

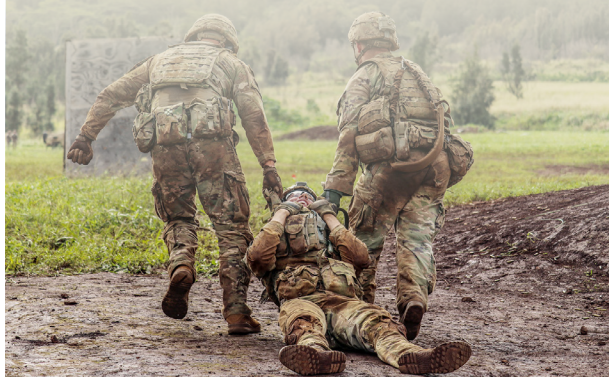
Combat Readiness – Medical Research Program

Strategic Plan

INTRODUCTION

The Congressionally Directed Medical Research Programs (CDMRP) represents a unique partnership among the U.S. Congress, the military, and the public to fund innovative and impactful medical research in targeted program areas. Programs managed by the CDMRP have formalized strategic plans that identify program-specific research priorities; how to best address these urgencies; short- and long-term goals; investment strategies; and ways to identify and evaluate program successes with respect to the priorities.

This document presents the current strategy for the CDMRP's Combat Readiness – Medical Research Program (CRRP). The CRRP Strategic Plan identifies the high-impact research goals that are most important to its stakeholders while providing a framework that is adaptable to changes in the medical research environment to address those goals. This plan has been formulated to provide greater clarity of the program's goals over time to the public and other stakeholders. Funding for the CRRP is congressionally appropriated on an annual basis; therefore, there is no guarantee of future funding. The CRRP Strategic Plan is annually reviewed during Vision Setting and updated as necessary.



CRRP BACKGROUND AND OVERVIEW

The CRRP was established in fiscal year 2019 (FY19) to pursue military-relevant advanced technology and therapeutic research related to forward-deployable solutions that can promptly address life-threatening injuries, medical threats, and treatments for Service Members in battlefield settings. The congressional appropriation from FY19 to FY20 is \$45M. The congressional language for the CRRP encompasses research that would enable the Warfighter to better respond to serious injury, as well as solutions to mitigate the long-term effects of battlefield trauma,^{3,4} including identifying current gaps in medical planning and resources, considering medical capabilities that may mitigate fatalities, enhancing battlefield diagnostics, and finding solutions for life-threatening complications after battlefield injury.

Synergistic topics related to medical combat readiness research have been supported by Department of Defense (DOD) Core and other Congressional Special Interest programs and managed by the CDMRP since 2001 as part of several research programs, including the Military Burn Research Program; Joint Warfighter Medical Research Program (JWMP); Defense Medical Research and Development Program; Peer Reviewed Medical Research Program (PRMRP); Psychological Health and Traumatic Brain Injury Research Program; and Spinal Cord Injury Research Program. From FY15 to FY20, the CDMRP managed \$1.45 billion over 879 awards for research related to clinical management of injuries incurred on the battlefield (**Figure 1**).

VISION: Deliver high-impact medical solutions in diverse operational settings and closer to the point of injury to increase survivability and readiness of the Warfighter.

MISSION: Develop innovative solutions to improve medical readiness, optimally diagnose and treat life-threatening injuries, reduce fatalities, and promote positive long-term outcomes for the Warfighter.



RESEARCH AND FUNDING ENVIRONMENT

Treating and returning military personnel to duty, which maintains force strength, has always been a primary mission of the Services. In the wars in Iraq and Afghanistan, the U.S. military achieved the highest rate of survival from battlefield injuries in history. The wounded-to-killed ratio more than doubled from 4:1 during last century's world wars to 10:1 today.² Substantial credit for this achievement is due to a 2009 congressional mandate that stated wounded Warfighters should be provided with lifesaving care within 60 minutes of injury, a timespan that is referred to as the “golden hour.” This concept is predicated on the availability of multi-Service medical assets such as forward surgical teams, combat support hospitals, and medivac resources. However, the concept of the “golden hour” is one consideration of combat casualty care. Future battlespace conditions may limit the immediate availability of such medical assets and will require front-line providers to sustain prolonged care capabilities in the field. Combat scenarios may include engagement in non-conventional wars against peer or near-peer adversaries capable of disrupting the medical resource continuum in combat operations. Moreover, the combat landscape is no longer limited to rural and austere environments, but could also include operations in dense urban or subterranean environments. The possibility of urban warfare presents new challenges and considerations for civilian mass casualty events, such as defining the role of first-responders and emergency room physicians or operating in situations of disrupted communications. This shift requires a reassessment of existing approaches and innovation of new approaches for extending trauma care and maximizing survivability in complex environments.

STATE OF THE SCIENCE AND EMERGING NEEDS

Prior to the CRRP's inaugural Vision Setting Meeting, a Request for Information (RFI) was released to subject matter experts, and a Stakeholders Meeting was held to identify current research efforts and knowledge gaps in medical planning and resources for providing wounded Service Members lifesaving care within the “golden hour” after an injury occurs, as well as medical capabilities that may mitigate fatalities. The RFI asked survey respondents to assess existing approaches and consider innovative technologies for extending trauma care through combat casualty mitigation, battlefield diagnostics, and treatment of battlefield complications (Figure 2). The results of the RFI, compiled from over 340 responses, were used to inform stakeholders of primed research, as well as cutting-edge and forward-looking solutions, to address delayed resuscitation, prolonged field care, and longer-distance en route care.

The CRRP Stakeholders Meeting brought together a diverse group of experts from non-profit organizations, academia, industry, and government institutions. The stakeholder-identified research gaps addressed the challenges of multi-domain operations, including the potential for reduced medical provider capacity compounded by large numbers of casualties, limited resources over longer periods of time, and a highly mobile and lethal battlefield with little to no technology availability for communication. The information gathered through the Stakeholders Meeting was published on the CRRP website (<https://cdmrp.army.mil/crrp/default>) and continues to inform the CRRP Programmatic Panel and program staff in all aspects of the program cycle, such as Vision Setting.

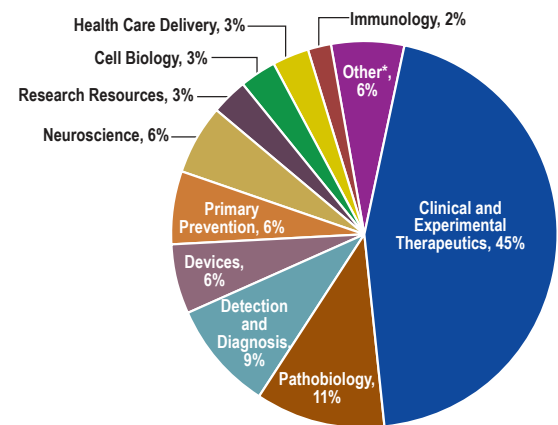


Figure 1. Percentage of Total CDMRP-Funded Awards with Synergism to the CRRP by Scientific Classification System (SCS),* FY16-FY20

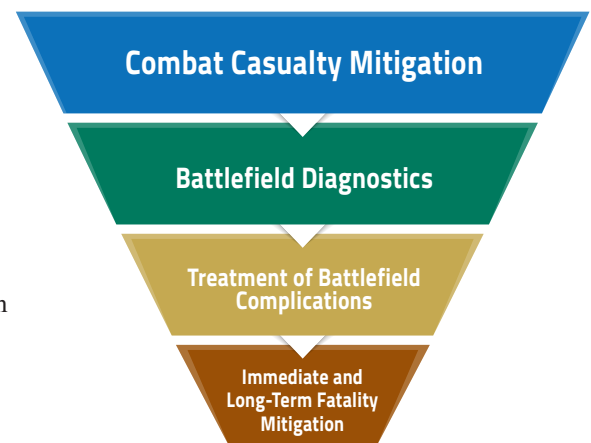


Figure 2. Overarching Gaps for the CRRP

* SCS codes representing less than 2% of total awards include Biobehavioral Sciences (12 awards), Genetics and Molecular Biology (11 awards), Epidemiology (11 awards), Computational Biology (6 awards), Complementary and Alternative Medicine (3 awards), and no awards aligned to Endocrinology.



RESEARCH FUNDING LANDSCAPE

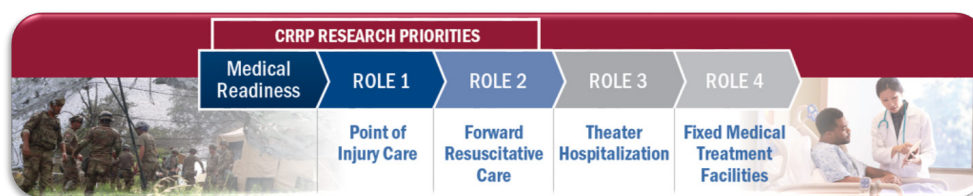
A comparison of research dollars invested in research areas related to medical combat readiness research between 2015 and 2022 by government funding agencies is shown in **Table 1**. In addition to the CDMRP, other major government funding agencies that supported research in areas related to medical combat readiness include the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention, and U.S. Food and Drug Administration (FDA) (Table 1). The CRRP continually evaluates the current funding landscape to avoid research overlaps from these organizations and target underrepresented avenues of research and novel applications of existing techniques.

Table 1. Medical Combat Readiness Research Funding by Organization (FY15-FY22)

Funding Agency	Dollars Invested
CDMRP	\$1.03B
Centers for Disease Control and Prevention	\$43.1M
U.S. Food and Drug Administration	\$9.7M
National Institutes of Health	\$12.7B
National Science Foundation	\$560M

STRATEGIC DIRECTION

Vision Setting allows the CRRP to annually reevaluate the program's trajectory. During these meetings, the Programmatic Panel considers the congressional language^{3,4} and advancements in the state of the science to develop a course forward for research in medical combat readiness. The CRRP Programmatic Panel is composed of clinicians and subject matter experts from the military Services, civilian trauma experts, academic scientists, and consumer representatives, as well as program officials from the U.S. Army Medical Materiel Development Activity (USAMMDA) and several Joint Program Committees (JPCs), including the Military Infectious Disease Research Program, Combat Casualty Care Research Program, and Military Operational Medicine Research Program.



Innovations developed by CRRP-supported research may be applied proactively as a way to establish medical readiness ahead of deployment, either in-theater at the point of injury, during periods of prolonged care, or during transport/en route care within and from theater. These solutions will not only help minimize the morbidity and mortality of combat-related injuries sustained by the Warfighter, they will also often translate to civilian care.

STRATEGIC GOALS (NEAR-TERM)

The CRRP developed its near-term (3–5 year) strategic direction based on the FY19 and FY20 congressional language and recommendations from the CRRP Programmatic Panel for pursuing promising scientific opportunities, while also coordinating research funding, initiatives, and priorities across organizations. The Programmatic Panel considered the state of the science in medical combat readiness, including major unanswered questions, emerging technologies, and the research funding landscape. While the CRRP topic areas have increased since the program's inception, the strategic goals for the program remain focused on advancing products that can increase readiness and survivability of the Warfighter.

CRRP Near-Term Priorities

- Enhance medical capabilities at the point of greatest need to save the most lives in future combat scenarios
- Encourage faster development of products
- Accelerate the transition of CRRP-funded research into clinical outcomes
- Leverage, repurpose, modify, and/or enhance existing medical solutions for potential use in forward operational settings
- Integrate research and outcomes with other medical research and development programs, such as other programs and funding opportunities that are synergistic to the CRRP (e.g., JWMRP, PRMRP, USAMMDA, and Defense Health Program [DHP] Core programs and medical products and capabilities enhancements)
- Incorporate additional opportunities into future program cycles, such as different funding mechanisms and vehicles, to include clinical trials and expansion awards



Based on the CRRP near-term priorities, the anticipated outcomes include products that are accelerated into an advanced development pipeline, to include FDA approval. The CRRP also anticipates potential future utilization funding to bridge Science and Technology and Advanced Development efforts, as well as a broader range of award vehicles, as appropriate.

CRRP Focus Areas

The CRRP Focus Areas are not only developed in alignment with congressional language, but also high-priority gaps that are coordinated through the planning and execution activities of the JPCs. The JPCs were established to manage research, development, test, and evaluation for research supported by the DHP. The CRRP Focus Areas will be reevaluated every year in order to ensure alignment with direction from congressional language, which can vary between fiscal years.

FY22 CONGRESSIONAL TOPIC AREAS		FY22 FOCUS AREAS
<ul style="list-style-type: none"> Rapidly deployable, all-in-one acute and chronic care therapy to address complex trauma and start tissue regeneration Repairing and restoring damaged or missing genitourinary organs and tissues 	>	<p>Wound care solutions for complex trauma and tissue regeneration that span the operational medical care continuum or roles of care (e.g., acute through chronic care), such as:</p> <ul style="list-style-type: none"> Multi-modal wound care solutions that provide a combination of hemostasis, wound healing, infection prevention, and/or analgesia Repair and restoration of genitourinary injury and tissue damage
<ul style="list-style-type: none"> Telemedicine Medical simulation technology Freeze-dried plasma and platelets Ruggedized oxygen generation systems Handheld detection devices for TBI* Portable neurological devices in support of mTBI** assessment Head trauma injury Extracorporeal life support Highly infectious disease treatment and transport 	>	<p>Solutions to enhance combat care delivery through the far-forward environment, such as:</p> <ul style="list-style-type: none"> Telemedicine solutions that enable medical capabilities at far-forward battlespace locations worldwide Medical simulation technology that supports sustainment of critical skills and medical decision-making Blood productions, including freeze-dried plasma and platelets Ruggedized oxygen generation systems for medical use Solutions for the assessment of mTBI, to include portable and handheld devices Extracorporeal life support Initial treatment and transport of patients with highly transmissible infectious disease
<ul style="list-style-type: none"> Sleep disorders Myalgic encephalomyelitis/chronic fatigue syndrome Preventing and relieving Service-related arthritis Eating disorders Sarcoidosis Valley fever Complementary health measures to accelerate return to duty (RTD) Regenerative medicine 	>	<p>Solutions to enhance Warfighter readiness, such as solutions to address:</p> <ul style="list-style-type: none"> Sleep disorders Myalgic encephalomyelitis/chronic fatigue syndrome Service-related post-traumatic arthritis Eating disorders Sarcoidosis Valley fever Complementary health measures to accelerate RTD Regenerative medicine

* traumatic brain injury (TBI)
** mild TBI (mTBI)

STRATEGIC GOALS (MEDIUM TO LONG TERM)

Over the medium to long term (5–10 years), the CRRP intends to focus on translating research products (knowledge and materiel) into clinical practice, seeking opportunities to enhance cross-translational research that bridges military and civilian trauma care, and, where appropriate, implementing solutions into the training environment to encourage broad-user adoption of technology products. The CRRP expects that medium- to long-term priorities will evolve based on the results of research supported by the program in the near term and progress made by others in the field. The CRRP plans to build on early successes via mechanisms that expand and translate program investments.

INVESTMENT STRATEGY

To achieve the strategic goals identified above, the CRRP currently focuses its investment on advanced technology, as well as therapeutic and translational research. The CRRP Programmatic Panel will annually evaluate the research landscape and state of the science in order to balance its research priorities. Taking into account available congressional appropriations for each fiscal year, the specifics of the CRRP's investment strategy, including award mechanisms, focus areas, and funding levels, will be determined during the annual Vision Setting Meeting.

In FY19 through FY22, the CRRP offered the Rapid Development and Translational Research Award (RDTRA) mechanism. The intent of the RDTRA is to support high-impact research that will accelerate the movement of promising ideas into clinical applications, including military-relevant health care products, technologies, and/or practice guidelines to deliver lifesaving care to



the Warfighter during prolonged and en route care in austere and combat environments. This includes research that considers the varied expertise levels of the medical providers and the possible diverse environmental conditions in combat theater, characteristics relevant to military use in non-hospital settings in-theater, and solutions that can translate to advancements in civilian trauma care.

MEASURING PROGRESS

The CRRP measures its success in the near term based on successful investments in areas that are important to the program's strategy. The program intends to evaluate long-term success based on contributions to the scientific community and research expanding on CRRP-funded projects.

Progress toward the CRRP's strategic goals will be measured in multiple ways, including reviewing and monitoring the research outcomes of funded applications. Assessment of the progress made by the CRRP's research awards will inform the program on its impact and steer changes in the investment strategy in future years. The CRRP's metrics will not only include reviews of publications, patents, presentations, and follow-on funding obtained, but also evaluation of product advancement and transition, such as progression in the regulatory approval process, forging of strategic partnerships for developing scalable high-impact solutions, adoption of knowledge and/or technology products into clinical or operational practice, and commercialization.

REFERENCES

1. Evaluation of the Congressionally Directed Medical Research Programs Review Process. 2016. The National Academies Sciences, Engineering, and Medicine. The National Academies Press. Washington, DC.
2. Kotwal RS, Howard JT, Orman JA, et al. 2016. The effect of a golden hour policy on the morbidity and mortality of combat casualties. *JAMA Surg* 151(1):15-24.
3. House Report 115-769 – Department of Defense Appropriations Bill, 2019, pp. 299-300.
4. House Report 115-952 – Department of Defense for the Fiscal Year Ending September 30, 2019, and for Other Purposes, p. 451.
5. House Report 116-84 – Department of Defense Appropriations Bill, 2020, pp. 308-309.
6. House Report 116-453 – Department of Defense Appropriations Bill, 2021, p. 334.
7. House Report 117-88 – Department of Defense Appropriations Bill, 2022, p. 331.