The Congressionally Directed Medical Research Programs FY23 Overview

Presented by

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Vision and Mission





Vision

Transform health care through innovative and impactful research

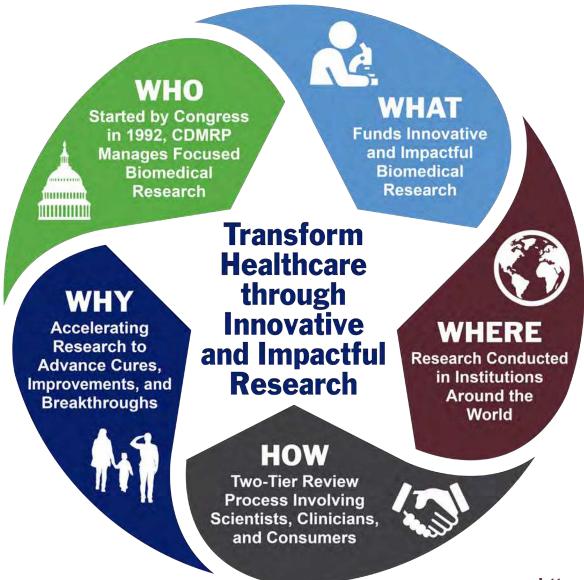


Mission

Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, Veterans and the American public

About CDMRP







https://cdmrp.health.mil

Background: Peer Reviewed Cancer Research Program



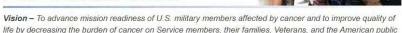
Began in Fiscal Year (FY) 2009 with an appropriation of \$16 Million (M) and congressional language directing the topic areas (specific cancers and other research areas) to be funded.

- FY09-FY22: \$784.8M, 921 awards
- FY23: \$130M, To be determined

- **■Vision** To advance mission readiness of those U.S. military members affected by cancer.
- Mission To successfully promote high-impact cancer research in prevention, detection, treatment, quality of life, and survivorship for Service Members, their families, Veterans, and the American public



Peer Reviewed Cancer



Since Fiscal Year 2009, the Peer Reviewed Cancer Research Program (PRCRP) has been charged by U.S. Congress to fund innovative basic, applied, and translational cancer research to support Service members, their families, and the American public. Members of the military are exposed to hazardous environments due to the nature of their service and deployments and, thus, are at risk for the development of many types of cancers. The mission of the PRCRP is to successfully promote high-impact research for cancer prevention, detection, treatment, and survivorship. To accomplish this task, the PRCRP seeks to fund different areas of the research landscape. Funding innovative and translational research the PRCRP offers funding opportunities directed toward the special focus of Service members and potential cancer risks; focusing on the gaps in cancer research with respect to unique situations and military environments. Additionally, the PRCRP addresses growing and developing the future in research through targeted funding opportunities for early career investigators. With a funding program focused on military health and welfare in cancer research, the PRCRP strives to improve the quality of life by decreasing the impact of cancer on Service members, their families and the American public by funding highly relevant and innovative research



Peer Reviewed Cancer Research Program Overarching Challenges

cdmrp.health.mil/prcrp



https://www.youtube.com/watch?v=g3TiEf97Ch0

FY23 Topic Areas for Peer Reviewed Cancer Research Program

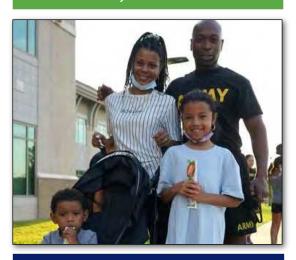


- Bladder Cancer
- Blood Cancer
- Brain Cancer
- Colorectal Cancer
- Endometrial Cancer
- Esophageal Cancer
- Germ Cell Cancers
- Head and Neck Cancer
- Liver Cancer
- Lymphoma
- Mesothelioma

- Metastatic Cancer
- Myeloma
- Neuroblastoma
- Pediatric, Adolescent and Young Adult Cancers
- Pediatric Brain Tumors
- Sarcoma
- Stomach Cancer
- Thyroid Cancer
- Von Hippel-Lindau
 Syndrome Malignancies
 (excluding cancers of the kidney and pancreas)

Applicants must address at least one of the Topic Areas, as directed by Congress

Funds may not be used for research into breast, kidney, lung, ovarian, pancreatic, prostate, rare cancers, or melanoma



Research must be relevant to Service Members, their Families, Veterans, and other military beneficiaries

The inclusion of the individual Rare Cancers Research Program **shall not** prohibit the PRCRP from funding the above-mentioned cancers or cancer subtypes that may be rare by definition

FY23 Congressional Language Relevance to Service Members and their families



Impact of Cancer on Military Health



Traumatic brain injury increases hazard ratio for development of brain cancer

Environmental exposures such as asbestos leads to mesothelioma risk

Exposures to ionizing radiation leads to uterine, thyroid, blood, and other cancers

Infectious diseases such as H. pylori is associated with stomach cancer risk

Cancer diagnoses in Service Members and their families lead to force vulnerabilities

Gaps in our knowledge of cancer care cause gaps in mission readiness

Cancer affects the whole unit's readiness, not just a single Service Member

Military Health Systems are burdened with healthcare costs due to cancer diagnoses and treatment

Requirement for all applicants to respond to **Military Health Focus Areas**

Military Health Focus	Required for All Applications	Programmatic Selection Factor
Cancer Risk Factors	Environmental Exposures	Occupational Exposures
Mission Readiness	Gaps in Research Spectrum	Gaps in Quality of Life

FY23 PRCRP: Topic Areas and Portfolios



General Oncology*	Hematology	Neurology	Otolaryngology	Pediatric	Reproductive Hereditary	Gastroenterology
Bladder Cancer Mesothelioma Metastatic Cancers	Blood Cancers Lymphoma Myeloma	Brain Cancer Pediatric Brain Tumors	Head and Neck Cancers	Pediatric, Adolescent and Young Adult Sarcoma Thyroid Cancer Neuroblastoma	Endometrial Cancer Germ Cell Cancers VHL malignancies	Esophageal Cancer Colorectal Cancer Liver Cancer Stomach Cancer

^{*}Portfolio are not directed by Congress and are used for management purposes only. Other Portfolios such as Legacy Portfolios cover topic areas no longer included under PRCRP.

FY23 PRCRP Cancer Capability Gaps Overarching Challenges – Research Gaps



Prevention



- *Develop innovative prevention strategies and early detection methods to decrease cancer burden
- *Elucidate the mechanisms underlying cancer development to improve prevention methods

Diagnostics



- *Identify strategies to predict treatment resistance, recurrence, and the development of advanced disease.
- *Distinguish unique features driving cancer occurrence across the spectrum of ages.
- *Develop and improve minimally invasive methods to detect cancer initiation, progression, and recurrence

Treatment



- *Transform cancer treatment, especially for advanced disease and metastasis
- *Improve current therapies including systemic and local treatments.
- *Longitudinal evaluation of disease progression and/or treatment response.
- *Elucidate the mechanisms of cancer development to improve treatment methods

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FY23 PRCRP Cancer Capability Gaps Overarching Challenges – Patient Outcomes Gaps



Patient Well-Being and Survivorship



- *Develop strategies to address survivorship issues including quality of life, overall mental health, psychological impact of recurrence, and/or survivor permanent disability
- *Develop strategies to reduce short- and long-term treatment effects, including neurocognitive deficits.
- *Bridge gaps between treatment and survivorship including alternative medicine, nutrition and lifestyle factors, and supportive care

Disparity



- *Improve prevention strategies, diagnosis, treatment, and outcomes for patients in <u>underserved or under recognized</u> populations
- *Develop strategies to improve <u>accessibility to care</u> and to address survivorship.
- *Advance <u>health equity and reduce disparities</u> in cancer care through research.

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PRCRP: PAYAC and Related Topics

PAYAC: Pediatric, Adolescent, and Young Adult Cancers



• General Military Health Facts

- **◆** More than 1.3M people serve in the U.S. military (2020); >90% under 40 years old.
- ◆More than 1.5M family members including spouses and children.

Active Duty Children (n = 964,485)



35.9% Active Duty members with children



Funding for PAYAC Associated Awards

Topic Area	Investment FY22
Blood Cancers	\$3.62M
Brain Cancer	\$1.46M
Colorectal Cancer	\$3.81M
Germ Cell Cancer	\$5.72M
Lymphoma	\$4.32M
Neuroblastoma	\$0.64M
PAYAC	\$5.82M
Pediatric Brain Tumors	\$7.19M
Sarcoma	\$4.66M
Thyroid Cancer	\$1.26M
Special Award Mechanism	Investment FY22
Convergent Science Cancer Consortium Development Award	\$3.17M

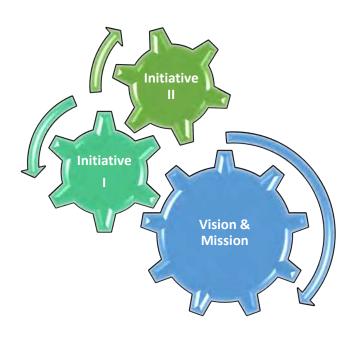
FY09-FY21 Total Investment = \$144M

https://www.militaryonesource.mil/data-research-and-statistics/military-community-demographics/2020-demographics-profile/

*Only includes PAYAC associated awards, not all awards from that topic area

PRCRP Major Areas of Investment





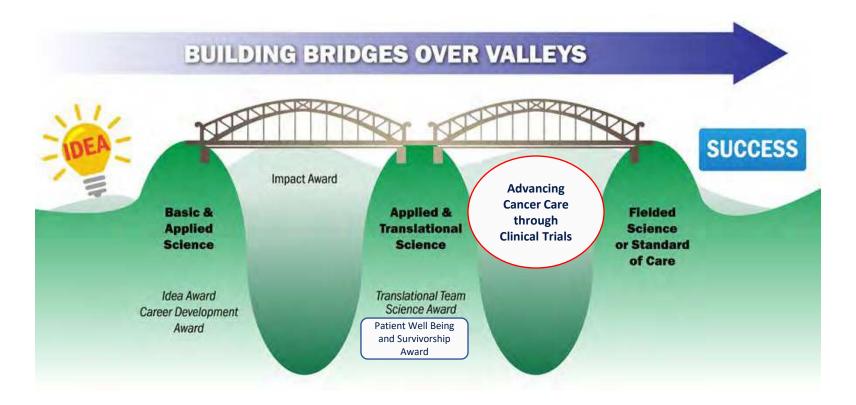
Initiative I: Advance Convergent Science in Cancer Research

- Convergent Science Virtual Cancer Center to catalyze training of early career investigators in an interactive multi-cancer network.
- Cultivate convergent science to advance cancer research through innovative funding opportunities.
- Initiative II: Support the Research Continuum toward Fielded Science
 - Support innovative, discovery-based research.
 - Enhance translational research.
 - Accelerate research toward fielded science.

Initiative II: Support the Research Spectrum FY23 Investment Strategy



- ✓ Choose the right funding opportunity
- ✓ Not all funding opportunities are alike



FY23 PRCRP Funding Opportunities



	DEPARTMENT OF DEFENSE		
Mechanism	Key Characteristics	Funding (Direct Costs)	Deadline Dates
Advancing Cancer Care through Clinical Trials Award (ACCCT)	 Pre-application screened for invitation Supporting a clinical trial with focus on cancer care Preliminary data required Transition to next phase of development 	\$3M over 4 years	Preapp: 25 May 2023 Full App: 12 Sept 2023
Career Development Award – Fellow Option	 Letter of Intent: No invitation needed Eligibility: Research Assistant Professor, instructor. Early career investigators not fully independent. Intended to support the wider independence 	\$400K over 2 years	Letter of Intent (LOI): 25 July 2023 Full App: 10 Aug 2023
Career Development Award – Resident Option	 Letter of Intent: No invitation needed Eligibility: Physician Scientist in Residency. Research Funding levels for 1 year or 2 years Protected time required 	\$200K over 1 year \$400K over 2 years	LOI: 3 Aug 2023 Full App: 24 Aug 2023
Idea Award	 Pre-application screened for invitation High-risk/high-gain, innovation is key! Preliminary data discouraged 	\$400K over 2 years	Preapp: 25 May 2023 Full App: 12 Sept 2023
Impact Award	 Pre-application screened for invitation Supports research toward clinical applicability Clinical trials allowed Preliminary data required 	\$1M over 3 years	Preapp: 25 May 2023 Full App: 12 Sept 2023
Patient Well-Being and Survivorship Award	 Letter of Intent: No invitation needed Formerly Behavior Health Science Award Studies focusing on survivorship and Quality of Life Allows pilot clinical trials 	\$1M over 3 years	LOI: 25 July 2023 Full App: 10 Aug 2023
Translational Team Science Award	 Letter of Intent: No invitation needed Supports 2-3 Principal Investigators Correlative studies associated with a clinical trial Preliminary data required 	\$2.5M over 4 years	LOI: 25 July 2023 Full App: 10 Aug 2023

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Invitation-Required Opportunities



Idea Award

- One-page pre-proposal
- Preliminary data is discouraged!
- Basic, high-risk/highgain research
- Independent PIs
- \$400k over 2 years

Impact Award

- <u>One</u>-page pre-proposal
- Clinical trial option
- Preliminary data is required
- Continuity of research with emphasis on nearterm impact
- Assistant Professor or equivalent
- \$1M over 3 years

Advancing Cancer Care through Clinical Trials (ACCCTA)

- Three-page preproposal
- Pre-clinical data is required
- Clinical trial is required
- <u>No</u> preclinical projects allowed
- IND/IDE submission by time of application deadline
- Assistant Professor or equivalent
- \$3M over 4 years

Idea and Impact Awards: Pre-proposal due 25 May 2023 Invitation by 29 June 2023 Full application due 12 September 2023

ACCCTA: Pre-proposal due 25 May 2023 **Invitation** by 29 June 2023 **Full application** due 27 September 2023

Letter of Intent Opportunities



Patient Well-Being and Survivorship Award

- Letter of Intent: Pilot Clinical Trial (PCT) Option Preliminary data only required for PCT Option
- Independent Investigator
- Quality of life, preservation of function, neurocognitive issues, long-term side effects
- \$1M over 3 years

Translational Team Science Award

- Letter of Intent: Clinical Trial Option
- Preliminary data required for supporting correlative studies associated with ongoing or completed clinical trial
- At least 2-3 PIs at the level of Assistant Professor
- \$2.5M for 4 years

Career Development Award – Fellow Option

- Letter of Intent: For scientists or Physician Scientists within 7 years of terminal degree
- Preliminary data not required
- Supports early career investigators toward further independence
- Research Assistant Professor, Instructor independent lab space is not required
- \$400k over 3 years

Career Development Award – Resident Option

- Letter of Intent: For Residents to participate in research
- Preliminary data not required
- Supports two different research levels-required to perform work between June 2024-2026
- Research level 1: \$200K over 1 year, or Research Level 2: \$400K over 2 years

Letter of Intent due 25 July 2023 Full application due 10 August 2023

Funding Opportunities



- Pre-announcements and funding opportunity release notifications
 - CDMRP website and email blasts
- Funding opportunity postings
 - Grants.gov (CFDA 12.420)
 - CDMRP website (cdmrp.health.mil)
 - electronic Biomedical Research Application Portal (eBRAP) system (ebrap.org)
- Quickly find open CDMRP Funding Opportunities on the CDMRP website here:
 - Home > Funding Opportunities > Synopsis of Open Program Funding Opportunities



Applying for Funding



Understanding the goals of the program, intent of the award mechanism, and review criteria is critical for a successful application



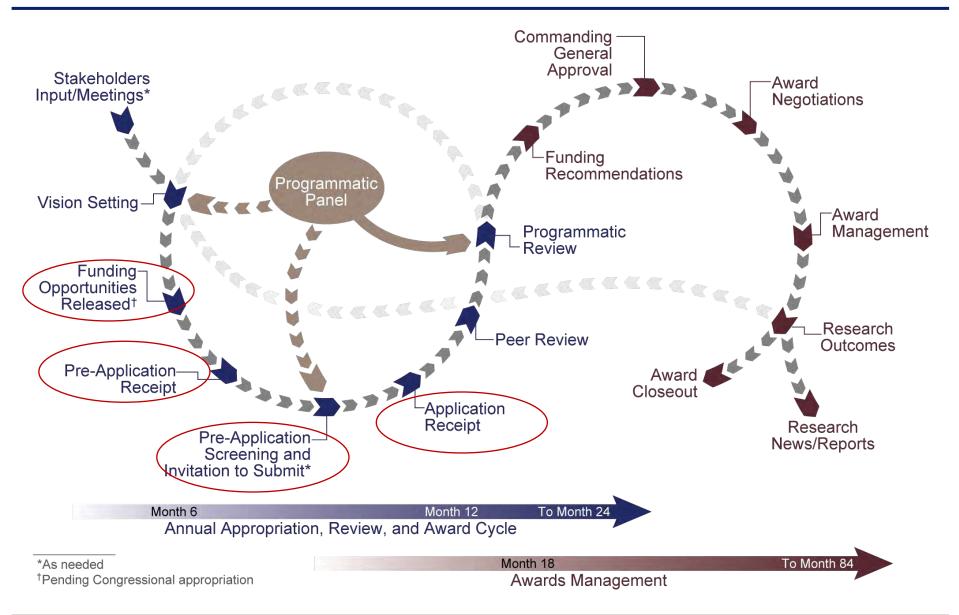
- The funding opportunity announcement contains information on:
 - Program Goals
 - Focus Areas/Topics
 - Award Intent
 - Required Elements, Eligibility, and Funding
 - Review Criteria
 - Deadlines

Single most important tip:

Read the announcement carefully

Program Cycle





Goal of the Two-Tier Review Process



To develop funding recommendations that balance *the most meritorious science* across many disciplines and offer the highest promise to *fulfill the programmatic goals* set forth in the funding opportunity

Peer Review

- Criterion-based evaluation of full proposal
- Determination of "absolute" scientific merit
- Outcome: Summary Statements
 - No standing panels; reviewers are recruited based on expertise needed
 - No contact between applicants, reviewers, and program staff

Partnership



Programmatic Review

- Comparison among proposals of high scientific merit
- Determination of adherence to intent, program relevance, and potential for impact
- Outcome: Funding Recommendations
 - No "pay line" (portfolio balance)
 - Funds obligated up-front;
 limited out-year budget
 commitments
 (but milestones imposed)
 - No continuation funding



Video and additional information available at: https://cdmrp.health.mil/about/2tierRevProcess

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Peer Review Criteria



(PRCRP verbiage example)

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:

Example Peer Review Criteria			
Scored		Unscored	
Principal Investiç	gator	Personnel	
Career Development Plan, Environment, Career Guide		Budget	
Research Strategy and Feasibility		Application Presentation	
Impact	Principal Investigator		



- - Whether the PI meets the eligibility requirements.
 - To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research.
 - How relevant the research would be to support the early-career investigator toward wider independence and success.
 - To what extent the PI's record of accomplishments and letters of support demonstrate their potential for advancement as a productive, independent investigator in cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1 and at least one of the FY23 PRCRP Overarching Challenges.
 - Whether the application demonstrates that the candidate has been named on and awarded nominal career development funding.

Programmatic Review Criteria



(PRCRP verbiage example)

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- · Ratings and evaluations of the peer reviewers
- · Relevance to the mission of the DHP and FY23 PRCRP, as evidenced by the following:

Fellow and Resident Options:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance to the FY23 Military Health Focus Areas
- Programmatic relevance to the FY23 PRCRP Overarching Challenges
- Relative impact

Programmatic Panel membership lists are available on the CDMRP website







Strategies to Answer Challenges



Plan Ahead

- **◆** Deadlines are important!
- **◆** Dissect the Funding Opportunity and Understand it
- ◆ Coordinate your efforts: bring the team together early

Grantsmanship

- ◆ Clear voice, forget the jargon: don't tire the reviewers
- ◆ Review your documents prior to submission: use the verification period!
- ◆ Use the Peer Review Criteria as your check list!

What's the Intent

- ◆ The Ted Talk: state your idea upfront, then back it up!
- ◆ Make your case to how your research aligns with the intent

Questions? help@eBRAP.org

Impact

- ◆ Cool science is good: Impactful science is great!
- ◆ Show how it is impactful, important to patients
- ◆ Use plain language! You will be evaluated on this!

Feasibility

- ◆ Clearly define your team's skills
- ◆ Outline your justification on how and why you can achieve the anticipated outcomes



Pitfalls to Avoid in Application Submission



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- Do not include Programmatic Panel members for the program and fiscal year to which you are applying
- Do not exceed the page limits; check files after creating PDF version
- Do not miss the submission deadline
 - Grants.gov validation may take up to 72 hours
 - System-to-system submissions are sometimes problematic
 - Application verification in eBRAP is possible before the deadline
- Do NOT ignore the Verification Period!
- Submit the correct Project Narrative and Budget
 - These components cannot be modified during the verification period in eBRAP

FY23 Panel Member			
Organization			
t. Col. Della Howell, M.D., U.S. Air Force Retired (Chair)			
Methodist Children's Hospital			
Jill Barnholtz-Sloan, Ph.D.			
National Cancer Institute			
Clark Chen, M.D., Ph.D.			
University of Minnesota			
Cmdr. Michele Gage, M.D., U.S. Navy			
Walter Reed National Military Medical Center			
Doug Hawkins, M.D.			
Seattle Children's Hospital			
Adam Hayden, (Consumer)			
National Brain Tumor Society			
Yin-Fen Lee, Ph.D.			
University of Rochester			
Barbara Lind (Consumer)			
Society of Gemological Oncology			
Aaron Mansfield, M.D.			
The Mayo Clinic			
Robert Mesloh (Consumer)			
Lymphoma Research Foundatio			
Col. Thomas Newton, M.D., U.S. Air Force Retired			

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Inova Schar Cancer Institute

Heath Skinner, M.D., Ph.D.

Massachusetts General Hospital

University of Pittsburgh Kenneth Tanabe, M.D.

Col. Aaron Pitney, M.D., U.S. Army

U. S. Army Training and Doctrine Command

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Questions? For more information, please visit:



