

AWARD NUMBER: W81XWH-20-1-0505

TITLE: Improving Acceptability and Outcomes for Upper
Extremity Transplantation in Service Members and
Veterans

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14. ABSTRACT The purpose of this project is to study Veterans and retired Service members with upper extremity amputations to identify psychosocial factors influencing their candidacy for reconstructive transplantation and assess their valuation of this treatment option. Progress to date includes securing single IRB approval for both Hopkins sites, local IRB approval for the VAMC site, and HRPO approval at both Hopkins sites. The application for HRPO approval for the VAMC was recently submitted. Educational material, the Delphi survey, and study CRF have been completed to collect data under Aim 1; interview development for data collection under Aim 2 continues.		

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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	5
2. Keywords	5
3. Accomplishments	5
4. Impact	10
5. Changes/Problems	11
6. Products	13
7. Participants & Other Collaborating Organizations	14
8. Special Reporting Requirements	19
9. Appendices	19

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

The purpose of this project is to study retired Service members and Veterans with upper extremity amputations to identify psychosocial factors influencing their candidacy for reconstructive transplantation and assess their valuation of this treatment option. Using a mixed methods research approach will add significantly to our understanding of the relative value of VCA compared to other treatment options (e.g., prosthetics, orthotics, reconstruction).

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

VCA, vascularized composite allotransplantation, reconstructive transplantation, upper extremity amputation, upper limb loss, mixed methods research, Veterans, Service Members, Wounded Warriors.

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.

Major Task 1: Secure regulatory approvals for study.

Timeline: Months 1-9, 75% Complete

- Subtask 1: Prepare & submit documents to Johns Hopkins Medicine (JHM) IRB for approval.

Timeline: Months 1-2, 100% Complete (JHM IRB Submission: 25OCT2020)

- Subtask 2: Initiate Data Use Agreements (DUA) between sites.

Timeline: Months 1-3, 100% Complete

- Subtask 3: After securing single-IRB approval with Johns Hopkins as the IRB of record, submit study documents to NU & HHM VAMC IRBs for review/approval.

Timeline: Months 3-5, 100% Complete

- Milestone # 1 JHM single-IRB approval obtained.

Timeline: Months 3-4, 100% Complete (JHM IRB Approval with administrative changes: 19NOV2020; Final Approval: 11DEC2020)

- Milestone # 2 NU IRB review/approval obtained.

Timeline: Months 5-6, 60% Complete

- Milestone # 3 HHM VAMC IRB review/approval obtained.

Timeline: Months 5-6, 100% Complete (Approved: 27JUL2021)

- Milestone # 4 DUAs finalized.

Timeline: Months 4-6, 85% Complete

- Subtask 4: Submit documents for HRPO approval.

Timeline: Months 5-7, 80% Complete (HHM VAMC documents submitted 10SEP2021)

- Milestone # 5 HRPO approval obtained.

Timeline: Months 6-9, 75% Complete (HRPO Approval obtained for 2 Hopkins sites on 27MAY2021)

Specific Aim 1: To identify psychosocial factors related to the acceptability and barriers to upper extremity transplantation from Service members and/or Veterans with upper extremity amputations. (1a) Identify the most important factors for each upper extremity amputee group. (1b) Compare the most important factors for each group to the other groups to determine overlap and group-specific factors.

Major Task 2: Create Delphi materials & interview materials.

Timeline: Months 1-3, 90% Complete

- Subtask 5: Create, review, & finalize modified Delphi survey content.

Timeline: Months 1-2, 100% Complete

- Subtask 6: Create Delphi survey in Qualtrics.

Timeline: Months 2-3, 90% Complete

- *Milestone #6* First iteration of Delphi survey completed and ready for use by study participants.

Timeline: Months 3, 90% Complete

Major Task 3: Identify & Recruit participants.

Timeline: Months 9-18, 0% Complete

- Subtask 7: Identify, contact, & refer Veterans with upper extremity amputations to Johns Hopkins PRS team to consent & enroll in study (*n=60 participants over 6 months: 20 unilateral trans-radial amputees, 20 unilateral trans-humeral amputees, 20 bilateral upper extremity amputees*).

Timeline: Months 9-15, 0% Complete

- Subtask 8: Work with referring military physicians to identify Service members with UE amputations to Johns Hopkins for consent & enrollment in Delphi study (*n=30 to 45* participants over 3 months: 10-15 unilateral trans-radial amputees, 10-15 unilateral trans-humeral amputees, 10-15 bilateral upper extremity amputees*).

Timeline: Months 15-18, 0% Complete

- *Milestone #7* All Veteran & Service members with UE amputations identified, referred, & enrolled in the Delphi study.

Timeline: Month 18, 0% Complete

Major Task 4: Data compilation and Analysis.

Timeline: Months 15-24, 0% Complete

- Subtask 9: Analyze data from first round of Delphi survey; draft and finalize second survey according to results. Distribute to patients.

Timeline: Months 15-16, 0% Complete

- Subtask 10: Analyze data from second round of Delphi survey; draft and finalize third survey according to results. Distribute to patients.

Timeline: Months 17-18, 0% Complete

- Subtask 11: Analyze data for third round of Delphi survey. Determine if additional rounds are needed to arrive at consensus.

Timeline: Months 19-20, 0% Complete

- Subtask 12: If additional rounds of Delphi surveys are needed, conduct here.

Timeline: Months 21-22, 0% Complete

- *Milestone #8* Delphi questionnaire completed.

Timeline: Months 21-22, 0% Complete

- Subtask 13: Analyze & interpret final data from Delphi study.

Timeline: Months 22-23, 0% Complete

- *Milestone #9* Delphi questionnaire analysis completed.

Timeline: Month 24, 0% Complete

Specific Aim 2: To identify psychosocial factors related to the acceptability and barriers to upper extremity transplantation and recovery in Service members and/or Veterans who underwent UE transplantation. (2a)

What psychosocial factors are important to upper extremity transplant recipients? (2b) In what ways are important psychosocial factors for upper extremity transplant recipients and veteran and Service member upper extremity amputees similar or different?

Major Task 5: Create interview materials.

Timeline: Months 2-3, 50% Complete

- Subtask 14: Design & finalize interview guide and materials for qualitative interviews of patients who have undergone UE transplantation.

Timeline: Months 2-3, 50% Complete

- *Milestone #10* Qualitative interview guide completed and ready for use with UE transplant patients.

Timeline: Month 3, 50% Complete

Major Task 6: Identify & Recruit participants.

Timeline: Months 9-18, 0% Complete

- Subtask 15: Identify, contact, & consent patients who have undergone upper extremity transplantation; refer to NU for interviews (n=15 +/-3 participants over 9 months).

Timeline: Months 9-18, 0% Complete

- *Milestone #11 All patients who have undergone UE transplantation identified and referred for semi-structured interviews.*

Timeline: Month 18, 0% Complete

Major Task 7: Data compilation and Analysis.

Timeline: Months 10-22, 0% Complete

- Subtask 16: Coding of interviews using constant comparative methods and a 2-phase analytic strategy proceeding from descriptive to conceptual coding.

Timeline: Months 10-18, 0% Complete

- Subtask 17: Analyze data from interviews with transplant patients.

Timeline: Months 16-19, 0% Complete

- Subtask 18: Send list of themes back to transplant patients to confirm themes/concepts.

Timeline: Months 18-19, 0% Complete

- Subtask 19: Share lists of themes with transplant patients for ranking.

Timeline: Months 19-21, 0% Complete

- *Milestone #12 Interview data compilation & analysis completed.*

Timeline: Months 21-22, 0% Complete

Major Task 8: Conduct utility study using discrete choice experiment.

Timeline: Months 25-33, 0% Complete

Specific Aim 3: To quantify the value and benefits Service member and/or Veteran UE amputees attribute to UE transplantation.

- Subtask 20: Create discrete choice experiment (DCE) survey using data produced through Specific Aims 1 & 2. Get input from field experts regarding DCE survey design.

Timeline: Months 25-26, 0% Complete

- Subtask 21: Recruit participants to complete DCE (n=120).

Timeline: Months 26-27, 0% Complete

- Subtask 22: Administer DCE to Veterans & Service members with UE amputations.

Timeline: Months 27-28, 0% Complete

- *Milestone #13 DCE administration completed.*

Timeline: Month 29, 0% Complete

- Subtask 23: Analyze DCE data using descriptive & Bayesian statistics.

Timeline: Months 29-32, 0% Complete

- Interpret results & discuss with team.

Timeline: Month 32, 0% Complete

- *Milestone #14 DCE data analysis completed.*

Timeline: Month 33, 0% Complete

Major Task 9: Disseminate findings.

Timeline: Months 33-36, 0% Complete

- Subtask 24: Present findings at a meeting or prepare & submit manuscript for publication in a peer-reviewed journal.

As relevant: Work with collaborators to draft presentation / manuscript

Timeline: Months 33-36, 0% Complete

- *Milestone #15 Complete manuscript summarizing findings.*

Timeline: Month 36, 0% Complete

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.

This summary includes Major Tasks under which activity occurred during Y1 of this project:

Major Task 1: Secure regulatory approvals for study.

Timeline: Months 1-9, 75% Complete

- Subtask 2: Initiate Data Use Agreements (DUA) between sites.

Timeline: Months 1-3, 100% Complete

- Hopkins Office of Research Administration initiated DUA with NU
- Hopkins Office of Research Administration initiated DUA with HHM VAMC

- Subtask 3: After securing single-IRB approval with Johns Hopkins as the IRB of record, submit study documents to NU & HHM VAMC IRBs for review/approval.

Timeline: Months 3-5, 100% Complete

- Hopkins team sent sIRB packet to NU on 07JAN2021 for local review
- Hopkins team sent IRB materials to HHM VAMC on 19JAN2021 for local approval

- *Milestone # 1 JHM single-IRB approval obtained.*

Timeline: Months 3-4, 100% Complete (JHM IRB Approval with administrative changes: 19NOV2020; Final Approval: 11DEC2020)

- Hopkins sIRB staff did not release approved study documents until 29DEC2020. This delayed the study team's ability to distribute documents to NU and HHM VAMC.

- *Milestone # 2 NU IRB review/approval obtained.*

Timeline: Months 5-6, 60% Complete

- Hopkins team added NU as a pSITE in JHMeIRB on 07JAN2021.
- Hopkins team has been communicating with NU Team regarding submitting local documents for IRB review. Local Context Questionnaire completed by NU PI & sent to NU IRB Reliance expert.
- NU site application was held up for review pending change of PI approval by USAMRAA from Dr. Zeeshan Butt (departed NU 16APR2021) to Dr. Sally Jensen (approved 17JUN2021).

- *Milestone # 3 HHM VAMC IRB review/approval obtained.*

Timeline: Months 5-6, 100% Complete

- VAMCs have exemption from Single-IRB, local approval required.
- HHM VAMC team submitted study materials to their local IRB (IRB for Central Virginia VA Health Care System/McGuire VA Medical Center) on 16FEB2021. Final IRB approval was pending completion of DUA with lead site (Hopkins).
- On 18MAY2021, after pursuing the DUA as instructed by the VAMC Privacy Officer for three months, the VAMC Privacy Officer informed us that the correct legal process through which to share VAMC patient data was not through a DUA, but by obtaining a HIPAA authorization signed by the participant allowing transfer of data to Hopkins, a process regulated through the IRB for Central Virginia VA Health Care System/McGuire VA Medical Center. IRB application was updated & resubmitted on 10JUN2021.
- IRB for Central Virginia VA Health Care System/McGuire VA Medical Center Approval obtained on 27JUL2021.

- *Milestone # 4 DUAs finalized.*

Timeline: Months 4-6, 85% Complete

- Hopkins Office of Research Administration initiated DUA with NU. Prior to finalization, the DUA was put on hold due to the impending PI change (Butt to Jensen). We anticipate DUA finalization in the project's next reporting period (Y2, Q1).
- Hopkins Office of Research Administration initiated DUA with HHM VAMC. On 18MAY2021, the VAMC Privacy Officer informed us that a DUA was not the correct legal process through which to share data and would not be needed. DUA with HHM VAMC was subsequently abandoned.

- Subtask 4: Submit documents for HRPO approval.
Timeline: Months 5-7, 80% Complete
 - HRPO Approval obtained for 2 Hopkins sites on 27MAY2021.
 - HRPO application for HHM VAMC submitted 10SEP2021.
 - Still waiting on local NU IRB review before submitting NU documents to HRPO.
- Milestone # 5 HRPO approval obtained.
Timeline: Months 6-9, 75% Complete
 - HRPO Approval obtained for 2 Hopkins sites (Dr. Shores' & Dr. Wegener's sites) on 27MAY2021.
 - HRPO application for HHM VAMC submitted 10SEP2021, awaiting HRPO's comments.
 - HRPO approval for NU will be sought as project amendment following relevant IRB reviews/approvals.

Major Task 2: Create Delphi materials. & interview materials.

- Timeline: Months 1-3, 90% Complete
- Subtask 5: Create, review, & finalize modified Delphi survey content.
Timeline: Months 1-2, 100% Complete
 - December 2020 Subject Matter Expert (SME) meetings finalized initial item list
 - Final Version 1 wording and item order approved 08FEB2021
 - Subtask 6: Create Delphi survey in Qualtrics.
Timeline: Months 2-3, 100% Complete
 - Delphi survey entered into Qualtrics 28FEB2021.
 - Patient education information on arm & hand transplantation text approved.
 - Formatting patient education into narrated presentation completed and approved for use by the JHM IRB on 20APR2021 and by the HRPO on 27MAY2021.
 - Milestone #6 First iteration of Delphi survey completed and ready for use by study participants.
Timeline: Months 3, 90% Complete
 - Study team is seeking feedback from upper extremity amputee patient stakeholders who are not VAMC patients to determine if additional edits are warranted.
 - Several patients have agreed to take the survey; the team is trying to obtain their comments.
 - Due to lack of response from stakeholders, team is offering modest stipend for feedback & contacting additional stakeholder group.

Major Task 5: Create interview materials.

- Timeline: Months 2-3, 50% Complete
- Subtask 14: Design & finalize interview guide and materials for qualitative interviews of patients who have undergone UE transplantation.
Timeline: Months 2-3, 50% Complete
 - Initial templates of interview guide have been identified for specific adaptation to this project.
 - Initial interview to be shared with Hopkins team for review & edits.
 - Milestone #10 Qualitative interview guide completed and ready for use with UE transplant patients.
Timeline: Month 3, 50% Complete
 - Initial templates of interview guide have been identified for specific adaptation to this project.
 - Initial guide to be shared with Hopkins team for review & edits.

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.

The study team will work with HRPO to secure approval to begin recruiting participants under specific Aim 1. In parallel, we will continue to finalize the DUA with NU and secure their local IRB review to be able to rely on the Hopkins IRB. Thereafter, we will submit documents to HRPO to approve the NU site so that we may recruit and refer participants to the NU Team to complete study goals and objectives under Specific Aim 2. We anticipate Milestone delays pertaining to recruitment and plan to accelerate participant recruitment as needed to achieve project deliverables.

Anticipating that some participant attrition may occur over the course of the study, the study team has devised a plan to expand enrollment to other VAMCs and amputee clinics. This will occur via self-referred candidates recruited through IRB- & HRPO-approved materials (e.g., flyers). The study team will also track participants to determine attrition rates (i.e., who stops participating and at what stage of the study) to ensure recruitment of the targeted sample size.

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.

The lead site (Hopkins, PI: Shores) was without a study coordinator from mid-February through August 15, 2021. Despite posting the position in early March 2021, few candidates applied. The lead site subsequently posted two coordinator positions to improve their chances of hiring one coordinator. The paucity of applicants was reflective of the worker shortage experienced in Maryland and other parts of the country secondary to pandemic shut-down conditions. Fortunately, a new coordinator was hired & started on 16AUG2021. This study coordinator is vital to participant recruitment and we are very pleased to have this position filled.

NU Site PI Zeeshan Butt, PhD, left NU in mid-April 2021. A PI Change Request was submitted to the USAMRAA in late March 2021 to approve the new site PI, Sally Jensen, PhD. The NU PI change was approved by the USAMRAA on 17JUN2021. This added 3-4 months to our original time estimate for securing IRB and HRPO approvals for the NU site. However, since the NU site's work occurs in Year 2 of this proposal, we are optimistic that this will not delay their project deliverables under Specific Aim 2. The Hopkins Team continues to work with the NU Team to facilitate local NU review; the NU IRB has not been as communicative with Dr. Jensen as the study team would have hoped and Dr. Jensen continues to follow up with the NU IRB to obtain the completed Local Context Questionnaire (LCQ) to send back to Hopkins Single-IRB for Reliance.

The VAMC Privacy Officer at HHM VAMC, who is new to that position, advised us to pursue a DUA instead of IRB approval (application was first submitted to the IRB for Central Virginia VA Health Care System/McGuire VA Medical Center 16FEB2021). After 3 months the privacy officer realized that the correct review process for our project was via IRB approval. This has delayed our ability to begin recruiting study participants. We were able to obtain VAMC IRB approval on 27JUL2021 and JHM IRB Single-IRB acknowledgement of VAMC approval on 26AUG2021. We subsequently submitted the HRPO application to approve inclusion of the HHM VAMC subsite on 10SEP2021 and are awaiting their review.

Although this study does not require in-person contact, it is unclear how COVID-19 pandemic restrictions may continue to directly or indirectly impact study activities. We continue to advance the project as needed, trying to anticipate potential obstacles and adjust appropriately in order to meet that study's goals and achieve our milestones in a timely fashion.

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.

The lead site (Hopkins, PI: Shores) was without a study coordinator for 6 months (mid-February through August 15, 2021), reducing its Y1 expenditure. Fortunately, a new coordinator was hired & started on 16AUG2021. This study coordinator is vital to participant recruitment and we are very pleased to have this position filled.

The delay in VAMC IRB and subsequently HRPO approval has delayed invoicing the lead site for work done at this subsite. After securing HRPO approval we anticipate being invoiced for billable study activities.

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

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Not Applicable

Significant changes in use of biohazards and/or select agents

Not Applicable

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

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

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

Nothing to Report

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

Nothing to Report

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

Nothing to Report

- **Website(s) or other Internet site(s)**

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

Nothing to Report

- **Technologies or techniques**

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

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:	Jaimie T. Shores, MD
Project Role:	Principal Investigator
Researcher Identifier:	0000-0002-4272-1389
Nearest person month worked:	0.6
Contribution to Project:	Oversaw study activities, Delphi survey, and hand/arm education material for patient documents, oversaw HRPO submission.
Name:	Carisa Cooney
Project Role:	Co-Investigator, Study Manager
Researcher Identifier:	0000-0002-5475-206X
Nearest person month worked:	4.2
Contribution to Project:	Worked with Dr. Webster to submit HHM VAMC local IRB, collaborated with Dr. Hughes on the Delphi survey, and drafted the hand/arm education presentation for patients, developing CRF in REDCap. Communicated with the IRB, completed the HRPO submission, & solicited & integrated feedback on study materials from co-investigators & staff. Communicated with NU team to facilitate PI change.
Name:	Gerald Brandacher, MD
Project Role:	Co-Investigator
Researcher Identifier:	0000-0001-7790-441X
Nearest person month worked:	0.6
Contribution to Project:	Attended team meetings, reviewed & provided feedback on protocol documents.
Name:	Vidhi Javia
Project Role:	Study Coordinator (<i>left _FEB2021</i>)
Researcher Identifier:	
Nearest person month worked:	2.2
Contribution to Project:	Assisted with IRB preparation and submission at JHU SOM, scheduled & attended study team meetings.
Name:	Ama Asamoah
Project Role:	Study Coordinator (<i>started 16AUG2021</i>)
Researcher Identifier:	
Nearest person month worked:	0.2
Contribution to Project:	Scheduled & attended study team meetings, assisting with CRF in REDCap.

Name:	Stephen Wegener, PhD
Project Role:	Partnering PI
Researcher Identifier:	
Nearest person month worked:	1.2
Contribution to Project:	Attended team meetings, reviewed & provided feedback on protocol documents.
Name:	Abbey Hughes, PhD
Project Role:	Co-Investigator
Researcher Identifier:	
Nearest person month worked:	1.2
Contribution to Project:	Attended team meetings, reviewed & provided feedback on protocol documents, completed Delphi instrument in Qualtrics, worked with study coordinator to identify amputee stakeholders to trial Delphi tool, developing CRF in REDCap.
Name:	Patricia Kirkhart
Project Role:	Study Coordinator
Researcher Identifier:	
Nearest person month worked:	3.0
Contribution to Project:	Attended team meetings, reviewed & provided feedback on protocol documents, identified several amputee stakeholders to review Delphi instrument, developing CRF in REDCap.
Name:	Sally Jensen, PhD
Project Role:	Partnering PI (<i>Approved by USAMRAA on 17JUN2021</i>)
Researcher Identifier:	
Nearest person month worked:	0.3
Contribution to Project:	Worked with Dr. Butt, NU administration, the lead site, and USAMRAA to secure approval as new NU site PI.
Name:	Zeeshan Butt, PhD
Project Role:	Partnering PI (<i>Former</i>)
Researcher Identifier:	
Nearest person month worked:	0.45
Contribution to Project:	Attended team meetings, worked to change site PI over prior to departing NU.
Name:	Sara Shaunfield, PhD
Project Role:	Co-Investigator
Researcher Identifier:	
Nearest person month worked:	1.2
Contribution to Project:	Attended team meetings, reviewed & provided feedback on protocol document and consent scripts, began draft of semi-structured questionnaire for transplanted patients.
Name:	Joseph Webster, MD
Project Role:	PI, McGuire Research Institute
Researcher Identifier:	
Nearest person month worked:	0.6
Contribution to Project:	Attended team meetings, reviewed & provided feedback on protocol documents, submitted IRB packet for local approval at HHM VAMC, worked with VAMC Privacy Officer & Ms. Cooney on DUA, identified correct IRB approval process through which to obtain local approval & resubmitted IRB packet, developed Veteran recruitment plan.
Name:	Neesha Singh
Project Role:	Research Assistant, McGuire Research Institute
Researcher Identifier:	
Nearest Person Month Worked:	0.25
Contribution to Project:	Worked with Dr. Webster and Carisa Cooney (JHU SOM) to submit HHM VAMC local IRB, communicated with the IRB to supply additional information/documents, helped Ms. Cooney complete HRPO submission for HHM VAMC approval.

Name:	Tiffany Lewis
Project Role:	Project Coordinator, McGuire Research Institute
Researcher Identifier:	
Nearest Person Month Worked:	0.25
Contribution to Project:	Worked with Dr. Webster and Carisa Cooney (JHU SOM) to submit HHM VAMC local IRB, communicated with the IRB to supply additional information/documents, helped Ms. Cooney complete HRPO submission for HHM VAMC approval.

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.

Jaimie Shores	Change: Ended - OMeGA Hand Fellowship for FY2020-2021 Role: PI/ Mentor Effort: 1% Dates 05/06/2020 – 07/31/2021
Jaimie Shores	Change: Ended - Acumed Hand Fellowship for FY2020-2021 Role: PI/ Mentor Effort: 1% Dates 06/08/2020 – 07/31/2021
Jaimie Shores	Change: Received - W81XWH-20-1-0825 “PolyEthylene Glycol (PEG) mediated fusion (PEG fusion) repair of mixed motor-sensory acute...” Role: PI Effort: 10% Dates: 09/15/2020 – 09/14/2025
Jaimie Shores	Change: Received – 5527 “Assessing the Comparative and Longitudinal Benefits of Vascularized Composite...” Role: Co-I Effort: 1% Dates 09/30/2020 – 09/29/2022
Jaimie Shores	Changes: Received - W81XWH-21-1-0172 “Vascularized Denervated Muscle Targets and Funnel Conduits for Surgical Prevention/Treatment of Symptomatic Neuromas” Role: Co-I Effort: 1% Dates: 03/01/2021 - 02/28/2023
Jaimie Shores	Changes: Received – “C00069632-2 Quantitative Ambulatory Assessment and Prognosis of the Impact of Severe Upper...” Role: Co-I Effort: 1% Dates: 03/01/2021 – 02/29/2024
Jaimie Shores	Changes: Received – Axogen Clinical “Peripheral Nerve Repair and Advance Nerve Graft” Role: PI Effort: 1% Dates 12/14/2015 – 07/29/2022
Jaimie Shores	Changes: Received – FY22 OMeGA Hand Fellowship Role: PI/ Mentor Effort: 1% Dates 07/01/2021 – 06/30/2022

Jaimie Shores	Changes: Received – Acumed Hand Fellowship 2021-2022 Role: PI/ Mentor Effort: 1% Dates 07/12/2021 – 07/11/2022
Gerald Brandacher	Change: Ended - W81XWH-16-C-0212 Phase II: Novel Super-cooling of Genitourinary Cells and Tissues for Transplant Role: PI Effort: 10% Date: 10/01/2018 – 05/24/2020
Gerald Brandacher	Change: Ended - Phase II: Non-Toxic, Highly-Effective Bioinspired Cryoprotectants Role: PI Effort: 1% Date: 11/01/2019 – 10/31/2020
Gerald Brandacher	Change: Ended - RT150085: Engineering a Hybrid Thymus to Unravel the Tolerogenic Properties of VCA Role: Co-I Effort: 1% Date: 09/30/2016 – 06/30/2020
Gerald Brandacher	Change: Received - 2R44A124835 - High Subzero Equilibrium VCA Cryopreservation Role: PI Effort: 1% Date: 04/01/2020 – 12/31/2021
Gerald Brandacher	Change: Received – 2020-MSCRFL-5414 Human iPSC-derived EGFR+ functional Schwann Cells to Enhance Nerve Regeneration Role: Co-I Effort: 2% Date: 06/30/2020 – 06/29/2022
Gerald Brandacher	Change: Received – 5527 - Assessing the Comparative and Longitudinal Benefits of Vascularized Composite Role: PI Effort: 1% Date: 09/30/2020 – 09/29/2022
Gerald Brandacher	Change: Received - R43HL152941- Feasibility of expanding ischemia time for hearts destined for transplantation Role: PI Effort: 1% Date: 01/01/2021 – 08/31/2022
Gerald Brandacher	Change: Received - 1R43A1155196 - A Novel and Clinically Feasible Co-therapy of Deceased Donor Bone Marrow Combine Role: PI Effort: 3% Date: 02/15/2021 – 06/30/2022
Gerald Brandacher	Change: Received - Replacing Sutures for Microvascular and Vascular Anastomosis Role: Co-I Effort: 1% Date: 01/13/2021 – 12/13/2021
Gerald Brandacher	Changes: Received – “C00069632-2 Quantitative Ambulatory Assessment and Prognosis of the Impact of Severe Upper...” Role: PI Effort: 2% Dates: 03/01/2021 – 02/29/2024
Carisa Cooney	Change: Received – 5527 - Assessing the Comparative and Longitudinal Benefits of Vascularized Composite Role: Co-I Effort: 1% Dates: 09/30/2020 – 09/29/2022

Carisa Cooney	Changes: Received – “C00069632-2 Quantitative Ambulatory Assessment and Prognosis of the Impact of Severe Upper...” Role: Co-I Effort: 2% Dates: 03/01/2021 – 02/29/2024
Carisa Cooney	Changes: Received - W81XWH2010333 - Large Volume Soft Tissue Reconstruction Using Acellular Adipose Tissue Role: Co-I Effort: 20% Dates:06/01/2020 – 05/31/2023

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.*

Nothing to Report

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.*