



PERSONNEL AND
READINESS

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

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

APR 15 2019

Dear Mr. Chairman:

The enclosed report is in response to Senate Report 114-263, page 195, accompanying S. 3000, the Department of Defense Appropriations Bill, 2017, on Orthotics and Prosthetics Outcomes Research. It provides details on the peer-reviewed Orthotics and Prosthetics Outcomes Research Program (OPORP) studies funded in fiscal year (FY) 2017, including the funding amount awarded to each project, and the anticipated effect on patient care.

The FY 2017 OPORP Programmatic Panel selected six projects for funding. The selections were based on peer-reviewed ratings and evaluations from scientific experts, clinicians, and prosthetics and orthotics consumers. Further, the panel considered projects' relevance to the Defense Health Program mission and the FY 2017 OPORP, as evidenced by adherence to the award mechanism intent, program portfolio composition, military relevance, and relative impact. These six projects reflect a diverse set of distinctive topics of scientific inquiry in orthotics and prosthetics research, with potential for significantly improving the welfare of Service members, Veterans, and others with limb deficit.

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,

A handwritten signature in black ink that reads "James N. Stewart". The signature is stylized with a large, sweeping initial "J" and "S".

James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties of
the Under Secretary of Defense for Personnel
and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member



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OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

APR 15 2019

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James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties of
the Under Secretary of Defense for Personnel
and Readiness

Enclosure:
As stated

cc:
The Honorable William M. "Mac" Thornberry
Ranking Member



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

APR 15 2019

The Honorable Richard C. Shelby
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties of
the Under Secretary of Defense for Personnel
and Readiness

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman



PERSONNEL AND
READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

APR 15 2019

The Honorable Peter J. Visclosky
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is in response to Senate Report 114-263, page 195, accompanying S. 3000, the Department of Defense Appropriations Bill, 2017, on Orthotics and Prosthetics Outcomes Research. It provides details on the peer-reviewed Orthotics and Prosthetics Outcomes Research Program (OPORP) studies funded in fiscal year (FY) 2017, including the funding amount awarded to each project, and the anticipated effect on patient care.

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Sincerely,

James N. Stewart

Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties of
the Under Secretary of Defense for Personnel
and Readiness

Enclosure:
As stated

cc:
The Honorable Ken Calvert
Ranking Member

REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES

**SENATE REPORT 114-263, PAGE 195, ACCOMPANYING S. 3000,
DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2017 ON
ORTHOTICS AND PROSTHETICS OUTCOMES RESEARCH PROGRAM**



The estimated cost of this report or study for the Department of Defense (DoD) is approximately \$1,770.00 in Fiscal Years 2017–2018. This includes 1,120 in expenses and \$640.00 in DoD labor.

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1. BACKGROUND AND PURPOSE

Senate Report 114-263, page 195, accompanying S. 3000, the Department of Defense Appropriations Bill, 2017, 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 OPORP. Senate Report 114-263 specified the requirement to provide 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 further integrate operational missions and capabilities in the Military Health System (MHS). The DHA J9, Research and Development Directorate, manages MHS operations in the area of medical research and development, including oversight for the execution of the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation.

The U.S. 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.

2. FY2017 OPORP RESEARCH

The OPORP was initiated in 2014 to provide support for research of exceptional scientific merit with the potential to improve significantly the health and well-being of Service members, veterans, and others with limb deficit. Appropriations for the FY 2017 OPORP were \$10 million. The programmatic strategy implemented by the FY 2017 OPORP called for applications in response to the OPORA program announcement. The program announcement was released in September 2017 and offered Funding Levels 1 and 2 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 three years.
 - The maximum allowable total (direct and indirect) costs for the entire period of performance are \$500,000.00.
- **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 four years.
 - The maximum allowable total (direct and indirect) costs for the entire period of performance are \$2.5 million.

OPORA pre-applications were received in October 2017 and screened in November 2017 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 January 2018, and peer review was conducted in February 2018, followed by programmatic review in April 2018. Projects were recommended for funding by the FY 2017 OPORP Programmatic Panel through the programmatic review process using criteria published in the program announcement:

- 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 FY 2017 OPORP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Military relevance
 - Relative impact

The total amount of the FY 2017 OPORP appropriation available for investment in research after final USAMRMC and CDMRP management costs was \$8,950,000.00. 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 2017 OPORP are summarized in Tables 2 and 3.

TABLE 1: FY 2017 OPORP OPORA Submission Responses and Recommendations

FY17 OPORP Program Announcement	Compliant Pre-Applications Received	Pre-Applications Invited to Submit Full Applications	Compliant Applications Received	Applications Funded (%)	FY17 OPORP Investment
OPORA Funding Level 1	13	10	8	3 (37.5%)	\$1,491,727
OPORA Funding Level 2	48	38	31	3 (9.7%)	\$7,276,195
Totals	61	48	39	6 (15.4%)	\$8,767,922

TABLE 2: FY2017 OPORP OPORA Funding Level 1 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY17 OPORP Investment
1	The Efficacy of Upper Extremity Wearable Robotic Orthosis on Improving Upper Extremity Motor Function and Activities of Daily Living in Persons with Spinal Cord Injury	Kessler Medical Rehabilitation Research and Education Corporation – West Orange, NJ	Spinal cord injury (SCI) is a medically complex and life-disrupting condition. Even though restoration of upper extremity function in people with SCI remains a high priority in rehabilitation and in the field of assistive technology, there are currently few wearable powered devices that are developed specifically for increasing upper extremity activity, especially wrist and hand function. The proposed study will evaluate the feasibility of a smart upper extremity wearable orthosis (MyoPro, Myomo, Inc.) to better understand its effectiveness on improving upper extremity motor function, daily living activities, and quality of life in persons with incomplete SCI. This MyoPro orthosis can assist elbow, wrist, and hand function using built-in motors that are activated by a patient’s will, as represented by the residue voluntary muscle activities detected by built-in sensors.	\$499,477
2	Objective Clinical Prescription of Passive-Dynamic Ankle-Foot Orthoses to Optimize Patient Outcomes	University of Delaware – Newark, DE	Spring-like ankle braces are a special type of ankle brace that can replicate and replace the function of muscles that has been lost due to injury or disease. To optimize a patient’s outcomes, such as an individual’s walking ability, the characteristics of these spring-like ankle braces must be matched to each individual patient’s needs. However, despite increasing prescription of these spring-like ankle braces, little information exists to guide prescription of these or any other types of ankle braces. Thus, the overall objective of this study is to compare the effectiveness of traditionally prescribed ankle braces to quantitatively prescribed spring-like ankle braces for individuals post-stroke.	\$500,000
3	An Evidence-Based Approach to Optimizing Selection of Below-the-Knee Prosthetic Prescription	Auburn University – Auburn, AL	Proper selection of a prosthetic device is crucial and relies on the ability to accurately determine patient needs, requirements, and priorities. Selecting a device is subjective, and individual patient differences, along with large numbers of options for prescription, make device selection inefficient. Currently, there is no specific set of rules or guidelines that are used in the clinic, and clinicians are faced with numerous choices to prescribe a device. Often times, selection is based on previous success rather than a measurement. Ultimately, this proposal seeks to utilize information regarding medical history, patient perceptions, and functional testing to develop an initial clinical tool that will recommend a prosthetic device and options.	\$492,250

TABLE 3: FY 2017 OPORP OPORA Funding Level 2 Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	FY17 OPORP Investment
1	Comparative Effect of Commercially Available Custom Dynamic Orthoses (CDOs)	University of Iowa – Iowa City, IA	Custom-fit carbon fiber braces, referred to as custom dynamic orthoses (CDOs), have been shown to dramatically improve function after lower leg trauma in active Service members. Various design characteristics of CDOs are known to have significant impacts on the ability of the device to improve function. Despite a recent increase in interest and information regarding these devices, little is known about how commercially available CDOs impact function. The objective of this research is to provide first-of-its-kind comparative effectiveness data for commercially available CDOs, determine their benefit relative to standard of care, and identify the factors most strongly associated with device preference and function in individuals with limited function due to traumatic limb injury. The overall intent is to provide insight that will help optimize care for Service members and veterans with limb impairment due to high-energy traumatic injury.	\$2,437,788
2	A Comparative Assessment of Conventional and Adjustable Transfemoral Prosthetic Sockets	University of Michigan – Ann Arbor, MI	The socket is the interface between the human and device and is thus integral to the success of any prosthesis. Discomfort in the sockets continues to be a challenge and is the most common symptom reported in a prosthetic clinic. Several adjustable socket systems have recently come on the market; however, there is no objective outcomes research. This study will compare new, commercially available, adjustable prosthetic sockets to conventional, non-adjustable sockets. The objective of the proposed work is to enhance understanding of the potential benefits of adjustable sockets and inform clinical decision-making. The study will explore a range of outcomes that have been found to be important for prostheses and specifically assess the claims made by device manufacturers.	\$2,398,239
3	Personalized Mobility Interventions Using Smart Sensor Resources for Lower Limb Prosthesis Users	Rehabilitation Institute of Chicago – Chicago, IL	Loss of a leg causes significant disability, affecting performance of daily tasks, leisure activities, and employment—and, for military Service members, the possibility of a return to active duty and deployment. Although a prosthesis is the best way to regain lost function, even with advanced rehabilitation care and the latest devices, many people do not use their prosthesis as much as they could, which limits their mobility and ability to do what they want to do. Reduced physical activity may have secondary effects on health and wellbeing, thereby reducing quality of life and increasing medical costs. The goal is to use multiple assessments of physical and social activity using smart phone and wearable sensors to determine which individuals are not using their prosthesis optimally; what limits their ability or desire to use their prosthesis; and whether targeted interventions can improve prosthesis use and enhance community mobility and social interaction.	\$2,440,168