



PERSONNEL AND
READINESS

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

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

FEB - 9 2021

Dear Mr. Chairman:

The Department's report in response to Senate Report 115-290, pages 210-211, accompanying S. 3159, the Department of Defense Appropriations Bill, 2019, on Orthotics and Prosthetics Outcomes Research (OPOR), is enclosed.

This report summarizes the projects selected for Fiscal Year (FY) 2019 funding, and covers the total congressional appropriations for OPOR during this period (\$10M). The FY 2019 OPOR Program Programmatic Panel selected 10 projects (29.4 percent of compliant applications received) for funding based on peer-reviewed ratings and evaluations from researchers, clinicians, biostatisticians, bioethicists, technology transfer experts, and consumer advocates. Further, the panel considered the relevance of each project to the Defense Health Program mission and the OPORP, as evidenced by adherence to the intent of the award mechanism, OPORP portfolio composition, military relevance, and relative impact. These 10 projects reflect a diverse set of distinctive OPOR topics of scientific inquiry, with potential for significantly improving the well-being of Service members, veterans, and others with limb deficits.

Thank you for your continued strong support of our Service members, veterans and families. I am sending similar letters to the other congressional defense committees.

Sincerely,

//S//

Virginia S. Penrod
Acting

cc:
The Honorable Richard C. Shelby
Ranking Member



PERSONNEL AND
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UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

The Honorable Betty L. McCollum
Chair
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

FEB - 9 2021

Dear Madam Chair:

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Virginia S. Penrod
Acting

cc:

The Honorable Ken Calvert
Ranking Member



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

FEB - 9 2021

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

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Sincerely,

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Virginia S. Penrod
Acting

cc:
The Honorable Mike D. Rogers
Ranking Member



PERSONNEL AND
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UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

FEB - 9 2021

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Sincerely,

//S//

Virginia S. Penrod
Acting

cc:
The Honorable James M. Inhofe
Ranking Member

Report to Congress



Orthotics and Prosthetics Outcomes Research

February 2021

In Response to: Senate Report 115–290, Pages 210–211, Accompanying S. 3159, the Department of Defense Appropriations Bill, 2019

The estimated cost of this report for the Department of Defense (DoD) is approximately \$3,600.00 for Fiscal Years 2019–2020. This includes \$2,800.00 in expenses and \$800.00 in DoD labor.

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BACKGROUND AND PURPOSE

Senate Report 115–290, pages 210–211, accompanying S. 3159, the Department of Defense (DoD) Appropriations Bill, 2019, requests that the Assistant Secretary of Defense for Health Affairs (ASD(HA)) provide a report to the congressional defense committees on Orthotics and Prosthetics Outcomes Research (OPOR). Senate Report 115–290 specifies this report should include the peer-reviewed projects that receive funding, the funding amount awarded to each project, and the anticipated effect on patient care.

As directed by the Office of the ASD(HA), the Defense Health Agency manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) provides execution management for the RDT&E OPOR Program (OPORP) Congressional Special Interest funds. The Department initiated the OPORP 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 deficits.

FY 2019 OPORP RESEARCH

Congress appropriated \$10 million (M) for the Fiscal Year (FY) 2019 OPORP. Senate Report 115–290, page 210, states that “[t]he focus of this research should be on outcomes-based best practices through analysis of the merits of clinical options currently available, not on the development or improvement of new and existing technology.”

The programmatic strategy implemented by the FY 2019 OPORP called for applications in response to Clinical Research Award (CRA) and Clinical Trial Award (CTA) program announcements. The FY 2019 program announcements, released in June 2019, offered Funding Levels 1 and 2 based on the scope of research as outlined below:

- **CRA Funding Levels**
 - Funding Level 1: Pilot research that has potential to make significant advancements toward clinical translation. Preliminary data are allowed, but not required.
 - The maximum period of performance is two years.
 - The maximum allowable total (direct and indirect) costs for the entire period of performance are \$350,000.
 - Funding Level 2: Research supported by preliminary data and that 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) cost for the entire period of performance is \$1.0M for FY 2019.

- **CTA Funding Levels**

- Funding Level 1: Pilot clinical trial that supports exploratory studies involving limited human exposure with potential to make significant advancements toward clinical translation. Preliminary data are allowed, but not required.
 - The maximum period of performance is two years.
 - The maximum allowable total (direct and indirect) costs for the entire period of performance are \$350,000.
- Funding Level 2: Clinical trial supported by preliminary data and that 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) cost for the entire period of performance is \$2.0M for FY 2019.

FY 2019 CRA and CTA pre-applications (letters of intent) were received in July 2019, and applications were received in August 2019. Peer review was conducted in September 2019, followed by programmatic review in December 2019.

The FY 2019 OPORP Programmatic Panel recommended projects for FY 2019 funding through the programmatic review process using criteria published in the program announcements:

- Ratings and evaluations of peer reviewers comprised of researchers, clinicians, biostatisticians, bioethicists, technology transfer experts, and consumer advocates.
- Relevance to the mission of the DHP and the OPORP, as evidenced by the following:
 - Adherence to the intent of the award mechanism.
 - Program portfolio composition.
 - Military relevance.
 - Relative impact (*for the CRA only*).
 - Relative clinical impact (*for the CTA only*).

FY 2019 OPORP appropriations invested in research after final USAMRDC and Congressionally Directed Medical Research Programs (CDMRP) management costs totaled approximately \$9.05M. 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. Tables 2 and 3 summarize details of each project selected for FY 2019 OPORP CRA and CTA funding, respectively.

Table 1. FY 2019 OPORP Submission Responses and Recommendations

OPORP Program Announcement	Compliant Pre-Applications*	Pre-Applications Invited to Submit Full Applications	Compliant Applications Received	Applications Funded (%)	OPORP Investment
CRA Funding Level 1	15	Not applicable	12	5 (41.7%)	\$1,698,320
CRA Funding Level 2	7	Not applicable	7	1 (14.3%)	\$999,767
CTA Funding Level 1	7	Not applicable	6	1 (16.7%)	\$347,123
CTA Funding Level 2	9	Not applicable	9	3 (33.3%)	\$5,999,869
Totals	38		34	10 (29.4%)	\$9,045,079

*Letter of Intent

Table 2. FY 2019 OPORP CRA Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Determination of Fall Risk for Lower Limb Amputees	University of Texas – Austin, TX	Falls are a major health risk for individuals with lower-limb amputations, and can have negative outcomes such as broken bones and impact on an amputee’s confidence in their balance and mobility. Evaluations of falling frequency, often based on an individual’s memory over an extended time, may lack accuracy. This project will create and test an advanced sensor package for placement on the prosthesis of a lower limb amputee to identify when falls occur. Knowledge gained from this research has the potential to improve the understanding of fall frequency and, as a result, improve rehabilitation outcomes. Reducing and/or preventing falls can assist in maximizing patient outcomes and quality of life, while reducing the emotional and monetary costs associated with falls.	\$346,373

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
2	Gait Coordination and Stability of Individuals Living with Transtibial Limb Loss	Narrows Institute for Biomedical Research – New York, NY	The number of Veterans and Service members who sustain amputations continues to grow yearly. A need exists for research to inform determinations regarding the best prosthetic device(s) to help them mobilize in their communities. This project will investigate how amputation can affect the coordination and stability of Veterans and Service members with below-the-knee-amputation during walking. After it identifies these factors, the study will determine if a particular prosthetic device is best to help them walk with more coordinated and stable movements. Knowledge gained from this research will provide evidence to inform the prescription of specific devices/types for optimal coordination and stability. Determining appropriate prosthetic foot prescriptions may allow for improved walking and decreased recovery time for patients.	\$303,145
3	Assessing Biomechanical Function and Hip-Stabilizing Muscle Quality Associated with Transfemoral Osseointegration	University of California at San Francisco – San Francisco, CA	Most prosthetic limbs for lower limb amputations fit the remaining limb into a socket; their use frequently results in pain, discomfort, and skin breakdown. With osseointegration (a relatively new approach), a bone-anchored implant extends from the base of the remaining limb and directly connects to a prosthetic limb. This study will compare walking mechanics and hip muscle health in osseointegrated and socket lower limb amputees. This research will generate important knowledge about the potential benefits and safety associated with the implant and use of an osseointegrated prosthetic. Study findings will also provide an understanding of muscle quality and biomechanical function, which could ultimately inform targeted rehabilitation to improve long-term outcomes for patients.	\$349,634
4	Predicting Clinical Outcomes Using a Physical Platform to Simulate Orthoses with Different Characteristics	Spaulding Rehabilitation Hospital – Charlestown, MA	Ankle-foot orthoses (AFOs) are tools used by clinicians to improve walking ability and balance in patients with lower leg weakness and stiffness. Identifying the appropriate AFO is a laborious task, and treatment success largely depends on the orthotist's experience. Even for an experienced orthotist, identifying the optimal AFO properties and predicting the clinical response for a patient can be challenging. The goal of this research is to develop ways to improve the selection of AFO characteristics optimized for individuals. This research has the potential to generate the necessary tools and knowledge to enable the selection of an optimal orthotic technology, reduce costs, and improve clinical outcomes for patients.	\$350,000

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Durability Testing of 3D-Printed Prosthetic Sockets	Rosalind Franklin University of Medicine and Science – North Chicago, IL	Although early provision and acceptance of a prosthesis is important for successful rehabilitation, prosthetic fittings may not immediately follow amputation, since traditional fitting methods take time. The use of 3-D printed prosthetic sockets (and eventually Immediate Post-Operative Prosthesis) offers potential for reducing the time to initial fitting, and as such, may improve early rehabilitation outcomes. This study will compare the durability of 3-D printed sockets using different printing materials with a standard laminated socket. Knowledge gained from this study will provide initial evidence as to whether 3-D printed sockets are sufficiently durable for use in early rehabilitation and potentially for extended periods thereafter.	\$349,168
6	Patient-Centered Measurement of Mobility Outcomes in Lower Limb Orthosis Users	University of Washington – Seattle, WA	Individuals with lower limb impairment depend on their healthcare providers to evaluate their needs, select an appropriate orthosis, and document their clinical outcomes. While patient-reported outcome (PRO) instruments are ideally suited for assessing the impact of an orthotic device in real-world situations, a need exists for more information regarding the performance of PRO instruments relative to one another, to select the right survey for an orthosis user, administer it appropriately, and understand its score. To address this need, this research will rigorously test four survey instruments, including one designed specifically for evaluating the effectiveness of orthotic devices. Anticipated findings from this research will advance the understanding of mobility (a primary health outcome for individuals with limb impairment), help guide treatment decisions, and improve patient outcome assessments.	\$999,767

Table 3. FY 2019 OPORP CTA Awards Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Combining Wearable Robotic Orthosis with Visual and Haptic Feedback to Enhance the Recovery of Upper Extremity Motor Function and ADL (Activities of Daily Living) in Persons with Acute SCI	Kessler Foundation – West Orange, NJ	Spinal cord injury (SCI) is a medically complex and life-disrupting condition. Although approximately half of the cases in the United States involve injury to a portion of the arm and hand, few effective, wearable powered devices exist specifically for increasing Upper Extremity (UE) functional capability. This study will evaluate the usefulness of combining a wearable powered orthosis (MyoPro) with visual feedback from virtual reality video games and haptic feedback to improve UE movement capability and increase the activity of daily living and quality of life for individuals with acute SCI. This study has the potential to provide evidence supporting the combination of a wearable powered orthosis with visual and haptic feedback as an innovative and effective rehabilitation option for patients.	\$347,123
2	Fall-Related Health Outcomes in Lower Limb Prosthesis Users: A Pragmatic Clinical Trial to Assess the Effectiveness of Microprocessor-Controlled Prosthetic Knees	University of Washington – Seattle, WA	Falls are a common and serious health risk for individuals with lower limb amputation. Although research suggests that microprocessor-computerized prosthetic knees (MPKs) reduce the number of falls a user may experience, it is unknown whether the increased safety provided by these knees affects a user’s ability to engage in meaningful activities. The objective of this project is to determine whether using an MPK can change a user’s perception about the activities they can safely perform, and whether their concerns about safety limit involvement in desirable life situations. The proposed research will generate new tools to measure fall-related outcomes, knowledge about prosthesis users’ fall-related health, and evidence informing if and how MPKs affect users’ lives.	\$1,999,931

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	Clinical Effectiveness of Intrasocket Cooling on Incidence and Severity of Dermatological Conditions in Lower Limb Amputees	Vivonics, Inc. – Bedford, MA	Despite improvements in the function of prosthetic devices, concerns remain with respect to the interface of the prosthetic and the residual limb. In particular, trapped heat and perspiration inside the socket are common causes for reduced quality of life and can lead to residual limb skin issues including folliculitis, friction blisters, and bacterial growth. Although studies exist on the use of cooling elements to combat dermatological issues, there is a lack of validated evidence that such cooling affects the overall quality of life by mitigating the incidence of these issues. This study will investigate the effect of clinically relevant intra-socket cooling [delivered by the Intra-socket Cooling Element (ICE) system] on the incidence of residual limb skin conditions and dermatological quality of life among lower limb amputees. Knowledge gained from this study has the potential to affect standard of care and improve the treatment of lower limb amputation by mitigating skin disorders and discomfort.	\$1,999,938
4	A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations	Seattle Institute for Biomedical and Clinical Research – Seattle, WA	The use of a prosthesis allows many individuals with lower limb amputation to regain functional abilities. However, walking may be more difficult, and impaired balance and falls are common. While initial evidence suggests that prosthetic foot stiffness affect balance and stability, and though there are many different types of commercially available prosthetic feet, there is limited evidence to guide which types of prosthetic feet provide the greatest benefit with respect to balance and stability. This research will study the effect of different types of prosthetic feet on stability and falls-related outcomes in Veterans with lower-limb loss. In addition, a test-drive strategy for selecting prosthetic feet to make the process inclusive of patient priorities and preferences will be studied. This research will provide evidence to guide prosthetic foot prescription, with the potential to benefit individuals with lower limb loss through improved stability, reduced falls, and increased participation in activities. The prosthesis emulator test-drive strategy may enable a patient-centered and evidence-based prosthetic foot prescription process with the potential to improve function and satisfaction outcomes.	\$2,000,000

SUMMARY

The FY 2019 OPORP appropriation invested in research totaled approximately \$9.05M after final USAMRDC and CDMRP management costs. The FY 2019 OPORP Programmatic Panel selected 10 projects (29.4 percent of 34 compliant applications) for funding. The panel selected these projects based on peer-reviewed ratings and evaluations from researchers, clinicians, biostatisticians, bioethicists, technology transfer experts, and consumer advocates. Further, the panels considered the relevance of each project to the DHP mission and OPORP, as evidenced by adherence to the intent of the award mechanism, OPORP portfolio composition, military relevance, and relative impact. These 10 projects reflect a diverse set of distinctive OPOR topics of scientific inquiry, with potential for significantly improving the well-being of Service members, veterans, and others with limb deficits.