AWARD NUMBER: W81XWH-18-1-0815

TITLE: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery Following Lower-Extremity Trauma

PRINCIPAL INVESTIGATOR: Stephen Sims, MD

CONTRACTING ORGANIZATION: Atrium Health

REPORT DATE: Oct 2019

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

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1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
Oct 2019	Annual	9/30/2018-9/29/2019

4. TITLE AND SUBTITLE

The Mobility Toolkit: Electronically Augmented Assessment

Of Functional Recovery Following Lower Extremity Trauma

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-1-0815

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S):
Stephen Sims, MD

E-Mail: Stephen.Sims@atriumhealth.org

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Charlotte-Mecklenburg Hospital Authority
d/b/a Carolinas HealthCare System
1000 Blythe Blvd.
Charlotte, NC 28203

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Background: The proposed effort directly involves the development and validation of standardized measures to objectively assess and improve rehabilitative outcomes, including multi-extremity trauma following neuromusculoskeletal injury. It involves the direct application of the Mobility Toolkit Project, which is a HIPAA-compliant, web-accessible, cloud-based application for data acquisition and quantitative analysis of performance-based measures (PBMs) in multiple wide-spread clinic and therapy settings. The proposed effort addresses the feasibility of data collection in clinical settings and describing the recovery trajectories for lower-extremity injuries in active duty and civilian orthopaedic trauma patients.
Objective/Hypothesis: The purpose of this study is to (1) evaluate implementation in multiple clinical centers in the context of a large orthopaedic research consortium; (2) generate normative data for patients with lower extremity articular injures and non-injured controls: and (3) to identify thresholds that indicate risk for diminished long-term function and complications.
Specific Aims: The specific aims are to (1) Determine the feasibility and burden of implementing the Mobility Toolkit in a clinical setting, in the context of a large, multi-center research consortium, (2) Establish normative data for adult patients with articular injuries (proximal tibia, pilon, ankle fracture and ankle fracture-dislocation, hind foot) as well as a cohort of non-injured adults, and (3) Identify thresholds that indicate risk for diminished long-term function and select complications (eg, malunion, hardware failure, range of motion complications). In addition, an exploratory aim 4 is to develop algorithms to translated AHRS data for additional physical performance measures selected by the Protocol Committee made up of orthopaedic surgeons, physical medicine and rehabilitation physicians, and physical therapists.
Study Design: The proposed study will prospectively enroll and follow 350 patients aged 18-55 with lower-extremity injuries. Each of the study sites will be provided with the Mobility Toolkit clinical data acquisition systems which consists of a tablet computer Bluetooth-paired with inertial sensor package for capturing patient kinematic data. Sites are also provided with internet access to the cloud-based Mobility Toolkit central site analytics and user database which allows real-time data analysis and report transmission back to the data acquisition site. During these visits, participants will also be asked to complete the PROMIS Physical Function and Mobility and Pain Interference subscales and provide information about physical therapy they have received. Data regarding injury related complications will be obtained from medical records. Instrumented assessment using the AHRS will also be conducted on 150 non-injured adults matched to the injured cohort on age and gender. These individuals will be assessed once. After completing the assessments, non-injured participants will be asked to complete a brief health questionnaire as well as the PROMIS assessments. Data collected on injured patients and non-injured controls will form the bases for reports that plot recovery trajectories the year following injury with respect to key gait parameters that may be adversely affected by injury. These reports will allow clinicians to compare patient progress to other patients with similar injuries and relative to non-injured adults.
Military Benefit: Lower-extremity injuries, ranging from simple to complex, are common during both war and peacetime and represent a significant portion of unfitting conditions and those qualifying for medical discharge. The opportunity to objectively measure rehabilitation following lower-extremity injury and to establish trajectories of recovery for specific injury patterns would represent a significant advance in the measurement of patient outcomes. Expected recovery trajectories for specific injuries are particularly important when one considers the cost to train and retain active duty personnel. The ability to predict with some certainty expected outcomes and times to final outcome would significantly affect fitness decisions on a patient by patient basis. The information will be used to aid in *targeting physical therapy resources and interventions to specific variables documented to impede physical performance*, improve return to duty and duration of time spent away from the unit.

15. SUBJECT TERMS

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

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The Mobility Toolkit (MTK) is a single chest mounted device that utilizes inertial measurement units (IMUs) to assess gait quality. The purpose of this project is to test the implementation of the Mobility Toolkit in multiple trauma centers around the country and generate normative data on lower-extremity injuries common among military and civilian patients. The long-term goal is for this to be a clinical tool for evaluating recovery progress. This study is an important first step in establishing feasibility and in creating a normative set against which patient progress can be measured.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Articular Injuries, Long-Term Function, Feasibility, Normative Data

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

1) Major Accomplishments:
2) Specific Objectives:
3) Significant Results or Key Outcomes:
4) Other Achievements:

Major Tasks:
Task 1: Study Initiation

- Finalize protocol (month 6)
- Develop case report forms (month 6)
- Program and pilot test REDCap (month 6)
- Obtain initial IRB approval at JHU (MCC), CMC (PI site) and HRPO (month 6)
- Distribute approved protocol and obtain IRB approval at all participating sites
- Develop training material for research coordinators (month 6)
- Train and certify sites to begin screening and enrolling patients (month 12)

Task 2: Enroll and Follow Patients

- Enroll injured patients at all participating centers (month 27)
- Enroll non injured patients at two participating centers (month 27)
- Follow injured patients for one year (month 39)
- Generate and distribute monthly data queries to monitor data quality (month 39)

Task 3: Data Analysis and Dissemination

- Develop final data files and conduct analysis (month 42)

- Facilitate focus groups of ortho trauma surgeons and physical therapists to get feedback on Mobility Tool Kit reports (month 44)
- Write final report for peer reviewed publication (month 48)

Site Specific Progress:

TOTAL PROTOCOLS: **11** Note: A single master Human Subject Research Protocol will be required to complete the Statement of Work. This protocol will be approved at Johns Hopkins Bloomberg School of Public Health, as well as the USAMRAMC HRPO. Once approval has been obtained, each of the 10 other sites participating in this research will obtain IRB approval. In total, the protocol will be reviewed by 11 IRBs, plus the USAMRAMC HRPO. Future iterations of this report will reflect the status of the protocols at these sites as they are submitted and approved.

PROTOCOL (1 of 11 total): Johns Hopkins Bloomberg School of Public Health

Protocol [HRPO Assigned Number]: [E00324.1a]

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma (Master Protocol)

Target required for clinical significance: 300 injured participants and 150 non-injured volunteers

(Two sites will be enrolling non-injured volunteers and that will begin next year. We will report on each sites progress of the injured participants.)

Target approved for clinical significance: N/A

Submitted to and Approved by:

- *Submitted to JHSPH IRB*
- *Approved by JHSPH IRB 6/5/2019*
- *Submitted to DoD HRPO*
- *Approved by DoD HRPO 8/19/2019*

Status:

(i) Number of subjects recruited/original planned target: N/A
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None

PROTOCOL (2 of 11 total): Carolinas Medical Center

Protocol [HRPO Assigned Number]: E00324.1b

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB ?*
- *Approved by local IRB 8/20/2019*
- *Submitted to HRPO 9/9/2019*
- *Approved by HRPO 9/17/2019*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (3 of 11 total): University of Texas Health Science Center, Houston

Protocol [HRPO Assigned Number]: E00324.1c
Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/3/2019*
- *Approved by local IRB 8/26/019*
- *Submitted to HRPO 8/27/2019*
- *Approved by HRPO 9/17/2019*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

None.

PROTOCOL (4 of 11 total): Mission Hospital

Protocol [HRPO Assigned Number]: E00324.1d

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/1/2019*
- *Approved by local IRB 7/18/2019*
- *Submitted to HRPO 9/4/2019*
- *Approved by HRPO 10/11/2019*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (5 of 11 total): University of Maryland, R Adams Cowley Shock Trauma Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/25/2019*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A

Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (6 of 11 total): Vanderbilt Medical Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/17/19*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (7 of 11 total): University of Kentucky

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/25/19*
- *Approved by local IRB 9/30/19*

- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (8 of 11 total): Washington University, Barnes Jewish Hospital

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB pending*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (9 of 11 total): San Antonio Military Medical Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following

Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 9/1/2019*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (10 of 11 total): Walter Reed Military Medical Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB pending*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (11 of 11 total): Womack Army Medical Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance:

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB pending*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Specific Aims: (1) Determine the feasibility and burden of implementing the Mobility Toolkit in a clinical setting, in the context of a large, multi-center research consortium. (2) Establish normative data for adult patients with articular injuries (proximal tibia, pilon, ankle fracture and ankle fracture-dislocation, hind foot) as well as a cohort of non-injured adults (3) Identify thresholds that indicate risk for diminished long-term function and select complications (eg, malunion, hardware failure, range of motion complications).

Major Activities (Study initiation): During Year 1, we completed development of the protocol and case report forms, programming and piloting REDCap for data capture, and obtaining IRB approval. The IRB application was approved by Johns Hopkins University IRB and submitted to HRPO on June 12th. HRPO approved our submission on 8/19/2019. Following approval at JHU, the materials were sent to Carolinas Medical Center and all participating sites, and as of the end of September, one site had HRPO approval . We expect to receive IRB approval at all of the sites by the end of October, and HRPO approval for all sites by the end of November. All sites have had remote training and one site had on-site training in September. All sites will have received on-site training in Mobility Toolkit data collection before study initiation.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

All sites have had the opportunity to be trained in Mobility Toolkit data collection remotely, and will receive on-site training before initiating the study.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

N/A

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We plan to complete the regulatory and site certification processes, and initiate enrollment in November 2019, with all sites initiating enrollment by January 2020.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

N/A

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

N/A

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

N/A

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

N/A

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Nothing to report.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

The CMC team has developed a stand-alone app for Mobility Toolkit data collection that has been tested at their site and at University of Kentucky.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*

- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Personnel at CMC	Role	Calendar Months
Stephen Sims	PI	No Change
Rachel Seymour	Co-Investigator	No Change
Christine Churchill	Research Coordinator	1.7
Nahir Habet	Research Engineer	2.5

Personnel at METRC/JHU	Role	Calendar Months
Renan Castillo	MCC PI	No Change
Lisa Reider	MCC Co-PI	No Change
Andrea Deluca	MCC Project Director	No Change
Manisha Kumar	MCC Finance Manager	No Change
Greg Mettee	Research Assistant	No Change
Jiawei Bai	Biostatistician	No Change
Jacek Urbanek	Biostatistician	No Change
Andre Hackman	Data Manager	No Change
Timothy Coppa	Student	No Change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<u>Partner's contribution to the project</u> (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Johns Hopkins University
Baltimore, Maryland
METRC Coordinating Center; collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

The Mobility Toolkit: Electronically augmented assessment of functional recovery following lower-extremity trauma

OR170181, W81XWH-17-PRORP-CTRA

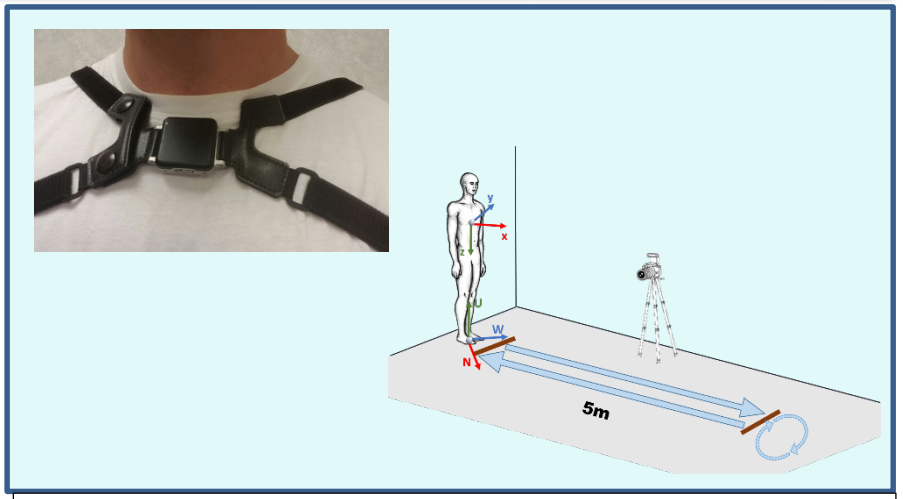
PI: Stephen Sims, MD **Org:** Carolinas Medical Center **Award Amount:** $2,000,000

Study Aims

Specific Aim 1: Determine the feasibility and burden of implementing the Mobility Toolkit in a clinical setting, in the context of a large, multi-center consortium.
Specific Aim 2: Establish normative data for adult patients (N=300) with articular injuries (proximal tibia, pilon, ankle fracture and ankle fracture-dislocation, hind foot) as well as a cohort of noninjured controls (N=150).
Specific Aim 3: Identify thresholds that indicate risk for diminished long-term function and select complications (eg, malunion, hardware failure, range of motion complications).
Exploratory Aim 4: Develop algorithms to translated AHRS data for additional physical performance measures selected by the Protocol Committee made up of orthopaedic surgeons, physical medicine and rehabilitation physicians, and physical therapists.

Approach

To prospectively collect data on targeted injuries that occur frequently in the military and civilian populations, and to follow those patients through recovery.



Inertial Measurement Unit (IMU): integration of accelerometers, gyroscopes, and magnetometers with onboard data acquisition

Timeline and Cost

Activities	CY	18	19	20	21
Protocol Development and Approval; Coordinator training					
Patient Enrollment and baseline data collection					
Follow-up and data quality assurance activities					
Data analysis					
Budget ($2,000,000)		**$400k**	**$500k**	**$600k**	**$500k**

Updated: 10/29/2019

Goals/Milestones

CY19 Goals – Protocol Development and Approval
X Protocol submitted for master approval at PI site and MCC
X Protocol submitted for approval at all participating centers
☐Train staff at sites and initiate data collection
CY19-20 Goals – Enrollment and Data Collection
☐Enroll patients and obtain follow-up visits
☐Collect study data
☐Engage in monitoring and quality assurance activities to ensure high quality data
CY20-21 Goal – Data Analysis and Reporting
☐ Complete data analysis and reporting requirements
Comments/Challenges/Issues/Concerns: n/a
Budget Expenditure to Date
Projected Expenditure: $2,000,000
Actual Expenditure: $209,794.59