OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

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

JAN 27 2017

Dear Madam Chairwoman:

The enclosed report is in response to Senate Report 113-211, page 253, accompanying H.R. 4870, the Department of Defense Appropriations Bill, 2015, concerning Orthotics and Prosthetics Outcomes Research. This report provides details of the $10M provided in support of orthotics and prosthetics comparative research studies, including a list of the funded projects, the amount of funding provided to each project, and the anticipated effects on patient care.

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,

AMKurta

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

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

JAN 27 2017

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Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 27 2017

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

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A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

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

JAN 27 2017

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Sincerely,

A. M. Kurta
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

REPORT TO CONGRESSIONAL DEFENSE COMMITTEES

FISCAL YEAR 2015 ORTHOTICS AND PROSTHETICS OUTCOMES RESEARCH PROGRAM

DECEMBER 2016

The estimated cost of this report or study for the Department of Defense is approximately $2,860 in Fiscal Years 2015 - 2016. This includes $1,320 in expenses and $1,550 in DoD labor.
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Orthotics and Prosthetics Outcomes Research Program (OPORP)
Report to Congress

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TABLES

1. BACKGROUND AND PURPOSE

Senate Report 113-211, page 253, accompanying H.R. 4870, the Department of Defense Appropriations Bill, 2015, requests the Assistant Secretary of Defense for Health Affairs (ASD(HA)) provide a report, not 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 113-211 calls for 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."

The Defense Health Agency (DHA), established under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, through the ASD(HA), supports policy execution, exercises management responsibility, and provides shared services to consolidate common services and to further integrate operational missions and capabilities in the Military Health System (MHS). The DHA J9, Research & Development Directorate manages MHS operations in the area of medical research and development, which includes oversight for the execution of the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) appropriation.

The US Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) is responsible for the execution management of several Congressional Special Interest (CSI) research appropriations across a wide range of diseases and injuries applicable to the military and civilian population. The OPORP, a DHP RDT&E CSI appropriation, is executed by the CDMRP in support of the ASD(HA) and DHA J9, Research & Development Directorate.

2. FY15 ORTHOTICS AND PROSTHETICS OUTCOMES RESEARCH PROGRAM 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. Appropriations for the fiscal year (FY) 15 OPORP were $10 million (M). The programmatic strategy implemented by the FY15 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 2015 and included Funding Levels 1 and 2:

- Funding Level 1: 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 three years.
    - The maximum allowable total (direct and indirect) costs for the entire period of performance are $500,000.
- Funding Level 2: Advanced translational studies that have the potential for near-term clinical investigation.

- The maximum period of performance is three years.
- The allowable range of total (direct and indirect) costs for the entire period of performance is between $500,000 and $2.5M.

PORA and OORA pre-applications were received in August 2015 and screened in September 2015 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 2015 and peer review was conducted in January 2016 followed by programmatic review in March 2016. Projects were recommended for funding by the 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 DHP and the FY15 OPORP as evidenced by:
  - Adherence to the intent of the award mechanism
  - Military relevance
  - Program portfolio composition
  - Relative impact
  - Relative transition potential

The total amount of the FY15 OPORP appropriation available for investment in research after final USAMRMC and CDMRP management costs was $9,122,814. 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 FY15 OPORP are summarized in Tables 2-5.

TABLE 1: FY15 Orthotics and Prosthetics Outcomes Research Program Prosthetics Outcomes Research Award (PORA) and Orthotics Outcomes Research Award (OORA) Submission Responses and Recommendations

FY15 OPORP	Compliant Pre-Applications Received	Pre-Applications Invited to Submit Full Applications	Compliant Applications Received	Applications Recommended for Funding (%)	Budget
PORA Funding Level 1	36	32	27	2 (7.4%)	$852,325
PORA Funding Level 2	29	24	22	2 (9.1%)	$4,990,183

OORA Funding Level 1	9	9	8	1 (12.5%)	$500,000
OORA Funding Level 2	4	4	4	2 (50.0%)	$2,817,739
Totals	**78**	**69**	**61**	**7 (11.5%)**	**$9,160,247**

TABLE 2: FY15 OPORP PORA Funding Level 1 Award Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	Awarded Amount
1	New Technology for Early Detection of Residuum Tissue Damages	Queensland University of Technology – Brisbane, Australia	Socket-related problems are an ongoing source of pain and limb health decline for Service members with limb loss, limiting physical function, reducing health-related quality of life and often restricting a return to active duty. This project seeks to address these issues through the use of a non-invasive ultrasonic technique to quantify the mechanical properties and viability of both bone and soft tissues of the residuum of amputees to aid in the early detection, prevention, and management of tissue degeneration, breakdown, and ulceration.	$359,909
2	Characterizing Limits of Performance Imposed by Upper-Limb Prostheses	University of Michigan – Ann Arbor, MI	Approximately 25 percent of individuals with upper limb loss completely stop using their prostheses, and even those who heavily use their prostheses often report being dissatisfied. While it is clear that upper limb prostheses are not meeting users' needs, the limitations in performance that prostheses users experience are not completely understood. This project will study functionality during the performance of activities of daily living of users wearing commercially available body-powered and myoelectric prostheses. This knowledge will be used to design better prostheses. This research directly supports the FY15 PORA's call to "improve the understanding of prosthetic devices" by evaluating "the comparative effectiveness of prosthetic clinical interventions."	$492,416 ($454,983 from FY15 OPORP funding and $37,433 from FY16 DHP Guidance for Development of the Force funding)

TABLE 3: FY15 OPORP PORA Funding Level 2 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	Awarded Amount
1	Needs, Preferences, and Functional Abilities of Veterans and Service Members with Upper-Limb Amputation	Ocean State Research Institute, Inc. – Providence, RI	This study will provide an understanding of prosthetic use, functional abilities, needs, preferences, and risk tolerance of Veterans and Service members with upper limb amputation. This study will provide data on the quality of amputation care provided by the Department of Veterans Affairs (VA) and the Department of Defense (DoD), and provide evidence and the impact of new VA/DoD evidence based guidelines on the rehabilitation of persons with upper limb amputation. Data from this study will be used to improve the quality of the care provided by the VA and DoD, and inform evidence-based policies for device prescription, provision of rehabilitation services, and FDA regulatory approval.	$2,497,440
2	A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations	Seattle Institute for Biomedical and Clinical Research – Seattle, WA	The investigators have developed a customizable robotic prosthetic foot that mimics the mechanical properties of commercial prosthetic feet without physically changing the prostheses. This prosthetic foot emulator can be attached to a patient's prescribed prosthetic socket and worn like a regular prosthetic foot within the laboratory or clinic, providing lower limb amputee patients the opportunity to test-drive many prosthetic foot designs within a single visit to their prosthetist. In the proposed work, the ability of the emulator to accurately reproduce the experience of wearing the actual prosthetic foot will be rigorously tested.	$2,492,743

TABLE 4: FY15 OPORP OORA Funding Level 1 Award Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	Awarded Amount
1	Longitudinal Observation of Myoelectric Upper-Limb Orthosis Use among Veterans with Upper-Limb Impairment	Northwestern University – Evanston, IL	Wearable myoelectric upper limb orthoses detect and amplify trace myoelectric signals that are generated by individuals with an impaired arm and use them to power orthotic joints to perform an intended movement. To increase upper limb functionality, Myomo, Inc. recently combined a powered elbow orthosis with powered grasp assistance to create the MyoPro Motion-G. However, the benefits of adding powered grasp in conjunction with elbow function are unknown and have not been examined directly using patient-centric outcome measures. This study will determine if combining device training with motor	$500,000

			therapy and adding powered grasp may result in further improvements in arm function.	

TABLE 5: FY15 OPORP OORA Funding Level 2 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	Awarded Amount
1	Enhancing Quality of Orthotic Services with Process and Outcome Information	Rehabilitation Institute of Chicago – Chicago, IL	Orthotics, limb bracing devices, are much more widely used and prescribed than prosthetics, limb replacement devices. The most widely used and prescribed orthotic device is the Ankle-Foot-Orthosis (AFO). The objective of this project is to improve the quality of services for AFO users by applying state-of-the-art quality measurement methods to determine which quality concepts are relevant to AFO practice; which items and instruments may operationalize these concepts; which quality measures can be derived from items and instruments that are appropriate for AFO practice and fulfill the National Quality Forum's quality measure criteria; and what are the priorities for quality measures for AFO patients.	$1,590,406
2	The IM ABLE Study: A Cross-Sector, Multisite Initiative to Advance Care for Warriors and Veterans Following Neuromusculo-skeletal Injury of the Lower Limb	University of South Florida – Tampa, FL	The primary aim of this study is to determine if Veterans and Service personnel who have experienced limb injury and require the use of an orthotic device, and who are also ambulating at or above the independent level of community ambulation, will experience improved ambulatory performance with an advanced AFO compared to a conventional AFO. Additionally, this study seeks to determine if these individuals will experience improved self-reported function following accommodation with an advanced AFO compared to a conventional AFO. Finally, this study seeks to determine if these individuals will experience improvements in safety and pain measures following use of an advanced AFO compared to a conventional AFO.	$1,227,333