

AWARD NUMBER: W81XWH-19-1-0827

TITLE: Evaluating the Impact of Prosthetic Device Features on the Experience of Prosthesis Use

PRINCIPAL INVESTIGATOR: Emily Graczyk, PhD

**CONTRACTING ORGANIZATION: Cleveland VA Medical Research
and Education Foundation
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**PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012**

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

Our goal is to understand the critical factors associated with outcome acceptance following upper limb loss. We aim to develop a unified theoretical model that describes the psychosocial experience of upper limb prosthesis use and predicts outcome acceptance following upper limb loss. This conceptual framework will enable clinicians and researchers to evaluate and predict patient outcomes following limb loss, and to design interventions that improve outcomes. The proposed two-year study is a mixed methods (qualitative and quantitative) study using an observational design. The qualitative component of the study will involve data collection through telephone interviews with 18 participants and analyses using a grounded theory approach with constant comparison methods. The quantitative component involves administration of standardized measures quantifying constructs of the theoretical model in 120 participants and analyses to produce a structural equation model of outcome acceptance. Participants will include persons with unilateral acquired upper limb loss at the trans radial or trans humeral level who use currently available prosthetic devices.

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

Prosthesis; Outcome Acceptance; Qualitative research; Mixed methods; Upper limb loss; Amputee; Interview; Survey

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.

Specific Aims 1 and 2	Timeline	Completion
Major Task 1: Obtain regulatory approvals	Months	100%
Prepare regulatory documents and research protocol	1-2	12/5/19
Finalize consent form and human subjects protocol	1-2	11/15/19
Finalize participant interview guide	1-2	12/10/19
Coordinate with Sites for IRB protocol submission	1-2	12/6/19
Submit amendments, adverse events, and protocol deviations as needed	As needed	N/A
<i>Milestone Achieved: Local IRB Approval</i>	3	12/16/2020
<i>Milestone Achieved: HRPO Approval</i>	4	11/18/2020
Major Task 2: Coordinate study staff and prepare for study		95%
Advertise for, interview, and hire study coordinator	1-5	6/8/2020
Purchase study-related equipment and supplies	1-2	2/10/2020
Training of all study staff at Cleveland site visit	4-6	12/10/19

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.

1. Major Activities:

Our major activities this year include receiving HRPO approval on November 18th, 2020, and receiving VA R&D approval for the project on December 16th, 2020. We then began recruiting participants for the interview portion of the study. Overall, we have recruited and conducted interviews with 14 participants. We have focused on recruiting the remainder of interview participants, coding participant interviews, creating case summaries for each participant, and using the axial coding process to identify and understand the relationships between the nodes and subcategories we generated based on the interview data. Through this analysis process, we have focused on identify sub-constructs or sub-themes within each node/category in order to identify survey metrics and develop new survey items to measure each sub-construct in Aim 3. We have also begun making cross-case comparisons in order to identify themes related to prosthesis type. In addition, we created a publication plan for disseminating the findings of Aims 1 and 2.

This year, we submitted an IRB amendment that included changes to help expand our avenues for participant recruitment and exclude bilateral amputees from participating in the study. We submitted the amendment, and it was forwarded to reviewers on 05/06/2021. After responding to questions and comments from ISSO and primary reviewer, the amendment was officially approved on 07/17/2021. We submitted a protocol deviation on 06/25/2021, and the Central IRB uploaded a determination letter on 06/28/2021, stating that no further action was necessary as the deviation was not determined to be serious or continuing. Based on the reporting guidelines of HRPO, we determined that these changes did not need to be approved by HRPO.

We submitted a request for a no-cost extension of the award on April 12, 2021. Delays in securing IRB approval due to the COVID-19 pandemic significantly delayed the start of participant recruitment. The proposed no-cost extension would allow us to continue working on the project through September 2022. The no cost extension request was approved on September 30, 2021.

2. Specific Objectives:

Our objectives over the past year included:

1. Regulatory approvals to begin participant recruitment
2. Notify recruiting partners of study approvals
3. Prepare and distribute recruitment materials
4. Screen and consent participants
5. Recruit and enroll participants to the interview portion of the study (Aims 1 and 2)
6. Complete Interview 1 and Interview 2 with enrolled participants
7. Create a Case summary for each participant
8. Audio recordings transcribed by Transcription Outsourcing, LLC.
9. Code interview data with initial code set
10. Discuss and analyze preliminary findings to refine initial code set and definitions

11. Begin axial coding of interview data: Establish sub-nodes based on coded data to identify surveys for survey portion of study (Aim 3)
12. Prepare IRB amendment 1
13. Continue to recruit participants for the interview portion of the study
14. Identify the surveys to be used in next aim of study
15. Develop publication plan for dissemination of findings from Aims 1 and 2
16. Submitted no cost extension request

3. Key Outcomes

Throughout the months September through December 2020, we focused on acquiring IRB and HRPO approvals to begin participant recruitment. We received HRPO approval on November 18th, 2020, and we received VA R&D approval for the project on December 16th, 2020. Amputee Coalition and Hanger Prosthetics had previously agreed to assist in recruiting eligible participants from their patient population. Therefore, once we received all the regulatory approvals, we reconnected with collaborators to start the recruitment process. The study information was successfully listed on Amputee Coalition's website, and Hanger Prosthetics distributed our recruitment flyer and letter to their providers. We distributed our recruitment letters and flyers to our contacts at OrthoCarolina and contacted various colleagues to ask for assistance in recruiting the fourth category of participants who utilize sensory systems that are primarily in the research phase of development.

After posting the study listing on Amputee Coalition's website, we received our first call from an individual interested in participating in the study. On January 5th, 2021 Melissa Schmitt (our Research Analyst) screened and consented our first participant. The first interview was conducted by Melissa Schmitt on January 6th, 2021 followed by the second interview on January 7th, 2021. Once the interviews were conducted, the audio recordings were sent to Transcription Outsourcing, LLC, to be transcribed, and the participant was mailed two \$20 Visa gift cards as payment for their time completing both interviews. Once the data was transcribed, we began coding and discussing the first set of interview data.

In the months January through March of 2021, we continued to focus our efforts on participant recruitment, and continued screening, consenting, and enrolling participants. During these months we screened 12 participants and enrolled 10. The two participants who were not enrolled were not eligible for the study. At this point in the year, we had completed both interviews with the first eight participants. The recruitment goals for the interview portion of the study were four body-powered prosthesis users, four single-degree of freedom myoelectric prosthesis users, four multi-degree of freedom myoelectric prosthesis users, and six sensory augmented prosthesis users. In total, we had recruited 3- body powered users of the 4 planned, 1- one degree of freedom user of the four planned, 3- multi degree of freedom users of the four planned, and finally, one of the six sensory augmented prostheses users planned.

As the interview transcriptions became available, they were coded by two analysts on our team: Melissa Schmitt and Debra Kelty. The study team coded one set of interviews from one participant in each category of our four categories of prosthesis users. The goal of this initial coding was to identify common themes and concepts in the data and refine the coding structure for the interviews to follow. This analysis enabled us to generate a conceptual framework for understanding prosthesis outcome acceptance. We created a dashboard to organize our process and to keep track of participant screening, participant enrollment, interviews conducted, transcripts returned, and when coding was completed. Debra Kelty, the research assistant at the Providence VA site, created case summaries for participants one through six.

During the months April through July 2021, we recruited four additional participants, bringing our total enrollment to 12 participants. We submitted an amendment to the VA Central IRB on 04/12/2021 which included changes to the exclusion criteria and recruitment methods. The amendment excluded bilateral amputees from study participation and aimed to increase our options for recruitment. The amendment included a website listing on the FES Center (VA Center of Excellence) website, and we also created an advertisement to include on the Amputee Coalition's website which includes a link to the FES Center website listing. We proposed to increase the attempts that can be made to contact each participant to ensure that study

staff are given optimal opportunity to reach potentially interested individuals. We proposed to increase avenues for recruitment including the use of VA MedSAS and VINCI to extract participant names, addresses and telephone numbers from Corporate Data Warehouse (CDW) sources including VA MedSAS and the VHA Benefits file. In addition, we added other social media platforms to help recruit participants including the Federal Amputee Interest Group listserv, Upper extremity amputee Facebook support groups, and the Wounded Warrior project website. We also included an alternative method for participating through VA Qualtrics to help make participating in the study more accessible and convenient for participants. We proposed to include the link to the Qualtrics surveys on the FES Center website listing as well as the Amputee Coalition website. The amendment was forwarded to the reviewers on 05/06/2021, and was officially approved on 07/17/2021.

While we waited for the protocol amendment to be approved, we reached out to Dr. Joseph Webster, who is the Medical Director of the VHA Amputation System of Care (ASoC), to discuss avenues for assistance in recruitment. Dr. Webster agreed to send our approved recruitment flyer to a listserv of VA providers called FAIG. This led to the recruitment of two more participants. In total during these months, we recruited 4- body powered users (of the four planned), 2- one degree of freedom users (of the four planned), 3- multi degree of freedom users (of the four planned), and finally, two of the six sensory augmented prostheses users. We completed both interviews for all 12 participants, except for participant 011. We did not conduct interview 2 with participant 011 because we found a discrepancy in the information they provided during screening and the information provided during interview 1. We found the participant misunderstood one of the eligibility criteria and was in fact ineligible for the study because they had not been using the prosthesis that they were describing for at least 6 months. In response to this realization, we submitted a protocol deviation on 06/25/2021. The deviation informed the Central IRB of the miscommunication during screening. The Central IRB uploaded a determination letter on 06/28/2021, stating that no further action was necessary as the deviation was not determined to be serious or continuing. In the report, we decided that we would like to keep subject 011's data and conduct the second interview once the allotted time had passed which allowed them to be eligible to participate. This subject completed the second interview on Wednesday, October 13th.

From July to September 2021, the team worked to identify subcategories within the nodes, in order to identify specific constructs that could be measured in the survey portion of the study. We began discussing which existing survey instruments may measure the identified constructs, and whether new items or measures would need to be developed. In addition, the team created data matrices to compare experiences within each node and sub-node across participants. This will enable us to compare perspectives across the four prosthesis user groups, and is the first step in developing cross-case analyses. The team also created a plan for the first four publications to disseminate findings from this work, and began outlining the first manuscript. During this last quarter, we enrolled two more individuals: one individual used a one degree of freedom prosthesis and the other was included in the sensory augmented group.

Throughout the year, the team met weekly to discuss the project status, recruitment, enrollment, and qualitative analysis process. We managed the project through a Microsoft Teams dashboard in which we organize data and keep track of the interviews conducted, when transcription services were completed, when coding has been completed for each participant, and participant payment. We worked to identify in vivo codes and subdivide the existing codes into sub-categories, based on analysis of the collected data and discussions among the team. We have continued the process of axial coding to identify and understand the relationships among the nodes. We have also continued identifying constructs that we wish to measure with survey instruments in Aim 3, based on this analysis. We plan to finalize our set of instruments for Aim 3 and amend our IRB and HRPO protocols with this updated set of measures in the upcoming quarter. Overall, we have recruited and conducted interviews with 14 participants, and still need to recruit 1 more one degree of freedom prosthesis user, and 3 more individuals in the sensory augmentation category.

4. Accomplishments

The study received HRPO approval on November 18th, 2020, and we received VA R&D approval for the project on December 16th, 2020. On January 5th, 2021 we screened and consented our first participant. We submitted an amendment to the VA Central IRB on 04/12/2021 and it was officially approved on 07/17/2021. Overall, we have recruited and conducted interviews with 14 participants out of our total of 18 interviews.

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.

Emily Graczyk presented at several scientific conferences this year. The presentations were not related to the work in this project, but did provide training and networking opportunities. The conferences included: Joint Meeting of the North American Neuromodulation Society and Neural Interfaces Conference, American Spinal Injury Association Annual Scientific Meeting, BCI Society Workshop, and IEEE EMBS Conference.

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.

During the next reporting period, we will continue to recruit eligible participants for the interview portion of the study. We will also continue collecting, transcribing, and coding interview data with enrolled participants. We will continue to analyze the coded data to refine our coding structure. This analysis is allowing us to find common themes and concepts in the data to generate a conceptual framework for understanding prosthesis outcome acceptance. We will determine which concepts are of interest to measure during the quantitative component of the study (Aim 3). We will then select a definitive set of surveys and questionnaires to target those concepts and amend our IRB and HRPO protocols with this updated set of measures. We will continue holding weekly meetings between the Cleveland and Providence sites to discuss data collection and analysis processes. Once the IRB protocol is amended, we will begin recruiting for the survey portion of the study.

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.

While we have recruited 14 of the 18 proposed participants for the interview portion of the study, we have had difficulty recruiting participants for the sensory augmentation group. We have thus far recruited three of the proposed six participants in this group. This difficulty in recruitment was anticipated, as there are likely less than 100 people that fit these criteria in the world. We have reached out to several research collaborators and colleagues in an attempt to identify individuals who qualify for the sensory augmentation group. If we fail to recruit the remaining three participants in this group by December 2021, we will proceed with the qualitative analysis with a limited cohort, so that the overall progress of the study is not further impacted.

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

We submitted a protocol deviation to the Central VA IRB on 6/25/2021. After conducting interview 1 with participant 011, we found a discrepancy in the information they provided during screening and the information provided during interview 1. We found the participant misunderstood one of the eligibility criteria and was in fact ineligible for the study because they had not been using the prosthesis that they were describing for at least 6 months.

The participant was screened for eligibility on 06/07/2021 and was determined to be eligible for participation by study staff. The participant used two different types of prostheses and was asked to interview about their experience with one of the prostheses. The first interview was conducted on 06/07/2021, and the data was discussed in a virtual meeting with the entire study team on 06/22/2021. When discussing the data, the study team ultimately determined that the participant was providing details about his experience with the prosthesis that he had been using for only two months instead of the prosthesis he had been using for 6 months. The study eligibility criteria required the participant to have used the device they are speaking about for at least six months. The participant has used a prosthesis for six months, but not the prosthesis we interviewed him about. We attribute this deviation to a lack of understanding by the participant about which prosthesis we were asking them about. Therefore, we did not conduct the second interview, and waited to hear back from the Central IRB on how to proceed.

The Central IRB uploaded a determination letter on 06/28/2021, stating that no further action was necessary as the deviation was not determined to be serious or continuing. In our correspondence with the IRB, we decided that we would like to keep subject 011's data and conduct the second interview once the allotted time had passed which allowed them to be eligible to participate. This subject completed the second interview on Wednesday, October 13th.

As described above, we submitted an amendment to the VA Central IRB on 04/12/2021 which included changes to the exclusion criteria and recruitment methods for the study. The amendment excluded bilateral amputees from study participation and aimed to increase our options for recruitment. The amendment included a website listing on the FES Center (VA Center of Excellence) website, and we also created an advertisement to include on the Amputee Coalition's website which includes a link to the FES Center website listing. We proposed to increase the attempts that can be made to contact each participant to ensure that study staff are given optimal opportunity to reach potentially interested individuals. We proposed to increase avenues for recruitment including the use of VA MedSAS and VINCI to extract participant names, addresses and telephone numbers from Corporate Data Warehouse (CDW) sources including VA MedSAS and the VHA Benefits file. In addition, we added other social media platforms to help recruit participants including the Federal Amputee Interest Group listserv, Upper extremity amputee Facebook support groups, and the Wounded Warrior project website. We also included an alternative method for participating through VA Qualtrics to help make participating in the study more accessible and convenient for participants. We proposed to include the link to the Qualtrics surveys on the FES Center website listing as well as the Amputee Coalition website. The amendment was forwarded to the reviewers on 05/06/2021, and was officially approved on 07/17/2021.

Significant changes in use or care of vertebrate animals

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.

<https://fescenter.org/research/clinical-trials/amputation/upper-limb-amputees-experience-comprehension/>

- **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. 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”.

Example:

Name: Mary Smith
Project Role: Graduate Student
Researcher Identifier (e.g. ORCID ID): 1234567
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name:	Emily Graczyk
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-1467-8616
Nearest person month worked:	0.75
Contribution to Project:	Managed team and project, Oversaw coding analysis, and case summary development.

Name:	Melissa Schmitt
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Conducted interviews, Coded interviews for participants 001-007, Developed data matrices for cross-case comparisons

Name:	Alesia Lambert
Project Role:	Study Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.5
Contribution to Project:	Screened interested individuals, recorded screenings on VA REDCap, and scheduled interviews with eligible participants, Submitted Amendment 1, Answered Central IRB comments & clarifications, Submitted Protocol Deviation, Corresponded with collaborators assisting with recruitment

Name:	Linda Resnik
Project Role:	Site-PI of Providence Site
Researcher Identifier (e.g. ORCID ID):	0000-0002-0168-6759
Nearest person month worked:	0.3
Contribution to Project:	No change

Name:	Debra Kelty
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.5
Contribution to Project:	Coded interviews for participants 001-010, Created case summaries for participants 001 – 007, Refined coding structure and definitions, Led axial coding process

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:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (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.*

Organization Name: Amputee Coalition
Location of Organization: 900 East Hill Avenue, Suite 390, Knoxville, TN 37915
Contribution to Project: Collaboration in recruitment of participants

Organization Name: Richmond VA Medical Center
Location of Organization: 1201 Broad Rock Blvd, Richmond VA 23249
Contribution to Project: Collaboration in recruitment of participants

Organization Name: Hanger Prosthetics
Location of Organization: 10910 Domain Drive, Suite 300, Austin , TX 78758
Contribution to Project: Collaboration in recruitment of participants

Organization Name: OrthoCarolina
Location of Organization: 1915 Randolph Rd, Charlotte, NC 28207
Contribution to Project: Collaboration in recruitment of participants

Organization Name: Providence VA Medical Center
Location of Organization: 830 Chalkstone Ave, Providence, RI 02908
Contribution to Project: Collaboration

Organization Name: Case Western Reserve University
Location of Organization: 10900 Euclid Ave, Cleveland, OH 44106
Contribution to Project: In-kind support; Facilities

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.*