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TITLE: From Opinion to Evidence: Multisite Evaluation of Custom Dynamic Orthosis Best Practices

PRINCIPAL INVESTIGATOR: Dr. Jason Wilken, PhD

CONTRACTING ORGANIZATION: The University of Iowa

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6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

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The University of Iowa
105 Jessup Hall
Iowa City, IA 52242-1316

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13. SUPPLEMENTARY NOTES
N/A

14. ABSTRACT

Severe lower extremity trauma often leads to poor long-term outcomes for service members and civilians. Carbon fiber custom dynamic orthoses (CDOs) consist of (1) a full-length, custom-molded, rigid foot plate that supports the foot and acts as a lever to allow bending of (2) a posterior, carbon fiber, dynamic strut that stores and returns energy while transferring force from the foot plate to (3) a cuff below the knee that effectively transmits load proximally and have been shown to significantly improve mobility, quality of life, and limb function following lower extremity trauma in injured service members. Direct changes in alignment, and heel wedge–induced changes in alignment, most affect patient preference and limb mechanics. This presents the opportunity to systematically determine if subject matter expert–recommended and vendor–recommended benchmark configurations produce better outcomes than variations from this configuration or independent clinician decision making. The objective of this study is to provide data-driven guidance for CDO clinical fittings for two types of CDOs. This study leverages best available evidence, decades of combined experience, and multiple complementary measures to evaluate recommended CDO benchmark configurations relative to alternate configurations.

15. SUBJECT TERMS
Carbon fiber, orthosis, lower limb injury

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
U	U	U	UU	12	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.*

   Severe lower extremity trauma often leads to poor long-term outcomes for service members and civilians. Carbon fiber custom dynamic orthoses (CDOs) significantly improve mobility, quality of life, and limb function following lower extremity trauma in injured service members by supporting the limb and reducing pain. CDOs are an external brace consisting of (1) a full-length, custom-molded, rigid foot plate that supports the foot and acts as a lever to allow bending of (2) a posterior, carbon fiber, dynamic strut that stores and returns energy while transferring force from the foot plate to (3) a cuff below the knee that effectively transmits load proximally. CDO designs and fitting processes have evolved substantially over the last decade as clinicians and scientists have worked to further improve outcomes. However, an unstandardized trial-and-error process is typically used to determine CDO configuration. Objective scientific evidence, growing experience, and discussions within the network of clinicians providing CDOs has led to a growing consensus among subject matter experts and vendors regarding best practices, and the best configuration, for CDOs. We have demonstrated that direct changes in alignment, and heel wedge–induced changes in alignment, most affect patient preference and limb mechanics. This insight, and our experience developed through conduct of an ongoing randomized controlled clinical trial, present the opportunity to systematically determine if subject matter expert–recommended and vendor–recommended benchmark configurations produce better outcomes than variations from this configuration or independent clinician decision making. The objective of this study is to provide data-driven guidance for CDO clinical fittings for two types of CDOs. This study leverages best available evidence, decades of combined experience, and multiple complementary measures to evaluate recommended CDO benchmark configurations relative to alternate configurations.

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

   Carbon fiber, orthosis, lower limb injury

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.*

Activity	Months	Progress
Major Task 1: Overarching Project Activities		
Subtask 1: Identify, hire and retain top quality staff and students	0-48	60%
Subtask 2: Obtain and maintain local IRB and OHRO regulatory approvals	0-48	20%
Subtask 3: Project team teleconferences	0-48	10%
Subtask 4: Complete study reports, presentations, publish and disseminate study results	30-48+	5%
Milestone: Timely submission of progress reports	3-48	25%
Milestone: Submission of continuing review documents	12-48	0%
Milestone: Local IRB and OHRO approval at all sites	6	0%
Milestone: Submission of final report	48	0%
Major Task 2: Project Standup		
Subtask 1: Establish CRADA, contracts and other required agreements	0-2	55%
Subtask 2: Finalize collection procedures and REDCap data management	0-48	10%
Subtask 3: Fabricate and distribute device mechanical testing systems	0-6	100%

Subtask 4: Convene CDO consulting group to inform study procedures and guidelines	0-6	40%
Subtask 4: Staff training and collection procedure refinement	0-48	15%
Milestone: All approvals and agreements in place	2, 12	15%
Milestone: Ready to initiate recruitment and collection	12	0%
Major Task 3: Patient Fittings		
Subtask 1: Work with vendors to finalize distribution and training plan	0-3	10%
Subtask 2: Inter-site coordination of fitting processes and CPO training	0-12	0%
Subtask 3: Completion of study fitting manual describing procedures	0-12	95%
Milestone: Ready to initiate fittings	6	0%
Milestone: Patient fittings ongoing and logistics resolved	12	0%
Major Task 4: Participant Testing		
Subtask 1: Staff training and methods verification	3-39	0%
Subtask 2: Ongoing data quality and methods implementation checks	12-36	0%
Subtask 3: Recruitment, enrollment and collection (n=15 at each site)	12-36	0%
Subtask 4: Recruitment, enrollment and collection (n=10)	12-36	0%
Milestone: Enrollment complete	33	0%
Milestone: Collection complete	36	0%
Major Task 5: Data Analysis and Publication		
Subtask 1: Data audit and analysis- Patient reported and performance measures	14-45	0%
Subtask 2: Data audit and analysis- Biomechanical and mechanical measures	14-45	0%
Subtask 3: Finalize and implement statistical analysis plan	33-45	0%
Subtask 4: Interpretation of results and manuscript preparation	40-45	0%
Milestone: Analysis complete	45	0%
Milestone: Initial manuscripts complete	48	0%
Specific Aim 1: Determine the comparative effect of orthosis configuration on patient-reported preference, perceived comfort, and smoothness in individuals with limb impairment following severe lower extremity trauma.		
Specific Aim 2: Determine the comparative effect of orthosis configuration on biomechanical measures of limb function in individuals with limb impairment following severe lower extremity trauma.		
Specific Aim 3: Determine the comparative effect of orthosis configuration on physical performance in individuals with limb impairment following severe lower extremity trauma.		

- **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.*

Major Task 1: One research associate at the University of Iowa was identified and hired and has contributed to the preparation of the study procedures and study documentation.

A Human Subjects Research Determination Form was submitted to the University of Iowa Institutional Review Board (UI IRB) in support of the CDO consulting group convening to inform study procedures and guidelines. It was determined that the project comprises Research Not Involving Human Subjects at this time. This determination was shared and approved by the Office of Human Research Oversight (OHRO).

Although the University of Iowa IRB is a member of the SMART IRB, it was determined that they cannot be the IRB of record over a California site due to legal complexities. The Western IRB (WCG IRB) is a commercial IRB that will provide IRB oversight for the project. The PI met with WIRB to determined logistics. The UIowa PI and research associate met with the UIowa IRB to determine how the coordinating site should submit to WIRB and UIowa IRB.

Developed plans to convene CDO consulting group to inform study procedures and guidelines including timeline, location, facilitators, presentations, and criteria. Dave Hughes, Ben Wright and the PI, Jason Wilken, met to determine the CDO consulting group. Invitations were sent to potential group participants and most responses received.

Project teleconferences have been held to discuss regulatory strategy, finalize study measures, and coordinate the establishment of subawards to the sites. The Mayo Clinic site PI visited the University of Iowa to convene on data collection procedure refinement.

A project teleconference with University of Iowa IRB was held to determine appropriate steps for submitting protocol and obtaining IRB approval as the coordinating center. The IRB protocol and attachments were drafted in WCG Connexus.

Major Task 2: Study standup efforts are underway. Project coordination is ongoing between sites. The Research Electric Data Capture (REDCap) was used to create and refine study documentation that will be reviewed by the CDO consulting group during the next reporting period. A strategy has been developed for addressing data handling procedures. The initiation of material transfer and other agreements will be postponed due to later start of collection.

A teleconference was held with subject matter experts to inform study procedures and determine CDO consulting group meeting and experts. Project teleconferences have been held to discuss regulatory strategy, finalize study measures, and coordinate the establishment of subawards to the sites.

A mechanical testing device was fabricated and distributed to UIA. This device will be used to mechanically test all study devices to ensure data quality. The fabrication companies will ship the devices directly to UIA and UIA will then ship the devices to each site after testing.

Major Task 3:

The award PI coordinated with the vendors to gather the required information to add them to the University of Iowa procurement system. This step was completed and systems are in place for all device procurement. The study fitting manual describing procedures will be reviewed and revised again after feedback from subject matter experts, and finalized in the next reporting period.

The study fitting manual describing procedures has been completed and will be shared with the study sites with finalized collection procedures during the next reporting period.

- **Describe the Regulatory Protocol and Activity Status (if applicable).** *Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state "Nothing to Report."*
    - **Human Use Regulatory Protocols**
        - **TOTAL PROTOCOLS:** *State the total number of human use protocols required to complete this project (e.g., 5 human subject research protocols will be required to complete the Statement of Work."). If not applicable, write "No human subjects research will be performed to complete the Statement of Work."*

One human subject research protocol is required to complete the study.

- **PROTOCOL(S):** *List the identifier and title for all human use protocols needed to complete the project. Include information about the approved target number for clinical significance, type of submission, type of approval with associated dates, and performance status.*

Protocol (1 of 1 total):

Protocol [OHRO Assigned Number]: Pending affirmation of IRB approval.

Title: From Opinion to Evidence: Multi-site Evaluation of Custom Dynamic Orthosis Best Practices

Target required for clinical significance: 70 cumulative (Target 88 enrolled to account for dropout)

Target approved for clinical significance: 70 cumulative (Target 88 enrolled to account for dropout)

Submitted to and approved by:

New Protocol IRB Submission: anticipated submission in fall 2023

New Protocol OHRO Submission: pending IRB approval.

Status:

Recruitment/Screening/Enrollment/Completion:

Number of subjects recruited/original planned target: 0/88

Number of subjects screened/original planned target: 0/88

Number of patients enrolled/original planned target: 0/88

Number of patients completed/original planned target: 0/77

Amendments submitted to the IRB and USAMRMC OHRO for review:

N/A

Any adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

N/A

- **Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training**
  No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).
- **Animal Use Regulatory Protocols**

  No animal use research will be performed to complete the Statement of Work.
- **What opportunities for training and professional development has the project provided?** *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?** *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?** *Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

  During the next reporting period, we plan to convene the CDO consulting group to inform study procedures and guidelines. The CDO study fitting manual describing procedures will be shared with the study sites. The vendors and study sites will coordinate to arrange the date and time for CPO training at each site. The study will be submitted and receive IRB approval.

4. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about because of the project relative to:*
   - **What was the impact on the development of the principal discipline(s) of the project?** *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?** *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?** *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?** *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 Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.*
   - Administrative processes at study sites have delayed finalization of subawards. We expect subaward to be completed in 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.*

     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.

Nothing to report.

6. **PRODUCTS:** *List any products resulting from the project during the reporting period.*

   - **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. In addition to a description of the technologies or techniques, describe how they will be 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. State whether an application is provisional or non-provisional and indicate the application number. 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; biospecimen 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."

Name*:*	Jason Wilken, PT, PhD
Project Role:	Overall Award PI, UI Site PI
Researcher ID (ORCID ID):	0000-0002-5556-7667
Nearest Person Month Worked:	1
Contribution to Project:	Study direction, site management, regulatory approvals, review of patient fittings, work with vendors to finalize distribution and training plans.

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Name*:*	Molly Pacha, MS
Project Role:	Research Associate
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	1
Contribution to Project:	Data collection procedure refinement, regulatory approvals, technical report preparation and submission.

Additional individuals contributed less than 0.5 calendar months effort.

Name*:*	Patrick Ten Eyck, PhD
Project Role:	Co-Investigator/Lead Biostatistician
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Preparation of data collection forms in REDCap, data quality checks, statistical analysis.

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Name*:*	Kenton Kaufman, PhD
Project Role:	MC site PI
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Site PI, study standup activities.

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Name*:*	Michael Willey, MD
Project Role:	Co-Investigator
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Study direction, data collection, procedure refinement.

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Name*:*	Andrew H. Hanson, PhD
Project Role:	MVHCS site PI
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Site PI, study standup activities.

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Name*:*	Trevor Kingsbury, MS
Project Role:	NMCSD site PI
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Site PI, study standup activities.

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Name*:*	Joseph Hsu, MD
Project Role:	AH site PI
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Site PI, study standup activities.

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Name*:*	LTC Daniel Stinner, MD, PhD
Project Role:	VUMC site PI
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Site PI, study standup activities.

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Name*:*	Kristin Archer, PT, PhD
Project Role:	VUMC Co-Investigator
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Study design and interpretation of measures, enrollment.

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Name*:*	Lisa Reider, PhD
Project Role:	Co-Investigator/Director of Data Quality and Safety
Researcher ID (ORCID ID):	N/A
Nearest Person Month Worked:	0
Contribution to Project:	Study direction, data collection procedure refinement

- **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 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?** *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:	The University of Iowa (UI)
Location of Organization:	Iowa City, IA

Contribution to Project: Facilities, collaboration

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Organization Name: Mayo Clinic (MC)
Location of Organization: Rochester, MN
Contribution to Project: Facilities, collaboration

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Organization Name: Minneapolis VA Health Care System (MVHCS)
Location of Organization: Minneapolis, MN
Contribution to Project: Facilities, collaboration

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Organization Name: Navy Medical Center San Diego (NMCSD)
Location of Organization: San Diego, CA
Contribution to Project: Facilities, collaboration

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Organization Name: Atrium Health (AH)
Location of Organization: Charlotte, NC
Contribution to Project: Facilities, collaboration

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Organization Name: Vanderbilt University Medial Center (VUMC)
Location of Organization: Nashville, TN
Contribution to Project: Facilities, collaboration

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Organization Name: Johns Hopkins University
Location of Organization: Baltimore, MD
Contribution to Project: Collaboration

8. **SPECIAL REPORTING REQUIREMENTS**
   - **COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from **BOTH** the Initiating 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 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. Reminder: Pages shall be consecutively numbered throughout the report. **DO NOT RENUMBER PAGES IN THE APPENDICES.***

   Nothing to report.