

**AWARD NUMBER:** W81XWH-17-2-0029

**TITLE:** Women with Amputation: The Unique Needs of an Underserved Population

**PRINCIPAL INVESTIGATOR:** Roxanne Disla, OTD, OTR/L

**CONTRACTING ORGANIZATION:** Narrows Institute for Biomedical Research and Education  
**BROOKLYN NY 11209-7104**

**REPORT DATE:** October 2019

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

**DISTRIBUTION STATEMENT:** Approved for public release; distribution unlimited

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# REPORT DOCUMENTATION PAGE

*Form Approved*  
**OMB No. 0704-0188**

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<b>1. REPORT DATE</b> Oct 2019			<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 30 Sept 2018 to 29 Sept 2019	
<b>4. TITLE AND SUBTITLE</b>  Women with Amputation: The Unique Needs of an Underserved Population					<b>5a. CONTRACT NUMBER</b>	
					<b>5b. GRANT NUMBER</b> W81XWH-17-2-0029	
					<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Roxanne Disla, OTD, OTR/L (JJP VAMC site co-PI); Jason Maikos, PhD (NYHHS site co-PI); Kathryn Ellis, OTD, OTR/L (WRNMMC PI)  E-Mail: <a href="mailto:Roxanne.Disla@va.gov">Roxanne.Disla@va.gov</a> ; <a href="mailto:Jason.Maikos@va.gov">Jason.Maikos@va.gov</a> ; kathryn.m.ellis11.civ@mail.mil					<b>5d. PROJECT NUMBER</b>	
					<b>5e. TASK NUMBER</b>	
					<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  NARROWS INSTITUTE FOR BIOMEDICAL RESEARCH 800 POLY PL 151BROOKLYN NY 11209-7104					<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
					<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited						
<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b>  There is a growing population of women living with amputations, specifically in the VA and DoD healthcare system, yet little research has been performed to understand the unique needs of this population, which limits evidentiary support for clinical decision making. This investigation aims to conduct a 3-year national exploratory needs assessment that will focus on the unique physical, psychological and social needs of women living with amputations. The investigation is a collaborative effort between the VA, DoD, and civilian sector. To ensure a heterogeneous population of respondents, a convenience sample of 100 male and 100 female Veterans, Servicemembers, and civilians will be recruited from across the nation to participate. The participants will be asked to complete an online computer adaptive survey regarding their physical health, quality of life, prosthetic use and needs, and psychosocial experiences. Surveys will be completed anonymously and electronically without individually identifiable information.						
<b>15. SUBJECT TERMS</b> Amputation, Women with amputation, Quality of life, Physical health, Prosthetic use, Prosthetic needs						
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC	
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>			<b>19b. TELEPHONE NUMBER (include area code)</b>	
Unclassified	Unclassified	Unclassified	Unclassified	13		

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## 1. INTRODUCTION:

Due to the historic number of women serving in combat related positions, more women have experienced amputation of one or more limbs during the most recent conflicts. During the most recent conflicts, more than 135 American servicewomen gave their lives, over 600 were injured, and 27 have experienced traumatic limb amputation. In 2016, the Veterans Health Administration (VHA) served 1,805 female Veterans with amputations. Despite these numbers, females with amputation are studied less than their male counterparts in prosthetic and amputee rehabilitation research, which limits evidentiary support for clinical decision making in this demographic. While research on this demographic has been limited in scope, it has been shown that women with lower limb amputations face physical challenges. For example, women generally require smaller prosthetic components due to their smaller bone structure and muscle mass. Commercially available prosthetic components tend not to be gender-specific and are designed with male anthropometry and biomechanics, which leads to greater dissatisfaction with prosthetic fit and appearance for women living with amputation. Challenges with prosthetic fit stemming from the lack female specific components and heavy prosthetic weight can lead to skin integrity problems, pistoning, and an increased risk for secondary comorbidities. As such, women living with amputation are at a significantly higher risk for developing osteoarthritis in the contralateral limb compared to men. Women living with amputation also face unique psychosocial challenges. One in five female Veterans screen positive for military sexual trauma and female Veterans are 22% more likely to be diagnosed with a mental health condition compared to male Veterans. There is a significant need to fill this critical gap in knowledge of the unique needs of women living with amputation. As such, this investigation will aid in the determination of these unique needs and improve the evidentiary support needed for this expanding population. This study will help determine gaps in research, as well as commercially available products, which will guide appropriate treatment strategies.

## 2. KEYWORDS:

Amputation, Women with amputation, Physical, Psychological, Social, Prosthetics needs assessment

## 3. ACCOMPLISHMENTS:

### What were the major goals of the project?

The overall goals for study OP160081 include:

1. To determine the difference in physical needs of females living with amputation compared to males living with amputation, and to classify this difference.
2. To determine the differences in psychosocial needs of females living with amputation compared to males

<b>Major Task 1: Survey and Website development IRB Submission</b>	<b>% Completion</b>	<b>Completion Date/ Expected Completion Date</b>
Subtask 1: Survey/Website Development		
Finalize surveys and guided questions	100%	5/2018
Purchase of website, server space	100%	10/2018
Creation of the survey decision tree	100%	6/2018
Testing, Debugging, and Optimizing electronic survey	100%	12/2018
Final edits and Live Launch	100%	1/2019
<i>Milestone Achieved: Creation of electronic survey and decision tree</i>	100%	5/2/2018

<i>Milestone Achieved: Launch of website/online survey</i>	100%	1/2019
<b>Subtask 2: Prepare IRB Documents and Research Protocol</b>		
Coordinate with Sites for CRADA* submission	50%	ongoing
Refine eligibility criteria, exclusion criteria, screening protocol	100%	12/15/2017
Finalize human subjects protocol	100%	12/15/2017
Central IRB** protocol submission	100%	05/18/2018
Coordinate with Non-VA site for IRB** protocol submission	50%	Walter Reed site: 11/15/2018 NYU site: ongoing
Coordinate with Non-VA Sites for Military 2 <sup>nd</sup> level IRB** review (ORP/HRPO)	50%	Walter Reed: 2/21/2019 NYU: ongoing
PI/SC Central IRB** approval	100%	09/27/2018
Local Sites Central IRB** approval	78%	NYHHS: 12/4/2018 JJPVAMC: 2/27/2019 Washington DC: 6/24/2019 Cleveland: 6/24/2019 Tampa: 6/24/2019 Philadelphia: 8/22/2019 Denver: 8/22/2019 Augusta: ongoing Boston: ongoing
Coordinate with VA sites for Military 2 <sup>nd</sup> level IRB review (ORP/HRPO)	78%	NYHHS: 11/9/2018 JJPVAMC: 5/13/2019 Washington DC: 8/27/2019 Cleveland: 8/27/2019 Tampa: 9/30/2019 Philadelphia: 10/17/2019 Denver: 10/17/2019 Augusta: ongoing Boston: ongoing
<i>Milestone Achieved: Central PISC and LSI IRB** approval</i>	67%	-
<i>Milestone Achieved: HRPO** approval for all protocols</i>	67%	-
<b>Major Task 2: Coordinate Study Staff for Recruitment/Enrollment</b>		
<b>Subtask1: Hiring and Training of Study Staff</b>		
Coordinate with VA, DoD, and Private Sector for job description	100%	10/30/2017
Advertise and interview for project related staff	100%	11/15/2017
Coordinate with Sites for hiring, training, supervision and, fidelity checks as needed for attrition.	100%	3/2018
Recruit Point of Contact (POC) at each VA Polytrauma site and Regional Amputation Center (RAC)	100%	10/15/2017
<i>Milestone Achieved: POC of contact for recruitment identified at each RAC and Polytrauma site</i>	100%	10/15/2017
<i>Milestone Achieved: Project Research staff hired and trained</i>	100%	12/11/2017
<b>Major Task 3: Participant Recruitment</b>		
<b>Subtask 1: Subject recruitment</b>		

Coordinate with Prosthetics and Rehabilitation Clinic for Subject Recruitment as well as each POC at all RAC and Polytrauma Sites	ongoing	9/2018 -3/2020
Develop flyers with survey information	100%	6/4/2018
Coordinate with Prosthetics and Rehabilitation Clinic for Subject Recruitment as well as each POC at all RAC and Polytrauma Sites	ongoing	9/2018 -3/2020
Develop flyers with survey information	100%	6/4/2018
Complete local pilot study	100%	7/2/2019
<i>Milestone Achieved: Study begins</i>	100%	1/10/2019
<i>Milestone Achieved: First subject consented, screened and enrolled</i>	100%	1/10/2019
<b>Major Task 4: Data Collection</b>		
Subtask 1: Set up web- based data management system		
Maintain web site and server	ongoing	3/2018- 9/2020
Subtask 2: Conduct Study		
Collect electronic survey data according to the project timeline	ongoing	9/2018- 6/2020
<i>Milestone Achieved: All subjects have been recruited, consented, screened and enrolled</i>	ongoing	9/2018 – 3/2020
<i>Milestone Achieved: All subjects have completed the research protocol</i>	ongoing	3/2018 – 3/2020

### What was accomplished under these goals?

#### Major Activities and specific objectives for Year 2 include:

##### Finalization of Pilot Study

The computer adaptive survey for this project consists of standardized and gap/open-ended questions that were implemented into a fully functional test survey in Year 1, Quarter 4, allowing for pilot testing of this test survey to begin in Year 2, Quarter 1 and continue through Year 2, Quarter 3.

The pilot study was completed on 7/2/2019. 12 participants were enrolled of an original 10-15 planned. Pilot study feedback and potential changes to the survey were presented to the study team on a weekly basis over the past six months. At the completion of the pilot study, the survey was revised to include the addition of more sexuality/intimacy questions, remove redundant questions to decrease length and cognitive burden to the participants, and clarify that the survey is funded by the Department of Defense.

##### Participant Recruitment

Study staff attended several conferences and VA adaptive sports events to recruit survey participants, including the VA Wheelchair Games in July 2019, the Amputee Coalition National Conference in July 2019, and the Amputee Coalition Limb Loss Education Day (LLED) in September 2019. Participants took the survey on-site via use of an iPad, or were offered flyers with a link to the survey to complete the survey at home. Additionally, flyers have been provided to IRB-approved VA medical centers and the survey was shared via IRB-approved list-servs.

At the end of Year 2, 117 participants completed the survey: 59 females, 57 males, and 1 transgender female. Our goal is to have a minimum of 200 completed surveys, including 100 female participants and 100 male participants. Figure 1 depicts the breakdown of the genders according to their responses on the completed surveys.

**gender.** Which gender do you currently identify as?

Response	20%	40%	60%	80%	100%	Frequency	Count
Male						48.7%	57
Female						50.4%	59
Transgender Male						0.0%	0
Transgender Female						0.9%	1
Gender Queer						0.0%	0
Other						0.0%	0
Prefer not to answer						0.0%	0
						<b>Valid Responses</b>	<b>117</b>
						<b>Total Responses</b>	<b>117</b>

Figure 1: Gender results of completed surveys

Figure 2 illustrates the military status of participants who completed the survey. As we continue to on-board VA medical centers across the VA network, we expect the total number of Veterans to increase. Furthermore, Walter Reed National Military Medical Center began their recruitment efforts in October 2019, so we expect the number of active military participants to increase over the next year.

**milaffil.** Which one of the following describe your current service in the United States Armed Forces?

		gender. Which gender do you currently identify as?							
milaffil. Which one of the following describe your current service in the United States Armed Forces?		Male	Female	Transgender Male	Transgender Female	Gender Queer	Other	Prefer not to answer	Total
I have never served in the United States Armed Forces	Count	32	54	0	0	0	0	0	86
	% by Col	56.1%	91.5%	0.0%	0.0%	0.0%	0.0%	0.0%	73.5%
I currently serve in the United States Armed Forces as Active Duty, National or National Air Guard Unit, in a Reserve Unit	Count	1	0	0	0	0	0	0	1
	% by Col	1.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.9%
I have served in the Armed Forces in the past	Count	24	5	0	1	0	0	0	30
	% by Col	42.1%	8.5%	0.0%	100.0%	0.0%	0.0%	0.0%	25.6%
Prefer not to answer	Count	0	0	0	0	0	0	0	0
	% by Col	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Total</b>	<b>Count</b>	<b>57</b>	<b>59</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>117.0</b>
	<b>% by Col</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Figure 2: Military Status of completed surveys

To date, 166 participants have, at minimum started the survey (Figure 3). Thirty-four (20%) participants started the survey, but didn't complete it, 15 (9%) were branched out due to eligibility requirements, and 117 (71%) participants completed the survey. Due to the length of the survey, we expected approximately 20% would not complete the survey after starting it.

**Campaign Statistics**

Total Participants: 166

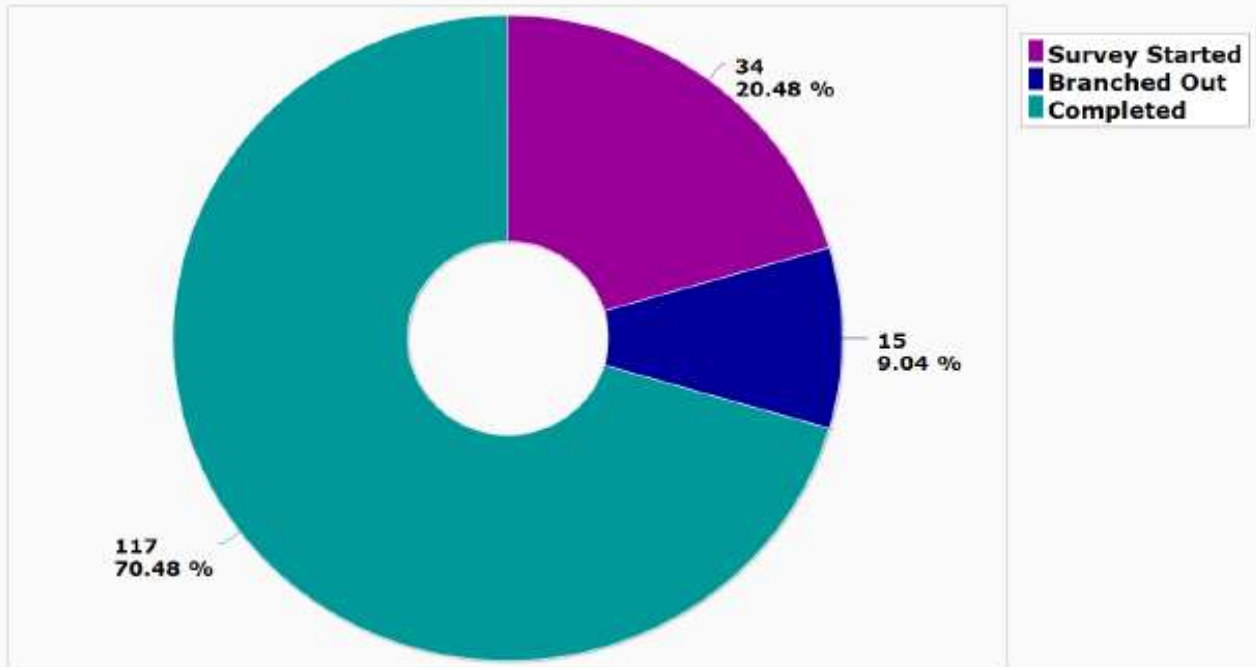


Figure 3: Campaign statistics of all surveys

**Regulatory Approvals**

Overall PI/SC approval for the project was granted on 09/27/2018. HRPO approval for the PI/SC application was received on 10/31/2018. Local site investigators were identified across the VA network. Table 1 outlines the VA Central IRB approval dates for these local sites. Approval has been granted for 7 of 9 sites. Approval is still pending at the VA Boston Healthcare System and the Charlie Norwood VA Medical Center. Additionally, HRPO approval has been achieved for all 7 sites with VA Central IRB approval.

Our two non-VA sites are Walter Reed National Military Medical Center (WRNMMC) and New York University (NYU) Langone. WRNMMC received local approval on 11/15/2018 and HRPO approval on 2/21/2019. Other regulatory documents are currently in the review and approval process, including a CRADA, subaward, and data sharing agreement. NYU Langone submitted their local IRB application on 09/09/2019 and are currently pending approval.

TABLE 1: Status of all Collaborating Sites

Site/HRPO Site #	IRB Status	Approval Dates	Study Stage
VA New York Harbor (New York, NY) A-20481.a	cIRB, local R&D, HRPO approved	cIRB: 12/4/2018 HRPO: 11/9/2019 R&D approval: 12/18/2018	Enrolling
Walter Reed National	Local IRB, HRPO	Local IRB: 11/15/2018	Enrolling

Military Medical Center A-20481.b	approved	HRPO: 2/21/2019	
James J. Peters VA Medical Center (Bronx, NY) A-20481.c	cIRB, local R&D, HRPO approved	cIRB: 2/27/2019 HRPO: 5/13/2019 R&D approval: 4/18/2019	Enrolling
Washington DC VA Medical Center A-20481.d	cIRB, local R&D, HRPO approved	cIRB: 6/24/2019 HRPO: 8/27/2019 R&D approval: 8/23/2019	Enrolling
VA Northeast Ohio Healthcare System (Cleveland, OH) A-20481.e	cIRB, local R&D, HRPO approved	cIRB: 6/24/2019 HRPO: 8/27/2019 R&D approval: 8/16/2019	Enrolling
James A. Haley VA Medical Center (Tampa, FL) A-20481.f	cIRB, local R&D, HRPO approved	cIRB: 6/24/2019 HRPO: 9/30/2019 R&D approval: 10/04/2019	Enrolling
Corporal Michael J. Crescenz VA (Philadelphia, PA) A-20481.g	cIRB, HRPO approved	cIRB: 8/22/2019 HRPO: 10/17/2019	Pending local R&D approval
VA Eastern Colorado Healthcare System (Denver, CO) A-20481.h	cIRB approved, HRPO approved	cIRB: 8/22/2019 HRPO: 10/17/2019	Pending local R&D approval
VA Boston Healthcare System	Pending cIRB approval	-	Pending cIRB approval
Charlie Norwood VA Medical Center (Augusta, GA)	Pending cIRB approval	-	Pending cIRB approval
New York University Langone	Pending local IRB approval	-	Pending local approval

**Goals Not Met:**

All goals have not been met for Y2. Subawards between NYHHS and NYU, as well as between NYHHS and WRNMMC have been developed and are currently under review. We expect all agreements to be in place by the end of Year 3, Quarter 1.

**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?**

- To accomplish the goals and objectives for Year 3, we plan to:
- Obtain IRB approval and complete all regulatory requirements at collaborating sites
  - Coordinate recruitment efforts at collaborating sites.
  - Complete enrollment of 200 completed surveys
  - Analyze results
  - Submit abstracts to leading conferences to present preliminary data
  - Begin manuscript preparation
  - Proposal development for continued funding

**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**

There has been a delay in on-boarding some of the collaborating sites (Table 1) due to delays in local or central IRB approvals. We are working closely with each site, as well as with central IRB, to gain all approvals in a timely manner to begin recruitment at all sites.

**Changes that had a significant impact on expenditures**

A delay with the transfer of funds to the Army Public Health Center (APHC) has resulted in decreased year 1 and 2 budget expenditures. However, a memorandum of understanding (MOU) is currently being reviewed by The Narrows Institute and APHC. Furthermore, both the Narrows Institute and APHC are reviewing ways to transfer funds from agency to agency.

**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**

There have been no significant changes in use or care of human subjects.

**Significant changes in use or care of vertebrate animals**

N/A

**Significant changes in use of biohazards and/or select agents**

N/A

**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:	Roxanne Disla, OTD, OTR/L
Project Role:	PI at NYHHS
Nearest person month worked:	2
Responsibilities/ Contributions:	Responsible for overall coordination and integrity of study.
Name:	Jason Maikos, PhD
Project Role:	Co-PI at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversaw pilot study, item-bank development, responsible for site-specific enrollment.
Name:	Michael Hyre, MS
Project Role:	Study Coordinator at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted with all regulatory activities at NYHHS.
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Hannah Tadley, BA
Project Role:	Study Coordinator at NYHHS
Nearest person month worked:	6
Responsibilities/ Contributions:	Oversees all regulatory activities for all sites, coordination with central IRB.
Name:	Alison Pruziner, PT, DPT
Project Role:	Co-I at National Veterans Sports Programs and Special Events
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted pilot study analysis, item-bank development, and recruitment at National Veterans Wheelchair games
Name:	Kathryn Ellis, OTD, OTR/L
Project Role:	Site-PI at Walter Reed
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, item bank development
Name:	Christopher Dearth, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Study overview
Name:	Michele Nordstrom
Project Role:	Co-I at Walter Reed
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted with item-bank development.
Name:	Joshua Jeffries
Project Role:	Coordinator at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Assist with IRB submissions and local site recruitment efforts.
Name:	Tamara Bushnik, PhD
Project Role:	Site-PI at NYU
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, item bank development.
Name:	Theresa Jackson Santo, PhD, MPH
Project Role:	Site lead at APHC
Nearest person month worked:	1
Responsibilities/ Contributions:	Responsible for site efforts and coordination, including regulatory requirements.
Name:	Jill Brown, PhD
Project Role:	Co-site lead at APHC
Nearest person month worked:	1
Responsibilities/ Contributions:	Survey item bank development and survey implementation plan development.

Name: Alyssa Coleman, MPH, CPH  
Project Role: Programmer at APHC  
Nearest person month worked: 1  
Responsibilities/ Contributions: Survey item bank development and survey implementation plan development.

Name: Patricia Erickson, MPH  
Project Role: Programmer at APHC  
Nearest person month worked: 1  
Responsibilities/ Contributions: Survey item bank development and survey implementation plan development.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Due to Dr. Pruziner leaving Walter Reed, Dr. Ellis has assumed the role as site-PI at Walter Reed. There are no changes to the study protocol.

**What other organizations were involved as partners?**

**Walter Reed National Military Medical Center**  
8901 Wisconsin Ave Bethesda, MD 20889  
Contributions to the Project: Collaboration and Facilities

**NYU Langone Ambulatory Care Center**  
**Rusk Rehabilitation**  
240 East 38<sup>th</sup> Street, New York, NY 10016

**Health Promotion and Wellness Directorate Army Public Health Center**  
8977 Sibert Road  
E1570, ATTN: MCHB-PH-PHA, OE103  
Aberdeen Proving Ground - EA, MD 21010

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** This report covers the reporting period for both NYHHS and WRNMMC.

**QUAD CHARTS:** Attached.

**9. APPENDICES:** None