the University of Connecticut's IRB review of the overall research study.
2. Addition of a site-specific consent form for the University of Central Florida addressing local requirements.
3. Acknowledgment that the participants enrolled in HR22-0038 may be recruited for a University of Central Florida study separately under the oversight of the University of Central Florida IRB as there are no restrictions or limitations for future research participation.
4. Revision to the University of Connecticut Consent Form – change to length of time data retained to conform to University of Connecticut policy and to standardize data retention across the three sites.

Enclosed are the validated consent forms, which are valid through March 30, 2023. **A copy of the approved, validated consent form (with the validation text) must be used to consent each subject.**

Please take note of the following:

- The IRB determined that this study is minimal risk.

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- The IRB reviewed this DoD-funded study in compliance with the Department of Defense Instruction 3216.02.
- Register this study as a clinical trial at clinicaltrials.gov. Please review the requirements at https://ovpr.uconn.edu/services/rics/clinical-trials/. For assistance with ClinicalTrials.gov, contact Ellen Ciesielski.
- On June 30, 2022, the University of Connecticut's IRB approved the University of Central Florida as an active research site for the above-referenced research. Documentation of the University of Central Florida's reliance on the University of Connecticut IRB's review was conducted via the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement. Please note the above referenced sites may have additional local requirements before research can proceed.

Amendment Approval Date: June 24, 2022
Approval is Valid Until: March 30, 2023

Please keep this Amendment Approval letter with your copy of the approved protocol.

Attachments:
1. Validated IRB-3 Amendment Review Form
2. Validated Revised IRB-1 Application and Study Protocol Forms
3. Validated Consent Forms

UCONN
UNIVERSITY OF CONNECTICUT

DATE: August 3, 2022

TO: Neal Glaviano, Ph.D.
Kinesiology

FROM: RCS IRB Office/nf
Institutional Review Board
FWA# 00007125

RE: Protocol #: HR22-0038, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)"
Please refer to the Protocol# in all future correspondence with the IRB.

The request for approval of an amendment received June 24, 2022 for the above-referenced protocol was approved by the Institutional Review Board (IRB) on June 30, 2022. This amendment is eligible for expedited review under 45 CFR 46.110(b)(2): minor changes in previously approved research during the period (of one year or less) for which approval is authorized. The amendment includes:

1. The IRB approval of the addition of the University of Toledo as a research site which will rely on the University of Connecticut's IRB review of the overall research study.
2. Addition of a site-specific consent form for the University of Toledo addressing local requirements.
3. Revision to the University of Connecticut Consent Form – change to length of time data retained to conform to University of Connecticut policy and to standardize data retention across the three sites.

Enclosed are the validated consent forms, which are valid through March 30, 2023. **A copy of the approved, validated consent form (with the validation text) must be used to consent each subject.**

Please take note of the following:

- The IRB determined that this study is minimal risk.
- The IRB reviewed this DoD-funded study in compliance with the Department of Defense Instruction 3216.02.
- Register this study as a clinical trial at clinicaltrials.gov. Please review the requirements at https://ovpr.uconn.edu/services/rics/clinical-trials/. For assistance with ClinicalTrials.gov, contact Ellen Ciesielski.

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- On June 30, 2022, the University of Connecticut's IRB approved the University of Toledo as an active research site for the above-referenced research. Documentation of the University of Toledo's reliance on the University of Connecticut IRB's review was conducted via the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement. Please note the above referenced sites may have additional local requirements before research can proceed.

Amendment Approval Date: June 24, 2022
Approval is Valid Until: March 30, 2023

Please keep this Amendment Approval letter with your copy of the approved protocol.

Attachments:
1. Validated IRB-3 Amendment Review Form
2. Validated Revised IRB-1 Application and Study Protocol Forms
3. Validated Consent Forms

Glaviano, Neal

From: Jessica Mendoza <jessica.l.mendoza19.civ@mail.mil>
Sent: Thursday, August 11, 2022 10:29 AM
To: Colby Mangum; Glaviano, Neal
Cc: Kimberly Odam; Andrea Kline; Tracey Harris; Katelyn Murter; Dr. Miriam Redington; Mr. Christopher Baker; Megan Hedges; Jessica Mendoza; Kenneth Furdella; Lisa Sawyer
Subject: E03213.1b - OHRO Performance Site Approval Memorandum (Proposal Number OR210126, Award Number W81XWH-22-1-0532)

SUBJECT: Performance Site Approval for the Protocol, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Lauren C. Mangum, PhD, ATC, University of Central Florida, in Support of the Proposal, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Neal Glaviano, Ph.D., University of Connecticut, Storrs, Connecticut, Proposal Log Number OR210126, Award Number W81XWH-22-1-0532, OHRO Log Number E03213.1b

1. The University of Connecticut (UConn) Institutional Review Board (IRB) approved the above-referenced protocol on 18 April 2022. On 24 June 2022 the UConn IRB approved an amendment adding the University of Central Florida (UCF) as a research site. The UCF relies on the review provided by the UConn IRB. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) reviewed the protocol and found that it complies with applicable DoD, U.S. Army, and USAMRDC human subjects protection requirements.

2. The USAMRDC OHARO OHRO approves this no greater than minimal risk study for the enrollment of 88 subjects across all sites, with 22 subjects to be enrolled at UCF. This approval is for the UCF site; additional performance site(s) require separate OHRO review and approval prior to implementation

3. The University of Connecticut Principal Investigator must provide the following post-approval submissions to the OHRO via email to usarmy.detrick.medcom-usamrmc.other.mrmc-cr-documents@mail.mil. Failure to comply could result in suspension or termination of funding. Send the following for OHRO review within the specified timelines:

a. Prior to implementation of a substantive modification – all documents related to substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects. Substantive modifications include change in Principal Investigator, 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 in research procedures that could potentially increase risks to subjects.

b. Prior to use of DoD funds for a new/additional performance site – the site-specific protocol documents, IRB approval letter, study team members' qualifications documents.

c. Upon change of the reviewing IRB – IRB application/protocol and other documents approved by the new IRB, IRB approval letter.

d. As soon as possible after receipt of re-approval from the IRB – the progress report and a copy of the IRB continuing review approval letter. It appears that continuing review by the IRB is due no later than 30 March 2023.

e. As soon as all documents become available – the final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents.

4. Promptly report the following study events via email to the OHRO by email to usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil or by telephone (301-619-2165). Provide all supporting documentation to include the report to the IRB, IRB determination, corrective action plan, and any required follow-up.

a. All unanticipated problems involving risk to subjects or others.

b. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

c. Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

d. 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.

e. The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

f. Change in subject status when a previously enrolled human subject becomes a prisoner.

g. Note: Events or protocol reports received by the OHRO that do not meet reporting requirements identified within this memorandum will be included in the OHRO study file but will not be acknowledged.

5. Please note: The USAMRDC OHARO OHRO conducts site visits as part of its responsibility for compliance oversight. The study team must maintain accurate and complete study records in a secure and confidential manner, and make them available to representatives of the USAMRDC. Please note that the OHRO may contact the study team for additional information and documentation for the purpose of routine study monitoring at any time during award performance.

6. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

7. The OHRO point of contact for this study is Mrs. Katelyn Murter, Human Subjects Protection Scientist, at 301-619-7839/katelyn.d.murter.ctr@health.mil.

8. The OHRO point of contact for post-approval oversight is Ms. Megan Hedges, Human Subjects Protection Scientist, at 301-619-6972/megan.e.hedges2.ctr@health.mil.

Ms. Jessica Mendoza, BA, BSN

Chief, Chem-Bio Research Review
Office of Human Research Oversight
Office of Human and Animal research Oversight

U.S. Army Medical Research and Development Command
Email: jessica.l.mendoza19.civ@health.mil

Glaviano, Neal

From: Jessica Mendoza <jessica.l.mendoza19.civ@mail.mil>
Sent: Thursday, August 11, 2022 11:10 AM
To: Glaviano, Neal
Cc: Kimberly Odam; Andrea Kline; Tracey Harris; Katelyn Murter; Megan Hedges; Jessica Mendoza; Kenneth Furdella; Lisa Sawyer
Subject: E03213.1c - OHRO Performance Site Approval Memorandum (Proposal Number OR210126, Award Number W81XWH-22-1-0532)

Message sent from a system outside of UConn.

SUBJECT: Performance Site Approval for the Protocol, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. David Bazett-Jones, University of Toledo, in Support of the Proposal, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Neal Glaviano, Ph.D., University of Connecticut, Storrs, Connecticut, Proposal Log Number OR210126, Award Number W81XWH-22-1-0532, OHRO Log Number E03213.1c

1. The University of Connecticut (UConn) Institutional Review Board (IRB) approved the above-referenced protocol on 18 April 2022. On 24 June 2022 the UConn IRB approved an amendment adding the University of Toledo as a research site. The University of Toledo relies on the review provided by the UConn IRB. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) reviewed the protocol and found that it complies with applicable DoD, U.S. Army, and USAMRDC human subjects protection requirements.

2. The USAMRDC OHARO OHRO approves this no greater than minimal risk study for the enrollment of 88 subjects across all sites, with 22 subjects to be enrolled at the University of Toledo. This approval is for the University of Toledo site; additional performance site(s) require separate OHRO review and approval prior to implementation

3. The University of Connecticut Principal Investigator must provide the following post-approval submissions to the OHRO via email to usarmy.detrick.medcom-usamrmc.other.mrmc-cr-documents@mail.mil. Failure to comply could result in suspension or termination of funding. Send the following for OHRO review within the specified timelines:

a. Prior to implementation of a substantive modification – all documents related to substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects. Substantive modifications include change in Principal Investigator, 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 in research procedures that could potentially increase risks to subjects.

b. Prior to use of DoD funds for a new/additional performance site – the site-specific protocol documents, IRB approval letter, study team members' qualifications documents.

c. Upon change of the reviewing IRB – IRB application/protocol and other documents approved by the new IRB, IRB approval letter.

d. As soon as possible after receipt of re-approval from the IRB – the progress report and a copy of the IRB continuing review approval letter. It appears that continuing review by the IRB is due no later than 30 March 2023.

e. As soon as all documents become available – the final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents.

4. Promptly report the following study events via email to the OHRO by email to usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil or by telephone (301-619-2165). Provide all supporting documentation to include the report to the IRB, IRB determination, corrective action plan, and any required follow-up.

a. All unanticipated problems involving risk to subjects or others.

b. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

c. Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

d. 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.

e. The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

f. Change in subject status when a previously enrolled human subject becomes a prisoner.

g. Note: Events or protocol reports received by the OHRO that do not meet reporting requirements identified within this memorandum will be included in the OHRO study file but will not be acknowledged.

5. Please note: The USAMRDC OHARO OHRO conducts site visits as part of its responsibility for compliance oversight. The study team must maintain accurate and complete study records in a secure and confidential manner, and make them available to representatives of the USAMRDC. Please note that the OHRO may contact the study team for additional information and documentation for the purpose of routine study monitoring at any time during award performance.

6. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

7. The OHRO point of contact for this study is Mrs. Katelyn Murter, Human Subjects Protection Scientist, at 301-619-7839/katelyn.d.murter.ctr@health.mil.

8. The OHRO point of contact for post-approval oversight is Ms. Megan Hedges, Human Subjects Protection Scientist, at 301-619-6972/megan.e.hedges2.ctr@health.mil.

Ms. Jessica Mendoza, BA, BSN

Chief, Chem-Bio Research Review
Office of Human Research Oversight
Office of Human and Animal Research Oversight
U.S. Army Medical Research and Development Command
Email: jessica.l.mendoza19.civ@health.mil

UCONN
UNIVERSITY OF CONNECTICUT

DATE: February 24, 2023

TO: Neal Glaviano, PhD
Kinesiology

FROM: Rachel Tambling, PhD, LMFT
Chair, Institutional Review Board
FWA# 00007125

RE: Protocol #: HR22-0038 "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)"
Please refer to the Protocol# in all future correspondence with the IRB.
Funding Source: Department of Defense
Approval Period: From: February 24, 2023 through: February 1, 2024
"Expiration Date"

At its meeting of February 2, 2023, the Institutional Review Board (IRB) reviewed the above-referenced research study and determined that modifications were required to secure approval. Those requirements have been met, and the IRB granted approval of the study on February 24, 2023.

Enclosed is the validated consent form, which is valid through February 1, 2024. **A copy of the approved, validated consent form (with the IRB's stamp) must be used to consent each subject.**

Please take note of the following:

- The IRB determined that this study is minimal risk.
- The IRB reviewed this DoD-funded study in compliance with the Department of Defense Instruction 3216.02.
- Register this study as a clinical trial at clinicaltrials.gov. Please review the requirements at https://ovpr.uconn.edu/services/rics/clinical-trials/. For assistance with ClinicalTrials.gov, contact Ellen Ciesielski.
- As of June 30, 2022, the UConn-Storrs' IRB approved the University of Central Florida and the University of Toledo as sites for the above referenced research. IRB review of this research is through the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement. Please note the above referenced sites may have additional local requirements before research can proceed.

As of August 31, 2020, approval of a COVID Safety plan from the OVPR is no longer required, however the research team must still have a COVID safety plan in place. Additional guidance regarding COVID safety plans and training requirements is available at https://uconn.edu/public-notification/coronavirus/covid-19-research/ The IRB is not responsible for COVID safety plans. Questions regarding these plans should be directed to ehs@uconn.edu.

Office of the Vice President for Research
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All investigators at the University of Connecticut are responsible for complying with the attached IRB "Responsibilities of Research Investigators."

Re-approval: It is the investigator's responsibility to apply for re-approval of ongoing research at **least once yearly**, or more often if specified by the IRB. The Re-approval/Completion Form (IRB-2) and other applicable re-approval materials must be submitted **six weeks** in advance of the expiration date noted above.

Modifications: If you wish to change any aspect of this study, such as the procedures, the consent forms, the investigators, or funding source, please submit the changes in writing to the IRB using the Amendment Review Form (IRB-3). All modifications must be reviewed and approved by the IRB prior to initiation.

Audit: All protocols approved by the IRB may be audited by the Research Compliance Monitor.

Please keep this letter with your copy of the approved protocol.

Attachments:

1. Validated IRB-2 Form
2. Validated Consent Forms
3. Validated Recruitment Material
4. "Responsibilities of Research Investigators"

Glaviano, Neal

From: Megan Hedges <megan.e.hedges2.ctr@health.mil>
Sent: Tuesday, March 7, 2023 12:10 PM
To: Glaviano, Neal
Cc: Kimberly Odam; Andrea Kline; Tracey Harris; Megan Hedges; Jessica Mendoza; Kenneth Furdella; Lisa Sawyer
Subject: E03213.1a - Continuing Review Acknowledgement Memorandum (Proposal Number OR210126, Award Number W81XWH-22-1-0532)

SUBJECT: Acknowledgement of the Continuing Review documents for the Protocol, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Neal Glaviano, Ph.D., University of Connecticut, in Support of the Proposal, "Optimizing Clinical Outcomes for Patients with Patellofemoral Pain Using Strength Training Rehabilitation Incorporating Power Exercises (STRIPE)," Submitted by Dr. Neal Glaviano, Ph.D., University of Connecticut, Storrs, Connecticut, Proposal Log Number OR210126, Award Number W81XWH-22-1-0532, OHRO Log Number E03213.1a

1. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) approved the subject protocol on 20 May 2022.

2. The USAMRDC OHARO OHRO received the University of Connecticut Institutional Review Board (IRB) approval on 28 February 2023. The University of Connecticut IRB approved continuation of the subject protocol on 24 Febraury 2023; this approval will expire on 01 February 2024.

3. This correspondence serves to acknowledge OHRO receipt of the continuing review documents for the protocol. No further action related to this continuing review is needed. The documents in support of this continuing review will be placed in the OHRO file.

4. The Principal Investigator must provide the following post-approval submissions to the OHRO via email to usarmy.detrick.medcom-usamrmc.other.hrpo@health.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 OHRO for approval prior to implementation. The USAMRDC OHARO OHRO 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 OHRO as soon as possible after receipt of approval. Please note that the OHRO 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 OHRO as soon as all documents become available.

d. The following study events must be promptly reported to the OHRO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil), or by facsimile (301-619-7803) or mail to the U.S. Army Medical Research and Development Command, ATTN: MCMR-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 OHARO OHRO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the OHRO that do not meet reporting requirements identified within this memorandum will be included in the OHRO study file but will not be acknowledged.

5. Please note: The USAMRDC OHARO OHRO 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.

6. 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.

7. The OHRO point of contact for this study is Ms. Megan Hedges, Human Subjects Protection Scientist, at 301-619-6972/megan.e.hedges2.ctr@health.mil.

Ms. Megan E. Hedges
Contractor - General Dynamics Information Technology
Human Subject's Protection Administrative Support
Office of Human Research Oversight
USAMRDC Office of Human and Animal Research Oversight (OHARO)
Email: megan.e.hedges2.ctr@health.mil