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

PRINCIPAL INVESTIGATOR: Stephen Wegener, PhD

CONTRACTING ORGANIZATION: Johns Hopkins University, Baltimore, MD

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5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Medical Research and Materiel Command
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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.

15. SUBJECT TERMS
None lised.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. INTRODUCTION:

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:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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

<u>Specific Aim 3</u>: 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?

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 07JAN2021for 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?

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

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:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays 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

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

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:

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

Journal publications.

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

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

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

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 (*left _FEB2021*)
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 (*started 16AUG2021*)
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 (*Approved by USAMRAA on 17JUN2021*)
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 (*Former*)
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?

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 - 2R44AI124835 - 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 - 1R43Al155196 - 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?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: