UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

JAN 18 2018

The Honorable Kay Granger
Chairwoman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed Orthotics and Prosthetics Outcomes Research Program (OPORP) report is in response to Senate Report 114–63, pages 201–202, to accompany S. 1558, the Department of Defense Appropriations Bill, 2016. The report language requests a report "on the peer-reviewed projects that receive funding [and required that it] should include the funding amount awarded to each project and the anticipated effect on patient care."

The OPORP was initiated in 2014 to provide support for the research of exceptional scientific merit with the potential to make a significant impact on improving the health and well-being of Service members, Veterans, and other individuals living with limb deficit. Fiscal year (FY) 2016 appropriation for the OPORP was $10M. A total of 14 projects were funded. The total amount of the FY 2016 OPORP appropriation available for investment in research is $9,435,414.00.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

Robert L. Wilkie

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

JAN 18 2016

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

JAN 18 2018

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

The Honorable Thad Cochran
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

JAN 18 2018

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Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

REPORT IN RESPONSE TO SENATE REPORT 114–63, PAGES 201–202 TO ACCOMPANY S. 1558, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2016

"ORTHOTICS AND PROSTHETICS OUTCOMES RESEARCH PROGRAM"

SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

The estimated cost of this report or study for the Department of Defense (DoD) is approximately $6,290.00 in Fiscal Years 2016 - 2017. This includes $4,820.00 in expenses and $1,470.00 in DoD labor.

Generated on October 13, 2017
RefID: F-D8415FD

I. BACKGROUND AND PURPOSE

This report is in response to Senate Report 114–63, pages 201–202; to accompany S. 1558, the Department of Defense Appropriations Bill, 2016, which requests the Assistant Secretary of Defense for Health Affairs provide a report, no later than 180 days after the enactment of the Act, to the congressional defense committees on the status of the Orthotics and Prosthetics Outcomes Research Program (OPORP). Senate Report 114–63 requests a report "…on the peer-reviewed projects that receive funding [and that it] should include the funding amount awarded to each project and the anticipated effect on patient care."

II. FISCAL YEAR 2016 OPORP RESEARCH

The OPORP was initiated in 2014 to provide support for research of exceptional scientific merit with the potential to make a significant impact on improving the health and well-being of Service members, Veterans, and other individuals living with limb deficit. Appropriation for the fiscal year (FY) 2016 OPORP was $10 million. The programmatic strategy implemented by the FY 2016 OPORP called for applications in response to two program announcements: the Prosthetics Outcomes Research Award (PORA) and the Orthotics Outcomes Research Award (OORA). Both program announcements were released in July 2016 and offered Funding Levels 1, 2, and 3, to support research at different stages of maturity as outlined below:

- Funding Level 1/New Investigator: Pilot research or research that is already supported by preliminary data and has the potential to make significant advancements toward clinical translation.
  - The maximum period of performance is two years.
  - The maximum allowable total (direct and indirect) costs for the entire period of performance are $300,000.00.

- Funding Level 2: Research that is supported by preliminary data and has the potential to make significant advancements toward clinical translation.
  - The maximum period of performance is three years.
  - The maximum allowable total (direct and indirect) costs for the entire period of performance are $500,000.00.

- Funding Level 3: Advanced translational clinical studies that are supported by preliminary data and have the potential for near-term clinical investigation.
  - The maximum period of performance is three years.
  - The maximum allowable total (direct and indirect) costs for the entire period of performance are $2 million.

PORA and OORA pre-applications were received in August 2016 and screened in September 2016 to determine which Principal Investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the program announcements.

Applications were received in November 2016, and peer reviews were conducted in January 2017, followed by programmatic reviews in March 2017. Projects were recommended for funding by the FY 2016 OPORP Programmatic Panel through the programmatic review process using criteria published in the program announcements:

- Ratings and evaluations of peer reviewers, comprised of scientific experts, clinicians, biostatisticians, technology transfer experts, and military and civilian prosthetics and orthotics consumers.

- Relevance to the mission of the Defense Health Program and the FY 2016 OPORP as evidenced by:
  - Adherence to the intent of the award mechanism
  - Military relevance
  - Program portfolio composition
  - Relative impact

The total amount of the FY 2016 OPORP appropriation available for investment in research after final U.S. Army Medical Research and Materiel Command and Congressionally Directed Medical Research Program management costs was $9,435,414.00.

III. CONCLUSION

Table 1 shows the overall submission responses as well as the allocation and number of applications recommended for funding for each award mechanism and funding level. Details of each project selected for funding by the FY 2016 OPORP are summarized in Tables 2–5. The Department is committed to continued research in orthotics and prosthetics to assist Service members and their families.

TABLE 1: FY 2016 OPORP PORA and OORA Submission Responses and Recommendations

FY 2016 OPORP Program Announcement	Compliant Pre-Applications Received	Pre-Applications Invited to Submit Full Applications	Compliant Applications Received	Applications Funded (%)	FY 2016 OPORP Investment
PORA Research Level 1	7	7	7	3 (42.8%)	$743,366
PORA Research Level 2	27	20	19	8 (42.1%)	$3,629,970
PORA Research Level 3	16	13	12	2 (16.7%)	$3,052,620
OORA Research Level 1	2	0	0	0 (0.0%)	$0
OORA Research Level 2	10	8	8	0 (0.0%)	$0
OORA Research Level 3	4	3	2	1 (50.0%)	$1,998,325
Totals	**66**	**51**	**48**	**14 (29.1%)**	**$9,424,281**

TABLE 2: FY 2016 OPORP PORA Funding Level 1 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
1	Can a Novel Beam-Walking Test Improve Fall Risk Assessment in Service Members, Veterans, and Civilians Who Use Lower-Limb Prostheses?	The University of Illinois at Chicago – Chicago, IL	Existing clinical balance tests cannot detect subtle, yet critical, differences in the balance of amputee Service members, Veterans, and civilians where such differences may increase the fall risk in those with lower limb prosthesis (LLP). This project aims to improve fall risk detection among LLP users by assessing the validity and reliability of a novel narrowing beam-walking test. The test will aid in early diagnosis and treatment of amputee balance impairments to prevent falls and secondary injuries. It will also optimize the evaluation of existing and emerging technologies and therapeutic interventions that may alleviate balance deficits and enhance overall patient function.	$300,000
2	Women-Specific Footwear with Prosthetic Feet	Henry M. Jackson Foundation – Bethesda, MD	The purpose of this study is to address footwear challenges unique to female prosthesis users. Comparing the effectiveness of different footwear and prosthesis combinations will help guide patient-centered clinical decision making regarding the prescription of prosthetic devices to optimize functionality and quality of life for patients with prostheses.	$143,366
3	Do Microprocessor Knees Improve Outcomes in Early Prosthetic Rehabilitation Compared to Non-Microprocessor Knees?	University of Washington – Seattle, WA	This project seeks to evaluate the potential for a microprocessor knee and a non-microprocessor knee to promote function, health, and quality of life following amputation. Early rehabilitation is especially challenging for individuals with transfemoral amputation due to the absence of supportive body structures, direct muscle control of multiple joints, and sensory feedback. Gathering high-quality empirical evidence during the crucial post-amputation period could optimize the early rehabilitation process, ensuring that Service members, Veterans, and civilians with limb deficit receive the highest quality care, regain mobility, and reintegrate into their communities.	$300,000

TABLE 3: FY 2016 OPORP PORA Funding Level 2 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
1	Enhancing the Prosthetic Limb Users Survey of Mobility (PLUS-M) to Improve Measurement of Service Members, Veterans, and Civilians with High Mobility	University of Washington – Seattle, WA	This project will verify extended, accurate, and reliable measurements of mobility outcomes in Service members, Veterans, and civilians with lower limb amputations, which is critical for guiding clinical decisions, informing selection of prosthetic device componentry, and evaluating the effectiveness of prosthetics and therapeutic interventions.	$499,205

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
2	Enhanced Auto-Diagnostic Adaptive Trainer for Myoelectric Prosthesis Users (eADAPT-MP)	Design Interactive, Inc. – Orlando, FL	Myoelectric prostheses provide the best current functional equivalent of a missing limb by utilizing muscle activity from the residual limb to drive prosthetic hand movement. However, intensive and expensive training is required of the amputee to effectively operate the myoelectric prosthesis and as a result, many amputees abandon their prosthesis. The Auto-Diagnostic Adaptive Trainer for Myoelectric Prosthesis (ADAPT-MP) system is a mobile pre-prosthetic training aid that consists of a mobile electromyography device, games targeting myoelectric training, and a web-based portal with data for clinicians. The project aims to rigorously evaluate the ADAPT-MP system for patient interaction, usability, and durability, and compare with the Enhanced ADAPT-MP (eADAPT-MP) system. A controlled trial will be conducted to compare how the systems alter prosthetic use, quality of life, and work/social reintegration.	$499,964
3	Women with Amputation: The Unique Needs of an Underserved Population	Narrows Institute for Biomedical Research – New York, NY	Women compose 35 percent of the current amputee population, yet research to understand the unique needs of female amputees is limited. Women have a higher rate of prosthesis rejection due to challenges with fit and appearance. Commercially available prosthetic components tend to be non-gender specific but designed with male anthropometry and biomechanics. The objective of this project is to conduct a needs assessment of the impact of amputation and currently available prosthetic devices for women, as well as their physical, psychosocial, and social needs.	$489,158
4	Effects of Temperature Control Liner Materials on Long-Term Outcomes of Prosthesis Use	University of Pittsburgh – Pittsburgh, PA	Flexible, elastomeric gel liners are worn between the skin and wall of the prosthetic socket to distribute contact forces and improve suspension. However, liners can result in excessive sweating of the residual limb, leading to discomfort, decreased liner contact, skin damage, and possible infection. Prosthetic liners that contain phase-change materials have recently become commercially available. These liners regulate the temperature between the residual limb skin and prosthetic socket to reduce the user's tendency to sweat. The purpose of this study is to determine whether these phase-change materials-based liners have clinically meaningful effects over long periods of time, as measured by prosthetic device utilization, physical performance, and quality of life.	$498,685

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
5	Effectiveness of a Peer Visitation Program to Improve Patient Activation and Functional Outcomes and Quality of Life During Amputation Rehabilitation	Prosthetic Design and Research – Tampa, FL	Peer Visitation Programs (PVPs) provide the opportunity for patients who are undergoing rehabilitation and engaged in community reintegration to speak directly with another amputee with similar experience. This type of patient-centric education reduces patient barriers to reintegration, enabling the patient to relate feelings and concerns about limb loss. While the Amputee Coalition PVP is the only nationally recognized PVP for amputees, it has not been tested for effectiveness. Moreover, there are no clinical trials regarding PVPs. The objective of this project is to determine if immediate and later participation in PVP will be effective in improving functional outcomes for individuals with amputations during rehabilitation.	$496,014
6	Control System Adaptation to Improve Upper-Extremity Prosthetic Limb Wear Time	Coapt, LLC – Chicago, IL	For over 40 years, myoelectric control strategies for powered prostheses remained virtually unchanged until the release of the first commercial muscle pattern recognition (MPR) controller in 2013. This controller provides more natural, intuitive control of a powered prosthesis by using the pattern of muscle activity in the user's residual limb. From time to time, the MPR controller must be user-recalibrated to ensure accurate behavior. This project will compare two recalibration technologies that have been developed since 2013. The goal is to determine which technology best enhances functionality, decreases user frustration, and results in increased functionality and compliance.	$460,377
7	Targeting Balance Confidence as a Strategy to Increase Integration and Improve Outcomes in Users of Lower-Limb Prostheses	Rosalind Franklin University of Medicine and Science – North Chicago, IL	This project focuses on lower limb prosthesis users (LLPUs). Low balance confidence is a prevalent issue in lower-limb prosthetic users occurring when an individual perceives that he/she has limited ability to maintain balance when performing daily activities. Functional ability may improve through rehabilitation without concurrently improving balance confidence. As balance confidence is a strong predictor of prosthetic use and community participation, it is important to address balance confidence during rehabilitation. The objective of this study is to determine whether an integrated therapy combining physical therapy and cognitive behavioral therapy for LLPUs can address fears associated with low confidence and activity restriction to therefore improve balance confidence and promote community participation.	$186,842

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
8	Determining the Functional Importance of a Powered Multifunction Wrist	Rehabilitation Institute of Chicago – Chicago, IL	Technological advances have resulted in the development of multi-articulating hands for individuals with limb amputations; however, their use is constrained by cost and limits of conventional myoelectric control strategies. The Rehabilitation Institute of Chicago has recently developed a light-weight modular prosthetic arm system with a 2-degree-of-freedom (DOF) wrist that provides rotation, flexion, and extension. The Institute has also developed a pattern cognition capability to provide seamless, intuitive control of prosthetic devices. The purpose of this study is to evaluate the relative functional importance of a 2-DOF wrist compared to a 1-DOF wrist in combination with a pattern recognition-controlled 1-DOF hand in individuals with transradial amputation. This information will help clinicians and patients understand the benefits of a more functional wrist and help individuals with amputation achieve better function with their device.	$499,149

TABLE 4: FY 2016 OPORP PORA Funding Level 3 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
1	Comparative Effectiveness of Various Interface Designs and Control Methodologies for Myoelectric Prostheses	The Ohio Willow Wood Company – Mt. Sterling, OH	Prosthetic terminal devices and control strategies are becoming more advanced, but their functionality is restricted to 1- or 2-DOF. The largest challenge is acquiring clean and robust muscle contraction signals non-invasively on the skin surface. It is unclear which socket interface design for creating contact between the skin and myoelectric electrodes would yield the most clinically relevant benefit. This project is a patient-centered comparative effectiveness study of different approaches for acquiring surface myoelectric control signals that will provide optimized sensor placement within the socket, and improve clinical decision making and patient outcomes.	$1,067,854

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
2	Effects of a Powered Ankle-Foot Prosthesis and Device-Specific Physical Therapy on Function and Pain for Individuals Living With Transfemoral Limb Loss	Narrows Institute for Biomedical Research – New York, NY	Standard passive prosthetic feet known as energy-storing and -returning feet are not capable of providing an adequate push for people with amputation, resulting in asymmetrical lower-limb distribution and stress-related anomalies. Advances in lower-limb prosthetics have resulted in powered ankle-foot devices that reduce kinetic and kinematic asymmetries and musculoskeletal imbalances. However, physical therapy intervention may be needed to train individuals to maximize their use of the powered prosthesis. The purpose of this project is to determine the effects of a powered prosthetic ankle-foot device and physical therapy intervention on walking patterns, functional efficacy, and pain for individuals with transfemoral amputation. In addition, the project will result in preliminary rehabilitation guidelines for advanced lower-extremity powered devices to minimize gait imbalances and maximize functions as well as establish guidelines to help clinicians prescribe the powered ankle-foot device.	$1,984,766

TABLE 5: FY 2016 OPORP OORA Funding Level 3 Award Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY 2016 OPORP Investment
1	The Effect of a Powered Ankle Foot Orthosis (PAFO) on Function, Safety, and Quality of Life in Military Service Members and Veterans Who Wear a Prescribed Orthosis	University of Tennessee Health Science Center – Memphis, TN	The design of the most commonly prescribed ankle foot orthosis (AFO), a brace to position and support the ankle, does not adequately replicate the complicated ankle movement and muscle power necessary for a safe and normal walking pattern. Newly available orthotic brace technology may improve functional performance, walking ability, safety, and quality of life for orthosis users. The powered ankle foot orthosis (PAFO) combines the new robotic exoskeletal technology with AFO design to assist with toe clearance and provide push off power. The purpose of this project is to determine if a PAFO, with greater range of motion and active power, will enhance functional performance, thus improving general quality of life and orthotic-related quality of life.	$1,998,325