

AWARD NUMBER: W81XWH-21-1-0173

TITLE: Quantitative Ambulatory Assessment and Prognosis of the Impact of Severe Upper Limb Injuries on Real-World Behavior

PRINCIPAL INVESTIGATOR: Scott H. Frey, Ph.D.

CONTRACTING ORGANIZATION: Curators of the University of Missouri Dept. of Physical Medicine & Rehabilitation 315 Business Loop 70W
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14. ABSTRACT Military personnel are at particularly high risk for severe upper limb injuries (SULIs)—often involving damage to the peripheral nerves—that adversely impact quality of life, limit occupational and recreational participation, and present major economic and readiness burdens on the military system. We predict that individuals with SULIs are at increased risk of developing chronic one-handedness through the mechanism of learned disuse of the injured limb. We deploy a novel, high spatio-temporal resolution, wireless accelerometry technique to evaluate this central hypothesis over multiple days of real-real-world activity.								
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INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose, and scope of the research.*

Military personnel are at particularly high risk for severe upper limb injuries (SULIs)—often involving damage to the peripheral nerves—that adversely impact quality of life, limit occupational and recreational participation, and present major economic and readiness burdens on the military system. The majority of these patients develop chronic neuropathic pain. Though rarely fatal, these injuries are associated with a 23% increased risk of attrition from duty. During acute recovery, SULI patients are forced to adopt unnatural, one-handed patterns of limb use due to the injury itself as well as bracing, bandaging and acute pain associated with post-surgical healing. If this ‘one-handedness’ becomes chronic, however, SULI patients are at greatly increased risk of developing long-term pain and disability. Successful functional recovery depends on unlearning this one-handed pattern and resuming more normal bimanual movements. The overarching hypothesis of this project is that *individuals with SULIs are at increased risk of developing chronic one-handedness through the mechanism of learned disuse of the injured limb.* We deploy a novel, high spatio-temporal resolution, wireless accelerometry technique to evaluate this central hypothesis over multiple days of real-world activity.

KEYWORDS: severe upper limb injury, rehabilitation, upper extremity, ecological momentary assessment, longitudinal cohort, accelerometry.

- 1. 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.

Major Task 1: Prepare Regulatory Documents, Maintain Compliance, and Other Administrative Tasks

- Subtask 1: Submission of human subjects research materials to local IRB and DoD HRPO. Continual maintenance of human research materials, including: compliance with annual reviews & submission of amendments, adverse events, and protocol deviations as needed; management of all study research records, ensure regulatory compliance, and maintain regulatory mind.
 - University of Missouri received local IRB approval (#2036363) with expedited status on 03/23/2021.
 - Washington University (WUSM) was added to the University of Missouri Single IRB as a site via Amendment #325020 on 07/01/2021.
 - Ohio State University (OSU) was added to the University of Missouri Single IRB as a site via Amendment #325515 on 07/20/2021.
 - Johns Hopkins University (JHU) was added to the University of Missouri Single IRB as a site via Amendment #311476 on 09/20/2021.
 - University of Missouri submitted regulatory package to DoD HRPO on 09/21/2021.
 - Received University of Missouri approval (E02020.1a) from HRPO on 10/29/21.
 - Received WUSM (E02020.1b), JHU (E02020.1c), and OSU (E02020.1d) approvals from HRPO on 11/17/21.

- Our Statement of Work goal was to obtain initial approval by Month 5 of the award. We obtained HRPO approval for University of Missouri in Month 6 of the award, and full approval for the rest of the study sites in Month 9 of the award.
 - As of the end of Year 2, all regulatory approvals are current and up to date.
 - At the end of Year 3, all previous regulatory approvals are still standing with the exception of changes made to the protocol that are still pending.
- Subtask 2: MU team conducts training visits to subaward sites to train teams on administration of behavioral tasks.
 - The WU team was trained in person by Research Coordinator Nick Henigman on February 24, 2023. Mr. Henigman met with two WU site coordinators and trained all on-site staff in all relevant tests (e.g. ARAT, Monofilament, Two-point Discrimination).
 - Research Coordinator Nick Henigman trained the OSU team virtually over zoom on February 28, 2023. Mr. Henigman trained the OSU team on all relevant tests (e.g. ARAT, Monofilament, Two-point Discrimination).
 - The JHU team has not yet been trained due to regulatory hurdles, but will be trained when recruitment begins at their site which is expected in early Year 4.
- Subtask 3: Organize and participate in biweekly teleconferences between sites to ensure timely progress on all SOW goals and discuss scientific aims.
 - Bi-weekly teleconferences between sites was halted during summer of 2022 as Ms. Buchanan (previous Research Coordinator at MU) took a different job. During this time, Dr. Davis-Stober transitioned from Co-I to Co-PI on the project. The bi-weekly teleconferences soon resumed at the beginning of Year 2 Quarter 3 (September) and have been ongoing since. The hiring of new lead coordinator Nick Henigman to replace Ms. Buchanan occurred in Year 2, Quarter 3. Mr. Henigman was trained and brought up to speed on the project during Year 2 Quarters 3-4.
 - Mr Henigman led bi-weekly teleconferences between the sites throughout Year 3.
- Subtask 4: Provide assistance, support, and corrective feedback to subaward sites as needed through email, phone and in-person.
 - University of Missouri maintains close email contact with all sites to aid, support, and provide corrective feedback as needed. Phone and in-person assistance is available when necessary.

Major Task 2: Data collection

- Subtask 1 (subaward sites): recruit and enroll cohort of participants (N=20 per site) and conduct initial in-clinic behavioral testing. 5 participants per site in Year 1, Quarter 3, Months 5-6; 7 participants per subaward site in Year 1, Quarter 3, Months 7-9; and 8 participants per subaward site in Year 1, Quarter 4, Months 10-12. MU's task: enroll all participants (entire cohort; N=20) in remote actigraphy testing and ecological momentary assessment.
 - At the conclusion of Year 2, Quarter 4, WU and OSU are actively recruiting. Data collection has been slowed by staff turnover at all three sub-award sites and general disruption due to COVID-19 pandemic.

- At the end of Year 3, a total of 3 participants are enrolled in the study with one having completed their first session.
- Recruitment is expected to increase from changes made to the protocol that increases the maximum eligible age from 45 to 65 years old.

Major Task 3: Data analysis and Prognostic Model Development

- Subtask 1: Establish factors related to use and disuse of the injured side through various analysis techniques. Refine existing analysis techniques for actigraphy data analysis and visualization/data representation techniques.
 - Not yet applicable.
- Subtask 2: Develop and apply advanced statistical methods (e.g., p=median clustering) to detect subgroups of individuals who have meaningfully different patterns of real-world upper limb use.
 - Not yet applicable
- Subtask 3: Utilize machine learning techniques to develop a prognostic model that will guide evidence-based decisions on severe upper limb injury care.
 - Not yet applicable.

Major Task 4: Manuscript Preparation and Dissemination of Results

- Subtask 1: Manuscript preparation and submission to journals based on cross-sectional and longitudinal analyses.
 - Not yet applicable.
- Subtask 2: Presentation of data at academic conferences.
 - Not yet applicable.
- Subtask 3: Attend DoD-sponsored scientific meeting.
 - Not yet applicable.
- Subtask 4: Attend DoD-sponsored In-Progress Review meeting.
 - Dr. Frey attended the March 23, 2022 In-Progress meeting.

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.

Please see above for progress on 1) Major Activities and 2) Specific Objectives organized by Statement-of-Work tasks. Overall, effort on the third year of the project was directed towards participant recruitment and resolving regulatory hurdles to participant recruitment. During the third and fourth quarters of Year 3, we successfully recruited our first participants (a total of three have now been enrolled). All sites worked to develop professional working relationships and engaged in

frequent communication regarding the project and its progress. MU continues to provide support and monitor timely progress at all sites.

3) Significant results or key outcomes.
Not yet applicable.

4) Other achievements.
Not yet applicable.

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.

Nothing to report.

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.

Nothing to report.

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.

In Year 4 of this award, we will continue tasks related to Major Tasks 2, 3, and 4. More participants are expected to be enrolled with changes to the protocol that increase the maximum eligible age from 45 to 65 years old. Data collection will continue with the recruitment of the study cohort (n = 20 per site). MU will enroll all participants in the remote protocol that involves actigraphy monitoring and ecological momentary assessment of daily pain levels. Initial data processing will take place. MU will provide continual support and corrective feedback to the study subaward sites. If necessary, the MU team, in collaboration with the sub-sites, will consider additional recruitment strategies (e.g., sending recruitment letters in addition to cold calls).

4. **IMPACT:** *Describe 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).

Nothing to report.

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.

Nothing to report.

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.*

Nothing to report.

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.*

Nothing to report.

- 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:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

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.

Problems/Delays

As described in Section 2, data collection has been significantly slowed. This has been due to myriad factors. All three subaward sites experienced significant staffing issues in Years 1-2. This resulted in time lost due to training/onboarding, etc. The staffing issues have now been largely resolved. Recruitment remains a challenge, but both OSU and WU are actively recruiting.

Plans

The staffing and training issues at the sites have now been largely resolved. We have begun the process of changing the protocol to extend the maximum eligible age of 45 to 65 years old. This is expected to improve recruitment and is not considered to impact the findings of this study. On a positive note, 2 of the 3 sub-sites (WU and OSU) have recruited a total of 3 participants with one participant completing their first full session. Recruitment is expected to improve during the next quarter.

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.

Since few participants have been enrolled, our expenditures have been lower than budgeted.

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. See p. 4 for all IRB / HRPO approval dates.

Significant changes in use or care of vertebrate animals

Not applicable, no use or care of vertebrate animals in this project.

Significant changes in use of biohazards and/or select agents

Not applicable, no use of biohazards or select agents in this project.

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.

Nothing to report.

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.

Nothing to report.

- **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.

The project team created a survey designed to measure pain at multiple timepoints throughout the day. The survey captures emotional and functional aspects of pain as well as the present pain rating. This survey will be deployed using the ecological momentary assessment data capture system utilized in this project.

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".

University of Missouri School of Medicine (MU)

Name: Scott Frey, PhD, EdM
Project Role: Co-Principal Investigator
Nearest person month worked: 2
Contribution to Project: Dr. Frey is the lead investigator for this project. He oversees all project activities. He developed the scientific approach for the study and monitors progress. He is available to provide corrective feedback to subaward sites as needed.

Name: Clinton Davis-Stober, PhD
Project Role: Co-Principal Investigator
Nearest person month worked: 1
Contribution to Project: Dr. Stober lends his statistical expertise to the project. He develops novel statistical methods to develop a prognostic model that will guide evidence-based decisions in severe upper limb injury care.

Name: Kelli Buchanan, MPH
Project Role: Lead Coordinator
Nearest person month worked: 2
Contribution to Project: Ms. Buchanan is the lead coordinator for this project. She manages regulatory approvals for this project (MU is the Single IRB of Record for this project, DoD HRPO oversees the MU IRB of Record), is the primary contact for subaward sites, leads bi-weekly coordinator meetings, assists with technical report writing, and completes other misc. tasks as needed to support the timely completion of project goals. Ms. Buchanan left the project at the end of Year 2.

Name: Nicholas Henigman
Project Role: Research Coordinator
Nearest person month worked: 4
Contribution to project: Mr. Henigman has replaced Ms. Buchanan as the lead program coordinator. He took over all responsibilities that Ms. Buchanan had.

Name: Binal Motawar, PhD
Project Role: Post-doctoral fellow
Nearest person month worked: 3
Contribution to Project: Dr. Motawar worked to develop an automated pipeline to export and clean data from our data capture systems.

Washington University School of Medicine (WUSM)

Name: David Brogan, MD
Project Role: Principal Investigator, Washington University.
Researcher Identifier (e.g. ORCID ID): 0000-0001-6259-4885
Nearest person month worked: 1
Contribution to Project: Dr. Brogan oversees all project activities at WUSM. In particular, Dr. Brogan provides expertise in selecting medical codes that will identify potential participants.

Name: Carrie Burk
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0002-8233-5001
Nearest person month worked: 2
Contribution to Project: Carrie is the coordinator for WUSM. Her duties include, but are not limited to, attending bi-weekly coordinator meetings with the lead site, managing local regulatory acknowledgements, coordinating the space and materials needed to conduct the space at WUSM, and leading recruitment efforts. Carrie left the project in early Year 3 and was replaced by Liz Wilson.

Name: Yosita Beamer
Project Role: Research Assistant
Nearest person month worked: 1
Contribution to Project: Yosita has contributed to the project by attending coordinator meetings and screening/recruiting for the study. Yosita left the project at the end of Year 3 and was replaced by Michelle Moore.

Name: Liz Wilson, MS, CCRP
Project Role: Senior Clinical Research Coordinator
Nearest person month worked: 2
Contribution to Project: Liz is the coordinator for WUSM. Her duties include, but are not limited to, attending bi-weekly coordinator meetings with the lead site, managing local regulatory acknowledgements, coordinating the space and materials needed to conduct the space at WUSM, and leading recruitment efforts.

Name: Michelle Moore
Project Role: Research Assistant
Nearest person month worked: 1
Contribution to Project: Michelle has contributed to the project by attending coordinator meetings and screening/recruiting for the study.

Ohio State University School of Medicine (OSU)

Name: Amy M. Moore, MD, FACS
Role on project: Principal Investigator – The Ohio State University
Nearest person month worked: < 1 person month
Contribution to project: Dr. Moore is the principal investigator at The Ohio State University site. She oversees all activities of the study and research staff.

Name: Irene Kapsan, MACPR
Role on the project: Clinical Research Coordinator – The Ohio State University
Nearest month worked: 2 person months
Contribution to project: Ms. Kapsan is part of the research study staff at The Ohio State University site. She is the primary contact for this site, completing site-specific documents (such as reliance agreements, ICF, etc). Over the past year, she worked on study start-up activities, such as outcome measure testing and CRF completion.

Name: Emily Rice, RDN, LD
Role on the project: Clinical Research Coordinator – The Ohio State University
Nearest month worked: < 1 person month
Contribution to project: Ms. Rice was hired in 2022 by The Ohio State University as a research coordinator. She is currently helping Ms. Kapsan with regulatory processes and will be administering tests to participants when recruitment begins.

Name: Tiam Mana Saffari, MD PhD MSc
Role on the project: Outcomes Evaluator – The Ohio State University
Nearest month worked: < 1 person month
Contribution to project: Dr. Saffari is part of the research study staff at The Ohio State University site. She will be conducting the outcome measures indicated in the protocol.

Johns Hopkins University School of Medicine (JHU)

Name: Gerald Brandacher, MD

Role on project: Site PI

Nearest person month worked: < 1 month

Contribution to project: Dr. Brandacher is overseeing the study team and ensuring that all necessary regulatory approvals are secured.

Name: Jaimie Shores, MD

Role on project: Co-I

Nearest person month worked: <1 month

Contribution to project: Dr. Shores is available to advise the team on local standard care processes and practicality of protocol implementation locally.

Name: Carisa M. Cooney, MPH

Role on project: Co-I

Nearest person month worked: < 1 month

Contribution to project: Ms. Cooney, who is the site expert in regulatory processes (e.g., IRB, HRPO), is working with Nicholas Henigman at MU to secure regulatory approvals at MU and Hopkins in order to start the study at Johns Hopkins. She liaises between Mr. Henigman and the Hopkins Team to accomplish study tasks and milestones.

Name: Jonathan Vullier

Role on the project: Clinical Research Coordinator – Johns Hopkins University School of Medicine

Nearest person month worked: < 1 month

Contribution to project: Mr. Vullier was hired by JHU in 2022 and is currently helping Ms. Cooney on regulatory processes. He will be administering tests to participants when recruitment begins. Mr. Vullier left the project at the beginning of Year 3.

Name: Shanmuga Priya Rajagopalan, MS

Role on the project: Senior Clinical Research Coordinator

Nearest person month worked: < 1 month

Contribution to project: Ms. Rajagopalan has taken over the responsibilities of Jonathan Vullier.

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.

University of Missouri School of Medicine– Nothing to report.

Washington University School of Medicine– Nothing to report.

Ohio State University School of Medicine– Dr. Moore devotes 15% on a DoD project (Promoting Healing of Nerves through Electrical Stimulation; W81XWH1920065) effective June 2021. This project does not impact Dr. Moore’s effort on this project.

Johns Hopkins University School of Medicine- 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.

Organization Name: Washington University School of Medicine

Partner's contribution to the project:

- 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);

Organization Name: Ohio State University School of Medicine

Partner's contribution to the project:

- 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);

Organization Name: Johns Hopkins University School of Medicine

Partner's contribution to the project:

- 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);

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://ebrap.org/eBRAP/public/index.htm> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil/Pages/Resources.aspx>) 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.*

Quantitative ambulatory assessment and prognosis of the impact of severe upper limb injuries on real world behavior.

W81XWH-19-DMRDP-CRMRP-RESTORE



PI: Scott H. Frey, Ph.D., Ed.M.

Org: Curators of the University of Missouri

Award Amount: 1,500,000

Study Aims

- Aim 1: Establish how patterns of real-world limb use by severe upper limb injury (SULI) patients evolve as they attempt to transition from sub-acute to chronic stages of recovery.
- Aim 2: Identify factors that predict success in re-establishing bimanual patterns of activity in real-world limb use and develop a prognostic model that can guide evidence-based decisions on SULI care and treatment.
- Aim 3: Determine the predictive validity of standardized tests of limb function for real-world limb use in SULI patients.
- Aim 4: Apply machine learning techniques to develop quantitative models of affected limb use based on individual-level pain estimation, taking into account documented over-estimation of pain.

Approach

The longitudinal design follows 60 patients who have undergone surgical repairs of one or more of the major forearm nerves (median, ulnar, radial) following complex volar forearm lacerations. Initial data is collected within 2-4 weeks after the limb is freed from all bandages, splints, braces or casts. In each of three years, we use accelerometry to acquire 7 continuous days of data on limb use during everyday life, and real-time ratings of pain throughout each day using Ecological Momentary Assessment. Participants also complete standardized assessments of limb function and validated survey and questionnaire instruments concerning quality of life and participation in occupational, recreation and social activities. Advanced statistical and machine learning techniques are used to analyze data and develop and test prognostic models of functional recovery based on these data.



Figure 1: The Action Research Arm Test (ARAT), a measure that quantifies upper extremity coordination, dexterity, and functioning. Participants are asked to manipulate and move objects in a standardized protocol. The measure contains four subscales: grasp, grip, pinch, and gross movement to assess a variety of different types of upper extremity function. All study teams are trained in administration of the ARAT. Additionally, teams follow a written script to ensure that administration is standardized across participants.

Timeline and Cost

Timeline: March 2021 – February 2024

Activities	CY	03/21-02/22	03/22-02/23	03/23-02/24
Major Task 1: Prepare Regulatory Docs, Maintain Compliance, and Other Admin Tasks.				
Major Task 2: Enrollment & Data Collection				
Major Task 3: Data Analysis and Prognostic Model Development				
Major Task 4: Manuscript Preparation and Dissemination of Results				
Estimated Budget (\$K)		517	485	498

Progress Update on Major Tasks from SOW

- A total of three participants have been recruited from WU and OSU sites.
- Washington University and Ohio State University have generated lists of potential participants and are actively recruiting. As noted below, we will expand our recruitment methods in the next quarter.
- University of Missouri stays in close contact with all study sites to ensure timely completion of SOW goals as well as provide support when needed.

Looking ahead:

- In the next quarter, we will focus on continuing recruitment. Both OSU and WU have each successfully enrolled one participant. The participant from the OSU site has completed the in-clinic session and accelerometry session. OSU and WU are continuing to actively recruit participants. MU will continue working with JHU to finish clearing regulatory hurdles and will then train JHU personnel so that they may also actively recruit participants.
- Budget Expenditure:
 - Budgeted/Projected to date: \$1,500,000
 - Actual Expenditures to date: \$948,939