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TITLE: Enhanced Autodiagnostic Adaptive Trainer for Myoelectric Prosthesis Users (eADAPT-MP)

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14. ABSTRACT

Amputation of upper limbs, including hands and arms, is extremely devastating. Myoelectric prostheses provide the best functional equivalent of the missing limb and utilize muscle activity from the residual limb to drive prosthetic hand movement. However, intensive training is required to control the myoelectric prosthesis, with the result that many amputees abandon their prosthesis. Difficult training has been implicated as the primary cause for device abandonment. Current training tools are expensive, restricted to use in the caregiver's office, do not embrace all aspects of device use, and do not provide feedback to the provider or amputee. Along with amputee care providers, we have recently developed the ADAPT-MP system, which uses a wireless muscle sensing band, a series of mobile games, and a web-based provider portal to improve myoelectric training. The ADAPT-MP system is inexpensive, mobile, encompasses all aspects of device use, and provides immediate training progress feedback to the user and provider. In the current effort, we used FDA recommendations to test the ADAPT-MP system for patient interaction, usability and durability, and will expand the software based on testing, and perform a controlled trial using recent upper limb amputees to compare how using the enhanced ADAPT-MP system alters amputee device use, quality of life, and ability to return to work/duty.

15. SUBJECT TERMS
Amputee, rehabilitation, prostheses, gaming

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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

1. Introduction

More than 1,650 American servicemen have lost a limb due to traumatic injury in combat during the recent conflicts in Iraq and Afghanistan. The Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthesis Users (ADAPT-MP) system was designed to train upper limb amputees on myoelectric prosthesis control. Under the current effort, the ADAPT-MP system developed and tested under the Phase II SBIR program underwent extensive testing for patient interaction, usability, and durability following FDA CDRH guidelines in Applying Human Factors and Usability Engineering to Medical Devices. The CDRH guidelines outline how to measure and assess device user characteristics, use environments, and user interfaces critical to device success. The eADAPT-MP system will then be used in a randomized controlled trial (RCT) to evaluate the use of novel mobile pre-prosthetic training on compliance and skill outcomes. During the pre-prosthetic training phase, usability and durability data will be gathered via patient and provider questionnaire. The frequency and type of device failure and software bugs will be analyzed. Following myoelectric device arrival outcome metrics will be gathered including compliance/abandonment as a primary outcome metric, skill of prosthesis use as a secondary outcome metric, and quality of life and work/social reintegration as other outcome metrics. Data from the Phase II SBIR RCT will also be assessed to determine the predictive value of acute assessments on long term outcomes.

2. Keywords

myoelectric prosthesis, amputation, electromyography, pre-prosthetic training, game-based training

3. Accomplishments

What were the major goals of the project?

1) Conduct Usability Evaluation of Existing System
    Target Completion Date: Jan 30, 2018
    Percent Completion: 100%

2) Collect Additional Clinical Trial Data
    Target Completion Date: Sept 30, 2021
    Percent Completion: 25%

What was accomplished under these goals?

1) Conduct Usability Evaluation of Existing System

The ADAPT-MP system underwent rigorous testing for patient interaction, usability, and durability following guidelines in the FDA CDRH standard: “Applying Human Factors and Usability Engineering to Medical Devices” as outlined in the 2018 annual report.

In summary, the ADAPT-MP system was found to be safe and effective for the intended users, uses and use environments. The ADAPT-MP system consists of 1) a physical interface: the Myo Gesture Control Armband (Thalmic Labs, Kitchener, Ontario Canada) a tablet, a charger block, and two chargers, and 2) a digital interface: a web provider portal and EMG setup application. During development of this system, upper limb specialists were consulted from Hanger Inc. to provide insight from a clinical viewpoint. Seven amputees tested the system, and a study was run on 12 able bodied participants to test the efficiency of the system. Feedback from all users was recorded to drive further development and enhancements, under a separate SBIR effort. A list of these future updates has been compiled in Table 1 by priority. System updates were kicked off during an SBIR Phase II enhancement effort (W81XWH-18-C-0106, start date Sept 24, 2018) and have been completed. Specific updates made to the ADAPT-MP build in the upcoming study included; ensuring ADAPT-MP can run on mobile devices (Android), improving Bluetooth connectivity, improving graphical assets, and improving gameplay.

Table 1: Table of enhancements focused on in the third phase of the ADAPT-MP development.

Enhancement	**Description/ Purpose**	**Status**
Optimize for mobile phones	Improved flexibility for users to play on both a tablet and mobile phone)	Complete, current software will run on Android phones
Update current gameplay	Improve functionality and gameplay of existing games	In progress. Updates were made to Dino Claw including adding a new feature to picking up certain objects.
Develop additional games/new themes	Increase user engagement/motivation with a larger selection of games; may be accomplished by re-skinning current games	Complete, developed a new them set for existing games.
Add pattern recognition capabilities	Train additional skills needed to operate advanced functionality	Complete, the COAPT kit which uses pattern recognition was successfully integrated into the ADAPT-MP system and was able to run the games
Improve ability to connect in noisy RF environments	Improve user access	Complete, improved connectivity with updated Bluetooth capabilities.

2) Collect Additional Clinical Trial Data

DI has entered into agreements with outside organizations to conduct usability evaluations of the existing ADAPT-MP II system (Objective 1) and act as the sites to randomized, controlled trials (Objective 2). Specifically, DI has partnered with Dr. Michael Highsmith of the University of South Florida (USF), the largest polytrauma provider in the US, to perform randomized controlled trials.

DI has a finalized NDA and SOW/budget agreement with the Tampa VA/USF to recruit participants and collect data for the study. Initial IRB documentation was developed with the Tampa VA/USF staff and,

following revisions, was submitted to the USF and Tampa VA IRBs for approval. IRB approval was received on 11/19/19, and HRPO approval was received on 3/2/20.

Due to COVID-19 there have been delays in study recruitment and a separate entity, a COVID committee, was setup at the Tampa VA for further study approval. The team has been working in close coordination with the committee to ensure patient safety is prioritized for the upcoming study. One major recommendation from the committee was to keep the number of onsite visitations as limited as possible. The team met up and revised the IRB to reduce the number of onsite visits from 5 to 3 to help mitigate risk. An updated protocol was submitted to the USF IRB and is currently in post-review finalization. Once full approval is given by the VA, study recruitment and data collection will begin.

In addition, DI and USF have approached the Florida High Tech Corridor (FHTC) for matching funds against a USF subcontract. The FHTC fosters applied research between Florida Universities (University of Florida, University of Central Florida, and University of South Florida) and high-tech industry partners and provides matching awards of up to $150k to university partners. $81,183 were solicited from the FHTC, and these funds were awarded in May 2019 for the sole purpose of USF/Tampa VA performing their data collection for the effort. The FTHC funds will be released and used upon the start of data collection to support the Tampa VA/USF during the study. What opportunities for training and professional development has the project provided? The DI team was invited to speak about the ADAPT-MP system at the Military Health Systems Research Symposium in Orlando, FL in August 2018. MHSRS is the Department of Defense's premier, annual scientific meeting which brings together DoD, industry, and academia to focus on health care initiatives to meet the unique needs of America's Service Members. The title of the presentation was "Expanding traditional pre-prosthetic therapy: a mobile, game-based approach to myoelectric training" which focused on use of the ADAPT-MP system. This topic was presented in the session "Rehabilitation Following Limb Trauma and Amputation" (**Error! Reference source not found.**).

How were the results disseminated to the communities of interest?

DI submitted a publication titled "Mobile, game-based training for myoelectric prosthesis control" to Frontiers which was published on 6/22/18. This manuscript was based on DI's work with the ADAPT-MP system on a healthy population. The publication has already received approximately 5,000 views and due to the success of the article, we have been invited to develop a special issue / Frontiers Research Topic by the editors of Frontiers in Bioengineering and Biotechnology surrounding game-based rehabilitation. DI presented early enhancements of ADAPT-MP to CDMRP on site at Walter Reed in late 2019 which was published in their newsletter https://cdmrp.army.mil/pubs/press/2019/CDMRP_DesignInteractive. DI was asked to provide information to the O&P Edge magazine in their "Game On" edition which covered how gamified rehabilitation has become more prevalent https://opedge.com/Articles/ViewArticle/2020-10-01/game-on-the-developing-realm-of-myoelectric-training-through-game-play. Finally, DI met with the COR Jason Ghannadian and several other groups funded by the same COR, CoAPT and LTI, for a demonstration during AAOP in March. DI demonstrated its updates to the ADAPT-MP system, specifically integration of CoAPT's control kit as a pattern recognition controller for the system.

What do you plan to do during the next reporting period to accomplish the goals?
Under the next reporting period, the team is expected to receive approval from the VA to begin recruitment and data collection. DI will setup an onsite training visit for USF/Tampa VA personnel once recruitment begins and will provide technical support throughout the duration of the study. DI and USF/Tampa VA will prepare a manuscript once the study is completed and will prepare material for future conferences at MHSRS and AOPA. Further, DI is seeking to collaborate with commercial organizations to license ADAPT-MP. As this next reporting period falls outside of the original contract timeline, an no cost extension (NCE) was requested in May 2020 and is expected to be approved in November 2020. This one-year NCE was requested due to the COVID-19 pandemic which has led to delays in IRB approvals and patient recruitment. With the updated IRB protocol and approval from the VA COVID committee, the team expects to fully recruit and collect data from the full 10 participants within the extended timeframe.

4. Impact

What was the impact on the development of the principal disciplines of the project?
The ADAPT-MP system increases access to engaging mobile rehabilitation tools for patients, while increasing provider efficiency via enhanced data availability. The ADAPT-MP system allows for telerehabilitation, which reduces the burden of travel on the patient, and the burden of scheduling patients for the providers. Providers can monitor patients by logging into the web portal which allows them to provide feedback as they see fit. Patients are given a system that is fun and engaging, while also having training that mimics of activities of daily living.

What was the impact on other disciplines?
The ADAPT-MP system has the capabilities of being transferred from an amputee patient population to patients suffering from ataxias. Previous research has indicated the potential for significant brain and motor plasticity within specific ataxias, including the ability to improve motor function with consistent effort and therapy. Given the time and effort required to retrain upper limb motor systems following various ataxias including stroke, several groups have turned to game-based approaches to post-stroke recovery. The ADAPT-MP system could be used to rapidly develop the capability to train muscle control for ataxias (a parallel domain) by utilizing a mobile patient application, a web-based provider portal, and a portable EMG band.

What was the impact on technology transfer?
Based on a strong commitment of support from CoAPT, and multiple discussions between DI and CoAPT, an initial business partnership is being developed. DI had originally sought to partner with Hanger, and has initial business plans in place which have identified ADAPT-MP as providing the following value:

1. Increasing trainee qualification rate through demonstration of cognitive capacity to operate prosthesis
2. Improving long term retention through improved quality of life due to game engagement

3. Improving Provider/Trainee relationship through provision of data through online portal to providers
4. Improving Quality of Life through training that improves ability to complete activities of daily living
5. Driving new insurance qualification standards by demonstrating the cognitive, physical and neurological function required to operate a myoelectric prosthesis.

What was the impact on society beyond science and technology?

The ADAPT-MP system will drive new insurance qualification standards by demonstrating the cognitive, physical and neurological function required to operate a myoelectric prosthesis. These new insurance qualifications will reduce costs for healthcare in the government and civilian sectors. The ADAPT-MP system will lead to better control of myoelectric prostheses, and higher upkeep of the devices, which will also decrease healthcare costs, while increasing the opportunity for amputees to return to work. In addition, the ADAPT-MP system was profiled by the Florida High Tech Corridor's magazine in Q4 2019 (interviews have been completed).

5. Changes/Problems

Changes in approach and reasons for change

DI worked with Hanger in Phases I and II of the ADAPT-MP project to gain insight into the wants and needs of civilian patients and providers. In this phase of work, DI is partnering with the DoD and VA to gain insight into the military population's perspective by subcontracting USF/Tampa VA. This will increase the applicability of the ADAPT-MP system to a wider audience.

Thalmic Labs rebranded to North, and is no longer continuing development for the Myo Band, therefore there was a need to identify new devices for use in the ADAPT-MP system. For the upcoming randomized controlled trial, DI stockpiled a set of Myo bands. DI has identified new potential devices, such as the CTRL or CoAPT kits, which are EMG armbands similar to the Myo band. DI began communication with CTRL-Labs and is currently seeking to get a developer kit for testing to determine the usability of the kit with ADAPT-MP. Additionally, DI began discussions with CoAPT to test and implement ADAPT-MP in their commercial CoAPT kit product.

Actual or anticipated delays and actions or plans to resolve them

The COVID-19 pandemic has led to delays in IRB acceptance for non-essential studies. ADAPT-MP has been waiting for final approval and is expected to be approved by late Q4 2020 to early Q1 2021. COVID-19 may continue to impact the study by reducing recruitment, however due to its nature, ADAPT-MP is meant to be a telehealth system which may make for easier recruitment and data collection than studies which require more onsite visitation.

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

6. Products

Journal publications

Winslow, B. D., Ruble, M., & Huber, Z. (2018). Mobile, game-based training for myoelectric prosthesis control. Frontiers in bioengineering and biotechnology, 6.

Books or other non-periodical, one-time publications

Nothing to report

Other publications, conference papers, and presentations

Ruble, M. & Winslow, B. D. Expanding traditional pre-prosthetic therapy: a mobile, game-based approach to myoelectric training; presented during the Rehabilitation Following Limb Trauma and Amputation at MHSRS 2018.

Websites and other Internet sites

DI published information regarding the ADAPT-MP system from Phase II on our website (http://designinteractive.net/adapt-mp/). Information will be updated based on the results from the PORA efforts and the enhancement funds.

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:	Brent Winslow
Project Role:	Principle Investigator
Researcher Identifier:	
Nearest person month worked:	3
Contribution to Project:	Dr. Winslow drafted and updated IRB documentation for submission to USF and HRPO and directed ADAPT-MP system usability analyses. Dr. Winslow also

	worked to finalize subcontracts and statements of work with subcontractors to perform the clinical evaluation.
Funding support:	W81XWH-17-1-0687

Name:	Mitchell Ruble
Project Role:	Program Manager
Researcher Identifier:	
Nearest person month worked:	4
Contribution to Project:	Mitchell Ruble drafted the Florida HTC documentation, and has been working closely with USF to answer questions regarding the IRB documentation. Mitchell also worked to draft the statements of work, usability evaluation, and budgets. Mitchell has acted as the trainer for the ADAPT-MP system and the liaison for technical issues.
Funding support:	Contract W81XWH-17-1-0687

Has there been a change in the active support of the PD/PI or senior/key personnel since the last reporting period?
Nothing to report.

What other organizations were involved as partners?
Organization name: University of Southern Florida (USF)
Location of organization: Tampa, FL
Partner's contribution to the project: USF was added to this study to provide the perspective of the veteran population through clinicians that treat veterans. This feedback will help round out the ADAPT-MP system to be more applicable to a broader patient population. Tampa VA/USF will also recruit and test the bulk of the participants for this study and has provided assistance through an application to the FHTC funds.

8. Special Reporting Requirement

Quad Chart

Auto-Diagnostic Adaptive Precision Training for Myoelectric Prosthesis users (ADAPT-MP)

Company: Design Interactive, Inc. **Phase II Contract #** W81XWH-17-1-0687

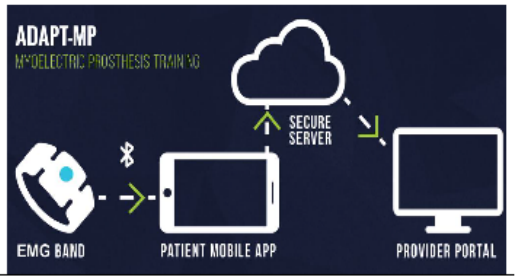
Awarded Amount to date: $949,928.67 **COR:** Jason Ghannadian **Topic Number** : DHP14-011

Product Objective

- A low percentage of upper limb amputee Service Members return to duty due to lack of training for expensive myoelectric prostheses
- ADAPT-MP provides device agnostic, mobile, engaging, game-based pre-prosthetic training to improve user compliance, skill, quality of life, and return to work/duty
- ADAPT-MP use is associated with significant improvements in muscle control needed for successful myoelectric prosthesis operation

Key Benefits/ROI for the DoD

- ADAPT-MP is the first game-based, mobile pre-prosthetic training system, allowing users to train anywhere
- The system allows providers to monitor training progress and intervene via tele-rehabilitation, saving time and money
- Game-based training improves on current in-office training approaches and allows users to progress faster



Timeline and Cost

Activities CY	14	15	16	17	18	19	20	21
Phase I								
Phase II								
Phase II E								
Phase III Funding*								
Est Budget ($M)	$0.2	$0.3	$0.2	$0.5	$0.2	$0.2	$0.2	$0.3

*Phase III funding – DHA Prosthetics Outcomes Research Award (PORA)

Transition Plan

1.Controlled clinical evaluation with the Tampa VA planned for FY21.

2. A business partnership has been developed in collaboration with Hanger and Southern Prosthetic Supply (SPS) to supply ADAPT-MP to civilian, DoD, and VA markets. DI has also begun approaching COAPT for a potential business partnership.

3. Additional use cases: recovery following upper limb ataxias, such as post-stroke recovery or cerebral palsy

Updated: October 15, 2020

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9. Appendices

Appendix 1: ADAPT-MP MHSRS 2018 presentation

Appendix 2: ADAPT-MP P2E Outbrief

ADAPT-MP P2E CSP

9/18/2020

Appendix 3: USF/VA IRB

Enhanced Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthetic Users (eADAPT-MP)

Principal Investigator
M. Jason Highsmith, PhD, DPT, CP, FAAOP
Professor

Rationale

Current prosthetic training is monotonous, expensive, specific to certain devices, and often cannot be brought home. The eADAPT-MP system has multiple engaging games of varying levels of difficulty, is inexpensive, is designed to be manufacturer and device agnostic, and is a tool users can bring with them almost anywhere. The upper limb amputee patient population would benefit from having a powerful telerehabilitation tool that is engaging and encourages prosthetic training to reduce abandonment of myoelectric prostheses and promote usability of myoelectric arms. However, there is a lack of randomized, controlled clinical data supporting myoprosthetic training on functional outcomes [1]. Previously published clinical research on the effect of pre-prosthetic training on amputee health outcomes is represented by small, uncontrolled case studies [1-5], or the reliance on non-amputee participants [6-11].

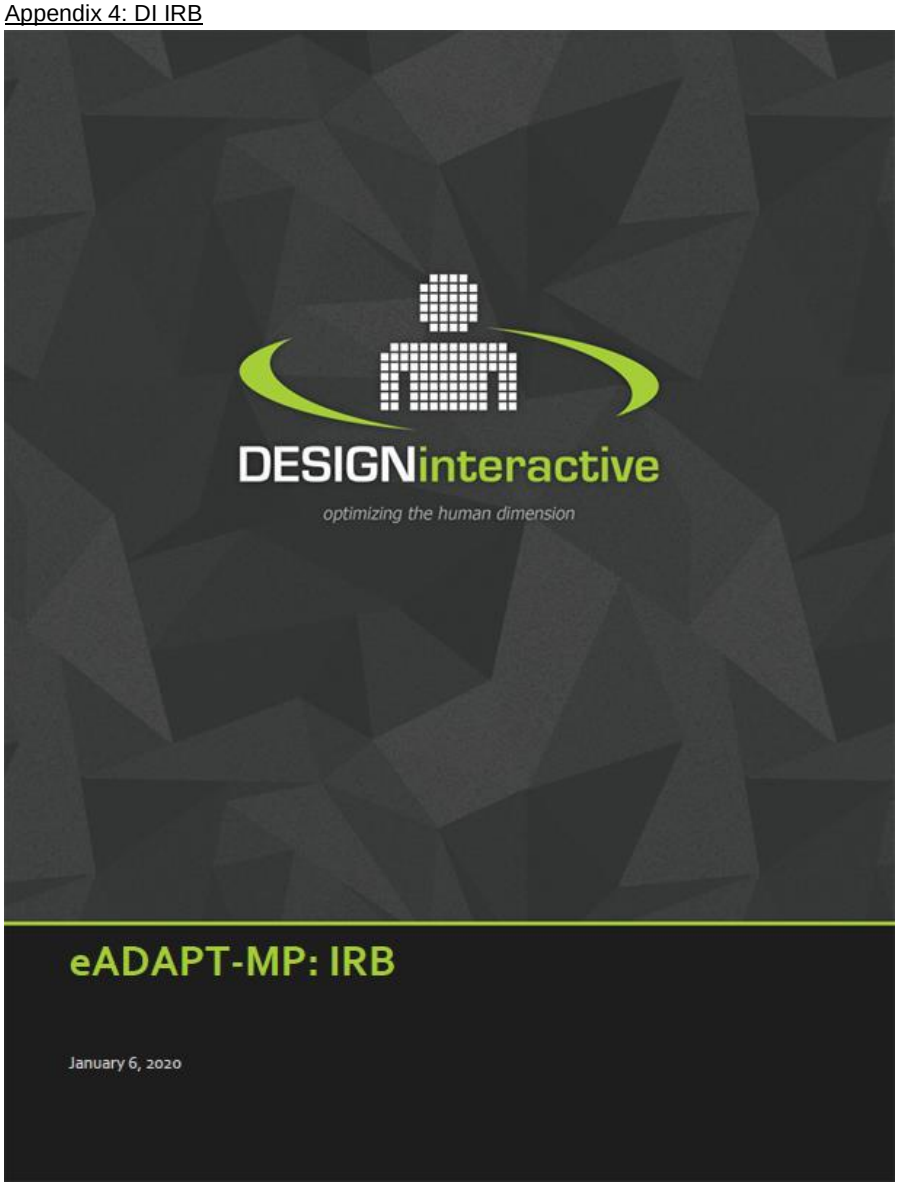
Background

More than 1,500 Americans have lost a limb due to traumatic injury in combat during the recent conflicts in Iraq and Afghanistan [12]. In the civilian population, major causes of amputation include trauma, peripheral vascular disease, and diabetes [13]. In total, there are nearly two million people living with limb loss in the United States, a number that is projected to double by the year 2050 [14]. Upper limb amputation in particular is extremely devastating. In addition to physical/functional movements, the role of the hand in human life is critical for psychosocial roles including gestures, communication, and sensation [15, 16].

Myoelectric prostheses provide upper limb movement control using electromyography (EMG) electrodes on the residual muscles to control arm and hand movements [17]. Control mechanisms can vary from a two-state amplitude modulation controller, where EMG signals from a single muscle group control the velocity of a single actuator of the prosthesis [18], to multi-site activation controls, that leverage additional muscle input sites that have been restored through targeted muscle reinnervation (TMR) procedures [19]. Within the current generation of advanced prostheses, research has shown that most amputees rely on assistive devices rather than prostheses (27 – 54% use prostheses), and many users do not use all available features or stop using the device altogether [20].

Part of the difficulty in learning to control upper limb myoelectric prostheses stems from the sequences of muscle inputs required to choose grips and modes, and move the limb [8]. Existing upper limb myoelectric prostheses use a limited range of muscle inputs to

Appendix 4: DI IRB



Appendix 5: HRPO Documentation

A-20473

US Army Medical Research and Materiel Command
Office of Research Protections

Human Research Protocol Submission Form for Headquarters Level Administrative Review of Extramural* Research

PURPOSE: All United States Army Medical Research and Materiel Command (USAMRMC) supported research involving humans, human data, human specimens, or cadavers must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the Office of Research Protections (ORP).

INSTRUCTIONS: Enter protocol information in the spaces provided to complete all appropriate sections of the form. Submit this completed form and the protocol documents to the electronic mailbox at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil. An incomplete submission will result in delay in review. This form is divided into three sections: Section A requests protocol information; Section B is a checklist of documents to be submitted to the ORP, and Section C lists the reporting requirements and responsibilities of the Principal Investigator to the ORP Human Research Protection Office (HRPO).

NOTE: Complete a Protocol Submission Form for each human subjects research protocol performed under the DoD/USAMRMC proposal. For example, if your research proposal includes three separate research protocols, submit one completed Protocol Submission Form for each protocol.

For multi-site studies, please complete this form for the Master Protocol only at this time. Identify all participating sites in the protocol. Additional site-specific documents will be requested at a later date.

For questions regarding ORP HRPO human research protocol review requirements or assistance in completing this form, leave a message at 301-619-2165 or usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil and a staff member will contact you.

NOTE: You are reminded not to initiate the study until you receive approval from the ORP HRPO.

** The ORP HRPO defines intramural research as research conducted by USAMRMC laboratories. All other USAMRMC managed research is considered extramural*

PROTOCOL SUBMISSION FORM v 6.0 4 May 2018