

Peer Reviewed Cancer Research Program (PRCRP) Funding Opportunities and Strategies for Success

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The views expressed in this presentation are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government



WHO is the CDMRP?



Department of Defense





Department of the Army





Army Materiel Command





U.S. Army Medical Research and Materiel Command (USAMRMC)



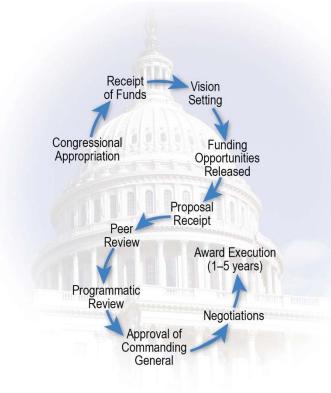


Congressionally Directed Medical Research Programs





About CDMRP



◆ CONGRESSIONAL PROGRAMS

- Manages extramural research programs directed by Congress
- Started in 1992 with a focus on breast cancer research; currently includes 30 research programs
- Congress specifies the focus area; the CDMRP determines research strategy and competitively selects the best projects
- Unique public/private partnership encompasses the military, scientists, disease survivors, consumers, and policy makers
- Funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

◆ DoD PROGRAMS

Provides support to Program Area Directorates (PADs)/Joint Program Committees (JPCs) for managing extramural and intramural research portfolios to advance their missions

♦ DIRECTOR

COL Stephen Dalal

CURRENT PROGRAMS:

- Alcohol and Substance Abuse Disorders
- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- · Breast Cancer Semipostal
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness

- Hearing Restoration
- · Joint Warfighter Medical
- Kidney Cancer
- Lung Cancer
- Lupus
- Military Burn
- Multiple Sclerosis
- · Neurofibromatosis
- Orthotics and Prosthetics Outcomes
- · Ovarian Cancer

- Parkinson's
- · Peer Reviewed Alzheimer's
- · Peer Reviewed Cancer
- · Peer Reviewed Medical
- · Peer Reviewed Orthopaedic
- Prostate Cancer
- Reconstructive Transplant
- Spinal Cord Injury
- · Tick-Borne Disease
- Tuberous Sclerosis Complex
- Vision

ADDITIONAL SUPPORTED DOD PROGRAMS:

- Armed Forces Institute of Regenerative Medicine II
- · Centers of Excellence
- Defense Medical R&D
- Defense Medical R&D Restoral
- Psychological Health and Traumatic Brain Injury
- Small Business Innovation/ Small Business Technology Transfer
- Trauma Clinical

Vision and Mission

Vision

Transform healthcare for FUNDING GROUNDBREAKING, HIGH-IMPACT RESEARCH

Mission

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



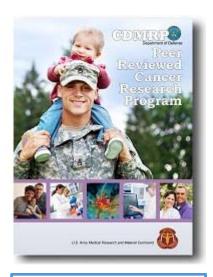
Congressionally Directed



Peer Reviewed Cancer



Vision - To advance mission readiness of U.S. military members affected by cancer and to improve quality of life by decreasing the burden of cancer on Service members, their families and the American public



Mission: To successfully promote high-impact research for cancer prevention, detection, treatment, and survivorship

- Congressional language stipulates the Topic Areas to be funded, the appropriation amount, and the requirement that research is relevant to Service members and their families
- •Over the ten years of the PRCRP, 24 Topic Areas have been included in the Congressional Language.



Strategic Guidance CDMRP Congressional Language: FY19 Topic Areas

FY19 Topic Areas

- Bladder Cancer
- Blood Cancers
- Brain Cancer
- Cancer in children, adolescents & young adults
- Colorectal Cancer
- Immunotherapy
- Listeria vaccine for cancer
- Liver Cancer
- Lymphoma
- Mesothelioma
- Neuroblastoma
- Pancreatic Cancer
- Pediatric Brain Tumors
- Rare Cancers
- Stomach Cancer

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

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

Research progress should be relevant to Service members and their families

Relevance to Military Health Focus Areas

Required for All Funding Opportunities

- ◆ Environmental/Exposure risk factors associated with cancer (e.g., ionizing radiation, chemicals, infectious agents, and environmental carcinogens)
- Gaps in cancer prevention, screening, early detection, diagnosis, treatment, and/or survivorship have a particularly profound impact on the health and well-being of Service members, Veterans, and their beneficiaries



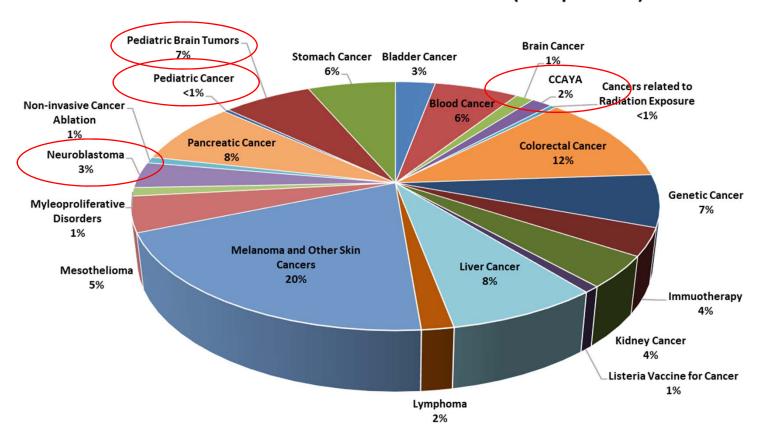
Environmental Exposures



Mission Readiness

FY09-17 PRCRP Investment per Topic Area Department of Defense (% dollars)

Total Amount Invested in Each TA FY09-FY17 (% of portfolio)



Application Statistics*



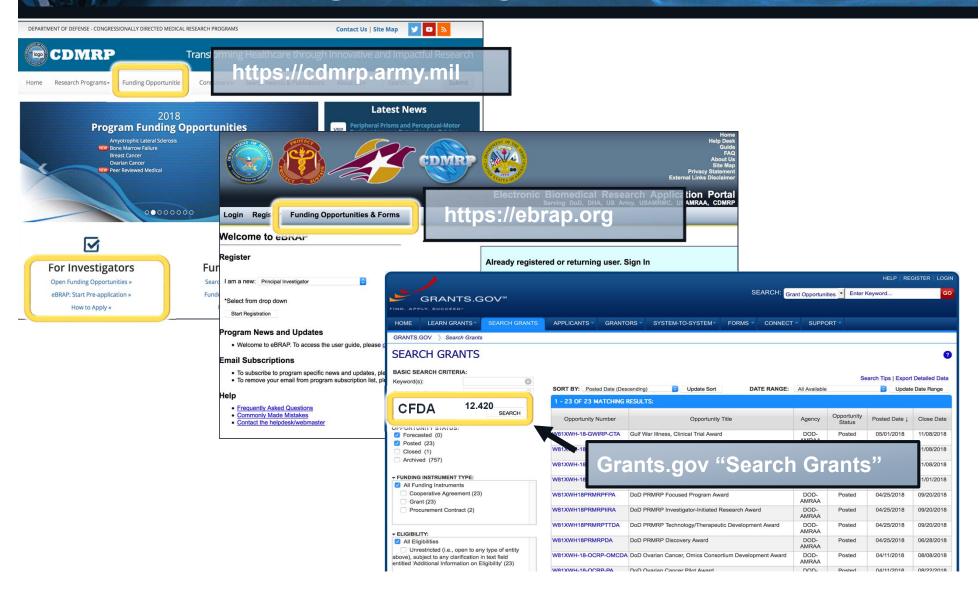
OUTTING EDGE RESEARCH Cancers in Children, Adolescents and Young Adults (CCAYA); Pediatric Brain Tumor; Neuroblastoma

Topic Area	# Awards	Research Dollars (Millions)
CCAYA	12	\$6.2M
Neuroblastoma	3	\$1.5M
Pediatric Brain Tumor	5	\$2.5M

*Application Statistics are not finalized until award negotiations are complete (30 September 2019). Application Statistics and final investment amounts are subject to change (i.e. withdrawals of applications due to overlap).



Finding Funding Opportunities







Idea Award with Special Focus

Impact Award

Translational Team Science Award

- All researchers with faculty level appointment eligible
- Supports

 innovative, high-risk/high gain
 research
- Emphasis on innovation
- Special Focus on military health
- Preliminary data not required
- Direct costs \$400k
 over 2 yrs.

- Assistant Professor or above eligible
- Support research projects or ideas that specifically focus on critical scientific and clinical cancer issues, have the potential to make a major impact on one of the FY19 PRCRP Topic Areas
- Clinical Trial support
- Emphasis on military health
- Preliminary data required
- Direct costs \$1M over 3 yrs.

- Assistant Professor or above eligible
- 2-3 Pls partner
- Supports
 correlative studies
 associated with an
 ongoing,
 completed trial
- Clinical Trial support
- Emphasis on military health
- Preliminary data required
- Direct costs -\$1.5M amongst the partners over 4 yrs.

FY19 PRCRP Funding Opportunities Letter of Intent



Horizon Award

- Pre-doctoral candidates or Postdoctoral fellows
- Mentor at level of Assistant Professor
- ResearchDevelopment Plan required
- Emphasis on Impact
- Military health requirement
- Preliminary data not required
- Direct costs -\$150k over 2 yr.

Career Development Award

- Independent investigator within 10 years of terminal degree
- Career Guide at level of Associate Professor
- Supports impactful research
- Focus on military health
- Preliminary data not required
- Direct costs -\$360k over 3 yrs.





Funding Opportunity Documents

Program Announcement

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Idea Award with Special Focus

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-PRCRP-IASF

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical

Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), May 22, 2019

Invitation to Submit an Application: June 26, 2019

Application Submission Deadline: 11:59 p.m. ET, September 11, 2019

End of Application Verification Period: 5:00 p.m. ET, September 16, 2019

Peer Review: November 2019

Programmatic Review: January 2020

General Application Instructions

General Application Instructions

Version 20180329

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

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This General Application Instructions document must be read in conjunction with the

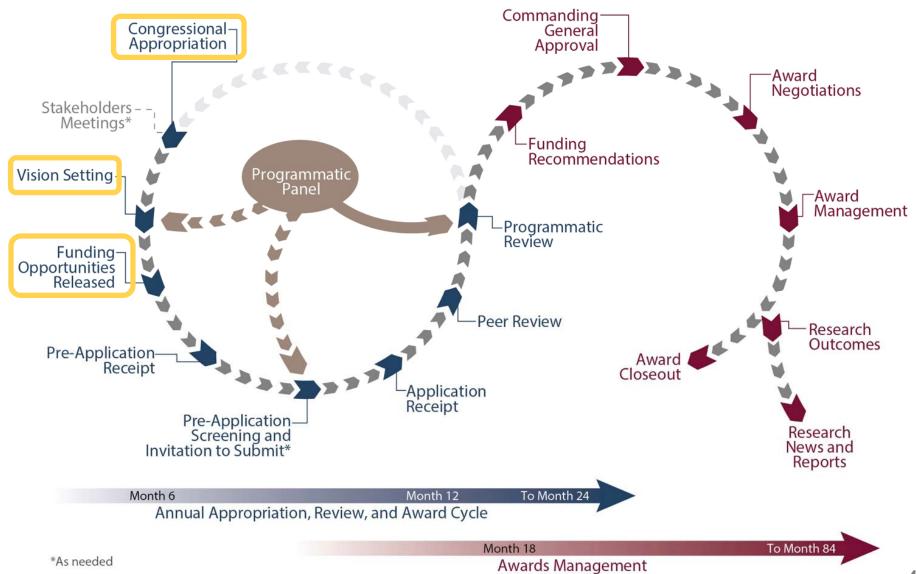
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Single most important tip: Read both documents carefully





Program Cycle

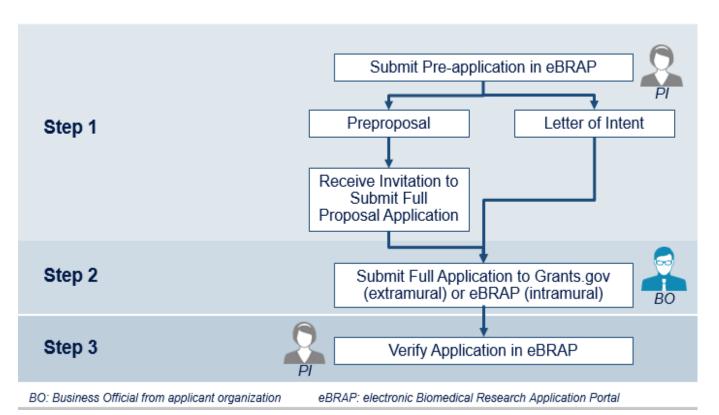






Submission Information

CDMRP utilizes a standard submission process



All PAs use a twostep submission process:

(1) Pre-apps (Preproposal or Letter of Intent) via eBRAP

(2) Full apps Grants.gov (extramural)





What's the Difference?

Pre-proposal v. Letter of Intent

- Submission through ebrap.orgfollow all instructions
- Preparation of a 1-2 page narrative
- Pre-proposal may include biosketches, other supporting documents
- ◆ Pre-proposal will be reviewed by Programmatic Panel
- Invitation to submitted full application is REQUIRED

Idea Award with Special Focus
Translational Team Science Award
Impact award

- Submission through ebrap.orgfollow all instructions
- **◆** Letter → state intent to apply
- Not reviewed
- Used for administrative purposes only
- ♦ NO invitation is required to submit full application

Horizon Award Career Development Award





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 relevant Program Announcement

Peer Review

Partnership

Programmatic Review

- Criterion-based evaluation of full proposal
- ◆ Determination of "absolute" scientific merit
- ◆ Outcome: Summary Statements
 - No standing Peer Review panels
 - No contact between reviewers and applicants



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





First Tier: Peer Review

How the evaluation process works

- Technical merit assessment based on an ideal application
- Criteria-based evaluation of entire application

Peer reviewers

- Panels comprised of scientific and consumer reviewers
- No standing panels
- Reviewers are recruited based on expertise needed
- Identities are unknown to applicants; contact between applicants and reviewers are not permitted



Outcome: Summary Statements



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:

Scientific Merit

- How well the proposed research addresses an important scientific question relevant to at least one of the FY19 PRCRP Topic Areas in <u>Section II.A.1</u>.
- To what degree the proposed research demonstrates the potential to generate robust preliminary data that can be used as a foundation for future research projects.
- How well the rationale, experimental design, and methodology are appropriate to test the hypothesis.
- To what degree the statistical plan is appropriate for the experimental methodology being used.
- How well the application acknowledges potential problems and addresses potential pitfalls and alternative approaches.
- Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.
- If applicable, to what extent the human subject population is described as being appropriate for the study and if there is clear access to the designated population.
- If applicable, whether the power analysis for the proposed study adequately addresses an assessment of the population or subpopulation available for study.

Answer ALL of the questions Peer Reviewers evaluate!



How the evaluation process works

- Comparison-based
- Strong scientific merit
- Adherence to award mechanism's intent
- Potential for impact
- Program relevance
- Consideration of portfolio composition

Programmatic reviewers

- Programmatic Panel members comprised of consumers, clinicians, and researchers
- Ad hoc reviewers



Outcome: Funding Recommendations





Programmatic Panel

Name, Organization

Dan Dixon, Ph.D. (Chair)

University of Kansas Medical Center

Jonathan Brody, Ph.D.

Thomas Jefferson University

Clark Chen, M.D., Ph.D.

University of Minnesota

LCDR Alden Chiu, M.D.

Walter Reed National Military Medical Center

Paul Doetsch, Ph.D.

National Institutes of Health, National Institute of

Environmental Health Sciences

Lt. Col. Della Howell, M.D.

Brooke Army Medical Center

Brant Inman, M.D.

Duke University Health

John Kuttesch, M.D., Ph.D.

University of New Mexico

Aaron Mansfield, M.D.

Mayo Clinic

Robert Mesloh (Consumer)

Lymphoma Research Foundation

Lopa Mishra, M.D.

University of Texas MD Anderson Cancer Center

COL Thomas Newton, M.D.

Walter Reed National Military Medical Center

Nancy Roach (Consumer)

Fight Colorectal Cancer

Kenneth Tanabe, M.D.

Harvard University

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 FY19 PRCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - o Program portfolio composition
 - Relevance to FY19 PRCRP Military Health Focus Areas
 - Relative innovation
 - Do NOT include ANY of the Programmatic Panel members in your application!
 - Pay attention to the details of the Programmatic Review Criteria!
 - Don't 'phone it in'!





Strategies for Success

✓ Relevance

- Address program-specific goals
- Align the proposed work with specific guidance from the announcement

✓ Impact

- Propose solutions to important problems
- Clearly articulate translatability how will this work make a difference?

✓ Innovation

Identify gap(s) that will be filled and novel approaches used

✓ Feasibility

- Justify a technically sound plan with clear approaches for contingencies
- Include evidence of appropriate EXPERTISE (collaboration, consultants, etc.)
- Ensure the study is APPROPRIATELY POWERED for the proposed research outcome
- Demonstrate AVAILABILITY and ACCESS to critical resources, reagents, and/or subject populations





Strategies for Success

✓ Planning/Timelines

- Include and allow adequate time in project plan for regulatory approvals if required
- For multi-organizational efforts, show a clear plan for COORDINATION and communication
- For DoD collaborations, understand rules and plan for differences in funding process



✓ Grantsmanship

- Explain the proposed work with CLARITY and UNBURDENED by jargon
- Understand the different audiences of the peer and programmatic reviews and COMMUNICATE effectively
- REVIEW application documents carefully before submission Enlist experienced colleagues to help
- Don't break the rules for deadlines or requirements BE COMPLIANT

CDMRP Pitfalls to Avoid in Application Submission



- 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
- Submit the correct Project Narrative and Budget
 - These components cannot be modified during the verification period in eBRAP



For more information, please visit: cdmrp.army.mil/prcrp

https://cdmrp.army.mil/pubs/video/CDMRP_overview

https://cdmrp.army.mil/pubs/Webinars/webinar_series

