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

PERSONNEL AND
READINESS

The Honorable Jon Tester
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

MAR 28 2024

Dear Mr. Chairman:

The Department's response to the Joint Explanatory Statement, page 148, accompanying H.R. 2471, the Consolidated Appropriations Act, 2022 (Public Law 117–103), "Orthotics and Prosthetics Outcomes Research," is enclosed.

The report summarizes the projects selected for Fiscal Year (FY) 2022 funding and covers the total congressional appropriations for Orthotics and Prosthetics Outcomes Research ($20 million). The FY 2022 Orthotics and Prosthetics Outcomes Research Program (OPORP) Programmatic Panel selected 12 projects 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 12 projects reflect a diverse set of distinctive orthotics and prosthetics outcomes research 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 for the health and well-being of our Service members, veterans, and their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

[redacted]

Ashish S. Vazirani
Acting

Enclosure:
As stated

The Honorable Susan Collins
Ranking Member

[redacted]

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

PERSONNEL AND
READINESS

The Honorable Ken Calvert
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

MAR 2 8 2024

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Sincerely,

[redacted]

Ashish S. Vazirani
Acting

Enclosure:
As stated

cc:
The Honorable Betty McCollum
Ranking Member

[redacted]

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

PERSONNEL AND
READINESS

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

MAR 28 2024

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Sincerely,

[redacted]

Ashish S. Vazirani
Acting

Enclosure:
As stated

cc:
The Honorable Roger F. Wicker
Ranking Member

[redacted]

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

PERSONNEL AND READINESS

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

MAR 28 2024

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Sincerely,

[redacted]

Ashish S. Vazirani
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

[redacted]

Report to the Congressional Defense Committees

Orthotics and Prosthetics Outcomes Research

March 2024

The estimated cost of this report for the Department of Defense (DoD) is approximately $3,400.00 for Fiscal Years 2023–2024. This includes $2,400.00 in expenses and $1,000.00 in DoD labor.

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BACKGROUND AND PURPOSE

This report is in response to the Joint Explanatory Statement, page 148, accompanying H.R. 2471, the Consolidated Appropriations Act, 2022 (Public Law 117–103), which requests that the Assistant Secretary of Defense for Health Affairs provide a report to Congress on orthotics and prosthetic outcomes research. The Joint Explanatory Statement 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 requested by the Office of the Assistant Secretary of Defense for Health Affairs, 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) Congressionally Directed Medical Research Programs (CDMRP) provides execution management for the RDT&E Orthotics and Prosthetics Outcomes Research Program (OPORP) Congressional Special Interest funds. The Department initiated the OPORP in 2014 to support 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 loss and limb impairment.

FISCAL YEAR 2022 OPORP RESEARCH OVERVIEW

Congress appropriated $20 million (M) for the Fiscal Year (FY) 2022 OPORP. The FY 2022 OPORP supports research that will provide the high-level scientific evidence required to inform development of clinical practice guidelines. Evidence-based research serves as the foundation for clinical practice guidelines and recommendations to optimize patient care. OPORP research studies focus on the optimization of patient-specific technology prescriptions, patient-specific rehabilitation regimens, and standardized assessment of patient outcomes related to prosthetic and orthotic device use.

FY 2022 OPORP AWARD MECHANISMS

The OPORP implemented its FY 2022 investment strategy through its Clinical Research Award (CRA) and Clinical Trial Award (CTA) program announcements. The FY 2022 program announcements, released in March 2022, offered Funding Levels 1 and 2 based on the scope of research outlined below:

- **CRA Funding Levels**
  - Funding Level 1: Pilot and early-stage research studies that have potential to make significant advancements toward clinical translation. Preliminary data are encouraged, but not required.
    - The maximum period of performance is 2 years.
    - The maximum allowable total (direct and indirect) cost for the entire period of performance is $350,000.

- Funding Level 2: Large clinical research projects that involve robust, statistically relevant participant numbers, with the potential to make significant advancements toward clinical translation. Proposed projects may include large-scale studies that, if successful, will produce high-quality outcomes that provide strong, definitive support for evidence-based practice and/or have the potential to drive changes in clinical practice. Pragmatic studies and comparative effectiveness studies are encouraged. Preliminary data relevant to the proposed clinical study are required.

    - The maximum period of performance is 4 years.

    - The maximum allowable total (direct and indirect) cost for the entire period of performance is $2.0M.

- **CTA Funding Levels**

    - Funding Level 1: Pilot and early-stage clinical trials that support exploratory studies involving limited human exposure (e.g., small sample size) with potential to make significant advancements toward clinical translation. Preliminary data, published or unpublished, are required.

        - The maximum period of performance is 3 years.

        - The maximum allowable total (direct and indirect) cost for the entire period of performance is $350,000.

    - Funding Level 2: Clinical trials with the potential to make significant advancements toward clinical translation. Proposed projects may include large-scale trials that, if successful, will produce high-quality outcomes with robust, statistically relevant participant numbers to provide strong, definitive support for evidence-based practice and/or have the potential to drive changes in clinical practice. Pragmatic clinical studies, randomized controlled trials, and comparative effectiveness studies are encouraged. Published preliminary data relevant to the proposed clinical trial are required. Unpublished preliminary data may be included to further support the study rationale.

        - The maximum period of performance is 4 years.

        - The maximum allowable total (direct and indirect) cost for the entire period of performance is $4.0M.

FY 2022 OPORP APPLICATION REVIEW

The OPORP received FY 2022 CRA and CTA pre-applications (Letters of Intent) on May 4, 2022, and received applications on June 1, 2022. The OPORP oversaw the scientific peer review conducted in August 2022, followed by programmatic review in October 2022.

The FY 2022 OPORP Programmatic Panel recommended projects for FY 2022 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.
  - Programmatic relevance to military health.
  - Relative impact.

FY 2022 OPORP INVESTMENT

FY 2022 OPORP appropriations invested in research, after Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) and USAMRDC withholds and CDMRP management costs, totaled approximately $18.59M (Table 1). Table 2 shows the overall submission responses, the allocation and number of applications recommended for funding for each award mechanism, and the funding levels. Tables 3 and 4 summarize the details of each project selected for FY 2022 OPORP CRA and CTA funding, respectively.

Table 1. FY 2022 OPORP Budget

Budget Allocations	Amount
FY 2022 Congressional Appropriation	$20,000,000
Less: SBIR/STTR Withholds (3.34%)	($667,000)
Less: USAMRDC Withholds (2%)	($386,660)
Less: CDMRP Management Costs	($355,308)
Amount Available for FY 2022 Research	**$18,591,032**

Table 2. FY 2022 OPORP Submission Responses and Funding Recommendations

OPORP Program Announcement	Compliant Pre-Applications Received	Compliant Applications Received	Applications Funded (%)	OPORP Investment
CRA Funding Level 1	20	12	3 (25%)	$1,048,953
CRA Funding Level 2	16	13	4 (30.8%)	$6,237,173
CTA Funding Level 1	3	3	2 (66.7%)	$699,939
CTA Funding Level 2	11	10	3 (30%)	$10,604,967
Totals	**50**	**38**	**12 (31.6%)**	**$18,591,032**

Table 3. FY 2022 OPORP CRA Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Translating Outcomes That Matter Most to Individuals Living with Orthotics and Prosthetics to Shared Decision Making in the Practice Setting	University of California, San Francisco – San Francisco, CA	Abandonment of prosthetic device rates remain high for reasons that are not well understood by clinicians. Opting to forgo use of an upper extremity prosthesis, despite decreased function for those with upper limb absence, is common. This study seeks to fill the gap in lack of outcomes measures for upper limb prosthesis users that represent the patient perspective. This study also aims to identify patient preferences and design a tool that can facilitate better communication between the user and clinicians to improve shared decision-making and long-term outcomes.	$1,999,999
2	The Impact of Prosthetic Frontal Plane Compliance to Residual Limb Health	The Ohio Willow Wood Company – Mt. Sterling, OH	Development of skin irritation and wounds on residual limbs are common problems experienced by amputees. The goal of this research is to use a suite of engineering and clinical evaluations to find the relationship between the development of these skin health complications and compliance of the prosthetic foot itself. With better knowledge of how these wounds develop, healthcare providers can better prescribe devices and correct problems patients may experience before they worsen, thereby improving quality of life.	$1,816,591

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	Comparison of Upper Limb Virtual Outcome Measures and Control Accuracy to Physical Outcome Measures with a Prosthetic Device	Shirley Ryan Ability Lab – Chicago, IL	Determining whether an individual is a suitable candidate to receive an upper limb prosthetic device is essential for providing personalized options to upper limb prosthesis users. The goal of this study is to develop a virtual reality platform that is capable of screening upper limb prosthesis user ability to control a prosthesis before the physical prosthesis is manufactured. This prediction tool will result in cost savings for users who otherwise must physically assess a device after it is manufactured and fitted. Upon validation, the virtual platform can also be used to examine control methods and training protocols.	$1,708,572

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
4	Modeling and Cross-Sectional Analysis of Movement Quality with Osseointegrated Prostheses	University of Maryland, College Park – College Park, MD	Osseointegration is gaining popularity as a primary option following amputation versus an alternative option after failure to successfully use a traditional prosthesis. It is believed lower limb osseointegration reduces altered gait biomechanics, which may contribute to secondary conditions such as osteoarthritis and cardiovascular disease. Preliminary data are currently limited by study design (i.e., comparison to a proper control) because isolating the impact of the prosthesis is difficult. The goal of this study is to isolate the impact of osseointegrated prostheses from traditional prostheses on biomechanics through between-group comparisons and development of software to simulate optimal representations of walking with the two types of prostheses. This modeling will provide a further framework to support or challenge the adoption of osseointegration for unilateral lower limb amputees into standard practice.	$712,011

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Patient-Specific Requirements of Upper Limb Prosthetic Technology	Cleveland VA Medical Research and Education Foundation (for Louis Stokes Cleveland VA Medical Center) – Cleveland, OH	Selection of an upper limb prosthesis that matches a user's preferences and functional needs is a complicated process. Even after the lengthy prescription process, these devices are often abandoned. This qualitative study will interview individuals with an upper limb amputation who have previously used an upper limb prosthesis for at least 6 months or are still using a prosthesis to produce a model to determine which variables influence prosthesis use and acceptance. Better understanding of which factors are most important when matching prosthesis users with a device will improve device recommendations and reduce abandonment.	$349,959

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
6	Standardized Multidomain Assessment of Rehabilitation Treatment for Prosthetics and Orthotics (SMART-P&O)	Orthocare Innovations, LLC – Edmonds, WA	Healthcare providers aim to individualize prosthetic and orthotic devices by weighing the needs and wants of the user with the capabilities of the device. This can be a challenging task, since meeting a patient's request often comes with a sacrifice of another device capability. This study aims to develop software that is standardized and gives patients the ability to consider their most meaningful outcomes. The development of this standardized patient-centric tool will provide clinicians with more meaningful data related to patient satisfaction. Such data can be used to develop a plan of care that is individualized, enabling each user to achieve their highest quality of life possible.	$349,935

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
7	Assessment of the Control and Utility of Multigrip Prosthetic Hands	University of Michigan – Ann Arbor, MI	Over one quarter of individuals with an upper limb absence do not use an upper limb prosthesis, despite data indicating a correlation between prosthesis use and positive outcomes such as higher health-related quality of life and employment rates. Non-users report their perception of minimal increase in function through use and/or discomfort as two reasons for not wearing a hand prosthesis. To mitigate causes related to lack of functionality, several models have been developed to improve dexterity and functional grips. However, the benefit of design modifications that enable multiple functional grips has not been studied. This project seeks to develop a tool that can quantify a device's ability to utilize different grips. Determination of whether currently available options are achieving the goal of improving function is critical for informing health care policy, establishing appropriate expectations for users, and improving device prescription.	$349,059

Table 4. FY 2022 OPORP CTA Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Investigating the Utilization Effects of Powered Wearable Orthotics in Improving Upper Extremity Function and Activities of Daily Living in Persons with Spinal Cord Injury (SCI)	Kessler Foundation – West Orange, NJ	SCI is a complex neurotrauma impacting approximately 17,700 people every year in the United States. Long-term consequences from this type of injury can significantly reduce an individual's mobility and quality of life, especially when the level of injury involves nerves that innervate the upper extremity. Currently, individuals with an SCI have very few options regarding wearable powered devices that are designed to assist with restoring movement of the hand and wrist. This study is a randomized controlled trial that seeks to evaluate the effectiveness of an existing orthotic technology known as the UE-MyoPro in improving upper extremity mobility. Results obtained from this project will provide insight on how this type of technology impacts the nervous system and the overall mobility of its user. Data generated will also help in the development of clinical practice guidelines for use of powered orthotic devices for the treatment of impairments arising from other neurological diseases or injuries.	$3,998,455

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
2	Comparing the Attentional Demands and Functional Outcomes of Pattern Recognition and Direct Myoelectric Control in People with Transradial Amputation	Virginia Common-wealth University – Richmond, VA	Advanced upper extremity prosthetics are often controlled myoelectrically (i.e., with electrodes placed near muscles of the residual limb) with two-site direct control. Multi-site pattern recognition control is a method believed to be superior to two-site direct control because it is more intuitive and requires less attentional demand. This study proposes to assess the benefits of multi-site pattern recognition through implementation of a large national randomized control trial. Data collected from this trial may help guide clinical practice for the care of transradial amputees.	$3,995,791

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	The Effectiveness of Frontal Plane Adaptability in a Novel Foot Prosthesis for People with Above-Knee Amputations, Bilateral Amputations, or Limited Mobility	University of Washington – Seattle, WA	Individuals with lower limb loss often have difficulty transitioning to prosthesis use due to skin irritation, pain, as well as problems with balance. One prosthetic foot solution is offered by the META Arc, which incorporates a frontal plane design that adapts to movement upon impact with the ground. This study seeks to investigate whether the addition of an extra plane of movement can help prosthetic users adapt to real-world scenarios that will translate to improved comfort and performance when wearing the prosthesis. Results from this study will provide valuable information, particularly for individuals with unique and high-level mobility requirements who want to participate in activities that require lateral movement or activities on uneven terrain.	$2,610,721

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
4	Identifying the Optimal Patient-Specific Dynamic Ankle-Foot Orthosis Bending Stiffness in an Evidence-Based Manner That Can Be Implemented by Clinical Providers	University of Delaware – Newark, DE	Dynamic ankle foot orthoses use stored potential energy to generate force to assist in movement of the foot and ankle. The force generated is mostly dictated by the stiffness of the device and user ability to overcome the stiffness. Levels of stiffness required depend on activities and the speed with which they are performed. Adjustments to stiffness levels are currently based on trial and error due to lack of evidence-based guidelines. This is time-consuming, costly, and can cause frustration for the patient and clinician. The goal of this study is to identify the impact of various levels of stiffness on gait function measured through cost of transport and walking speed. The study will evaluate five distinct levels of assistance, as well as user balance and satisfaction levels. Data compiled from this study can provide clinicians and patients with information to help guide decision-making when choosing and adjusting stiffness levels in ankle foot orthoses.	$350,000

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Transfemoral Osseointegrated Prosthesis Limb-Load Symmetry Training	University of Colorado at Denver – Aurora, CO	Lower extremity osseointegrated prostheses are rising in popularity. Some preliminary data suggest improvement in gait mechanics with an osseointegrated prosthesis have the potential to reduce secondary health conditions like osteoarthritis, which commonly develops with gait deviations observed when using a traditional prosthetic socket technology. However, conflicting data suggest that, while osseointegrated prostheses solve theoretical biomechanical problems, there are still asymmetries in load transmission that exist 1 year after beginning osseointegrated prosthetic use. To address this issue, this study seeks to develop and evaluate the impact of a 40-week bio-feedback training program on limb-loading symmetry. This type of program has the potential to inform clinical practice guidelines for more successful rehabilitation regimens post-amputation.	$349,939

SUMMARY

The FY 2022 OPORP appropriation invested in research totaled approximately $18.59M after SBIR/STTR and USAMRDC withholds and CDMRP management costs. The FY 2022 OPORP Programmatic Panel recommended 12 projects (31.6 percent of 38 compliant applications) for funding. The panel recommended these projects for funding based on peer-reviewed ratings and evaluations. Further, the panel members 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 12 projects reflect a diverse set of orthotics and prosthetics outcomes research topics, with potential for optimizing evidence-based care and clinical outcomes, and significantly improving the well-being of Service members, veterans, and others with limb loss and limb impairment.