The Congressionally Directed Medical Research Programs

FY21 Peer Reviewed Cancer Research Program Funding Opportunities

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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 Futures Command





U.S. Army Medical Research and Development Command (USAMRDC)





Congressionally Directed Medical Research Programs



Vision and Mission



Vision

Transform healthcare for FUNDING CROUNDBREAKING, HIGH-IMPACT RESEARCH

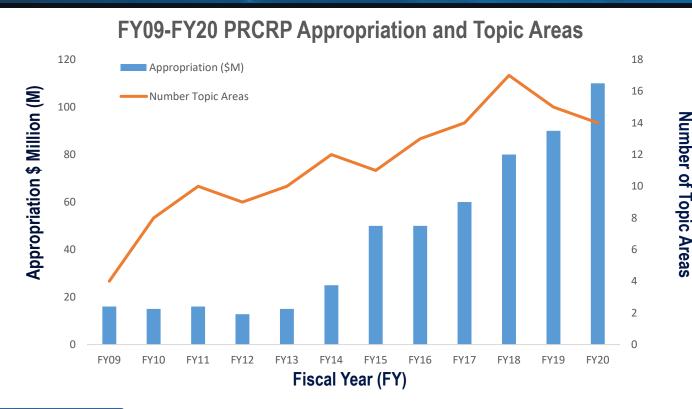
Mission

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

PRCRP Congressional Language

Vision: To advance mission readiness of those U.S. military members affected by cancer and to improve their 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, quality of life, and survivorship



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

The inclusion of the Rare Cancer Research
Program shall not prohibit PRCRP from
funding cancers, or cancer subtypes that
may be rare by definition

Research projects should be relevant to Service members and their families

FY21 Congressional Language

◆ FY21 Topic Areas

- ◆ Cancers related to use ◆ Lymphoma of beryllium
- Bladder Cancer
- Blood Cancers
- Brain Cancer
- Colorectal Cancer
- Endometrial Cancer
- **◆** Esophageal Cancer
- **Germ Cell Cancers**
- ◆ Head and Neck Cancer ◆ Stomach Cancer
- Liver Cancer

- Mesothelioma
- Metastatic Cancers
- Neuroblastoma
- Pediatric brain tumors
- Pediatric, Adolescent, and Young Adult Cancers
- Sarcoma
- **◆ Thyroid Cancer**
- **♦** Link between Scleroderma and cancer

♦ FY21 Details

- ◆ FY21 PRCRP Appropriation = \$115M
- **Topics areas = 20 (including new or returning)**
- **New Topics Areas = 6**
- **Prohibited cancers:**
 - ❖ Breast Cancer
 - ❖ Pancreatic Cancer
 - Prostate Cancer
 - Ovarian Cancer
 - Kidney Cancer
 - Lung Cancer
 - ❖ Melanoma
 - ❖ Rare Cancer*
- The inclusion of the individual rare cancer research program shall not prohibit the peerreviewed cancer research program from funding the above-mentioned cancers or cancer subtypes that may be rare by definition
- Relevance to Service Members and their families required



FY21 Congressional Language: 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)





Mission Readiness

- Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment
- Gaps in quality of life and/or survivorship







Mission Readiness

CUTTING EDGE RESEARCH

FY21 PRCRP Overarching Challenges Strongly Encouraged



Biology, Etiology Detection, Diagnosis, Prognosis

Treatment

Survivorship

Disparity

Resources

Identify and understand the unique and novel features driving cancer presentation to improve outcomes across the spectrum of ages (e.g., children, adolescents, young adults, older adults biology or etiology.

Identify and understand the mechanisms behind cancer epigenetics, biological development, etiology, and genetic basis

Develop strategies and biomarkers to predict cancer risk, treatment resistance, recurrence, and advanced disease to mitigate risk in target populations.

Develop and improve minimally invasive methods to detect cancer initiation, recurrence, and progression Transform cancer treatment through the identification of novel biomarkers and new targets especially for advanced disease (metastatic and/or recurrence); improve immunotherapy; and eliminate the risks of therapy-associated toxicity

Develop strategies to improve ease of care/accessibility and to address survivorship issues including quality of life, long-term treatment effects, psychological impact of recurrence, neurocognitive deficits, and overall mental health

Improve prevention strategies, diagnosis, treatment, and outcomes for patients in underserved or under recognized populations (e.g., military populations, rural populations, communities of color, other minorities, and women).

Develop open access platform(s) or methods to coordinate and integrate multiple databases, biorepositories, and data sharing interfaces.

Get the Facts: Funding and PRCRP Total Funding: \$91.5M



◆ Neuroblastoma

- ◆ FY13-FY19 PRCRP funding: \$15.9M; 28 awards
- ◆ FY20 Total Applications: 8
- **◆ FY20* PRCRP Funding: \$4.8M; 4 awards** (50%)

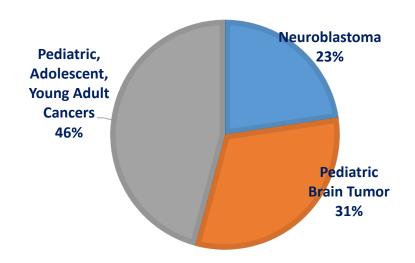
Pediatric Brain Tumors

- ◆ FY09-FY10; FY12-FY14; FY16-FY19 PRCRP Funding: \$22.8M; 47 awards
- ◆ FY20 Total Applications: 35
- ◆ FY20 PRCRP Funding: \$6.1M; 11 awards (31%)

Pediatric, Adolescent,Young Adult Cancers

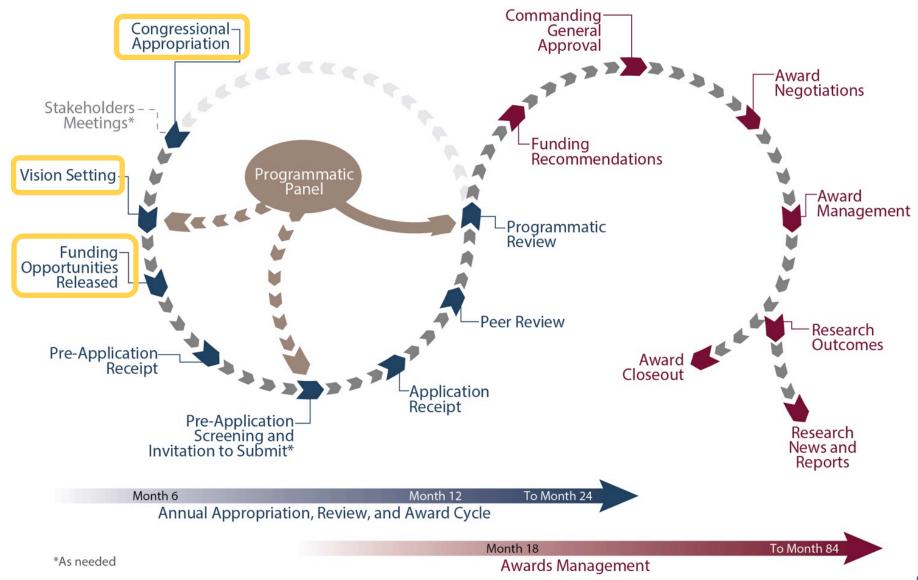
- ◆ FY11¥; FY17-FY19 PRCRP Funding: \$31.1M; 50 awards
- **◆ FY20 Total Applications: 43**
- ◆ FY20 PRCRP Funding: \$10.8M; 14 awards (33%)

% INVESTED IN EACH TOPIC AREA





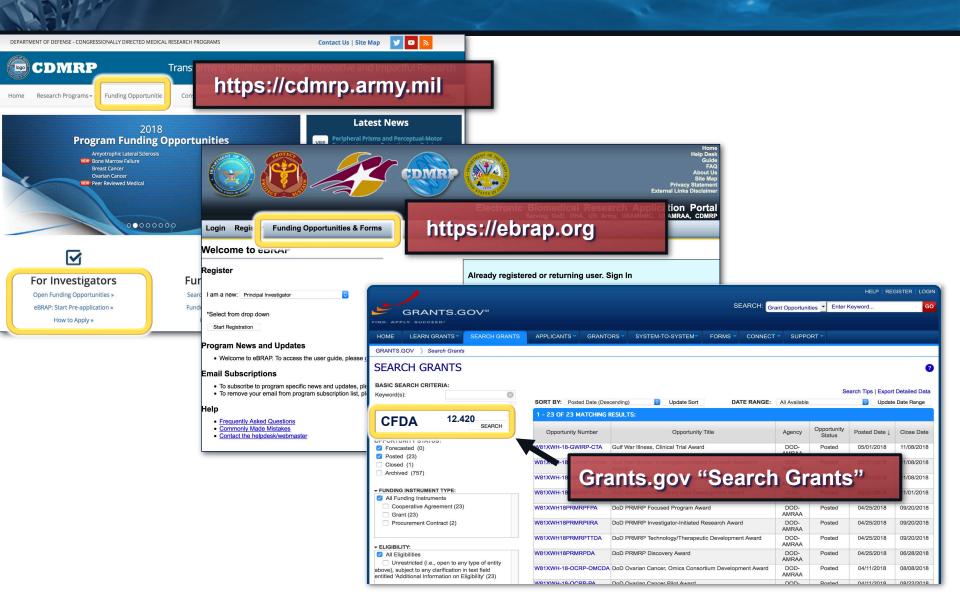




CUTTING EDGE RESEARCH



Finding Funding Opportunities

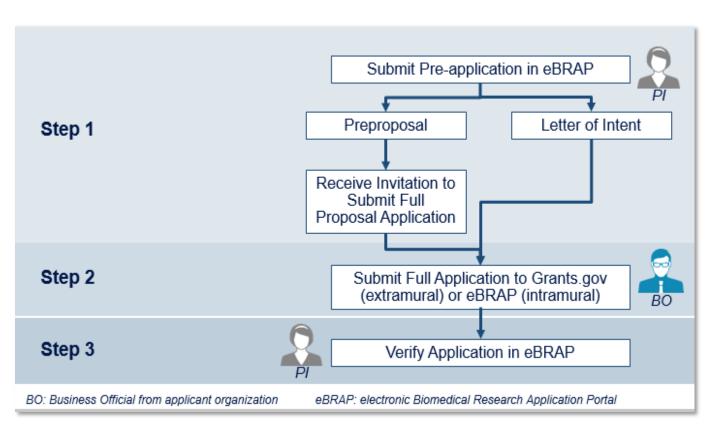








CDMRP utilizes a standard submission process



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.org follow all instructions
- **◆** Preparation of a 2 page narrative
- Pre-proposal may include biosketches, other supporting documents
- ◆ Pre-proposal will be reviewed by Programmatic Panel
- ◆ Invitation to submit full application is REQUIRED

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

Idea Award Impact award

Behavioral Health Science Award, Translational Team Science Award, Career Development Award

FY21 PRCRP Funding Opportunities

♦ Idea Award

- ◆Preproposal → invite required
- ◆All researchers with faculty level appointment eligible
- Supports innovative, high-risk/high gain research
- ◆ Emphasis on innovation
- Preliminary data not required
- ◆ Direct costs \$500k up to 3 yrs.

♦ Key Points for Success

◆Innovation

- ❖Argue your case → Justify!
- Innovation is NOT incremental advance, the next logical step in your research, changing cancers
- Preliminary data will be evaluated if included
- ◆ Pay attention to the newly minted FY21 PRCRP Overarching Challenges in the Impact Statement
- ◆ Don't phone in the Military Health Focus Areas

FY21 PRCRP Funding Opportunities

◆ Impact Award

- ◆Preproposal → invite required
- **◆** Assistant Professor or above eligible
- ◆ Support research that demonstrates the potential to have a major impact in the near term on an area of paramount importance in cancer
- **◆ Clinical Trial support allowed**
- ◆ Preliminary data required
- ◆ Direct costs \$1.25M over 3 yrs.

♦ Key Points for Success

- ◆Impact should be clearly stated how it will be near term
- ◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges
- **◆**Continuity of Research → Research Outcomes Plan
 - Einstein thought experiment for your outcomes/future plans
 - Why is this research distinct and should be funded for future patient outcomes



FY21 PRCRP Funding Opportunities

- **♦ Translational Team Science Award**
- **◆**Letter of Intent → No invite required
- **◆** Assistant Professor or above eligible
- **◆2-3 Pls partner**
- ◆ Supports hypothesis driven correlative studies associated with an ongoing or completed trial
- **◆ Clinical Trial support**
- ◆ Preliminary data required
- **◆** Direct costs \$2.5M amongst the partners over 4 yrs.

- **♦** Key Points for Success
- ◆ Collaboration → clearly show why and how all investigators are critical to the success
- ◆Translation → the bench should inform the clinic
- ◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges
- **♦** Research Outcomes Plan
 - Einstein thought experiment for your outcomes/future plans
 - Why is this research distinct and should be funded for future patient outcomes

FY21 PRCRP Funding Opportunities

♦ Behavioral Health Science Award

- ◆ Letter of Intent → No invite required
- ◆ Independent investigator with a faculty-level appointment (or equivalent).
- **◆** Supports innovative research
- **◆** Three Stages of Survivorship
- ◆ Survivorship, QoL, psychosocial effects related to cancer
- ◆ Allows support of *Pilot* Clinical Trial support
- Only 3 of the FY21 PRCRP Overarching Challenges are included
- Preliminary data required for applications proposing a pilot clinical trial
- ◆ Direct costs \$1M over 4 yrs

♦ Key Points for Success

- ◆ Impact → the point is to change the lives of patients with cancer, beyond only treatment!
- Patient Advocates must be involved and should be from the cancer being studied
- ◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges
- ◆ Understand the 3 Stages of Survivorship
 - Acute survivorship from diagnosis through to the end of initial treatment.
 - **Extended** survivorship end of initial treatment goes through the months after.
 - Permanent survivorship years have passed since cancer treatment ended. Long-term effects of cancer and treatment are the focus



FY21 PRCRP Funding Opportunities

- **♦** Career Development Award- Fellow
- ◆ Letter of Intent → No invite required
- ◆ Independent investigators at or above the level of Research Assistant Professor or Instructor (or equivalent) and within 7 years after completion of their terminal degree
- ◆ Career Guide at level of Associate Professor
- ◆ Supports impactful research
- **◆** History of extramural funding not required
- ◆ Preliminary data not required
- ◆ Direct costs \$400k over 3 yrs.
- ◆ 50% protected time

♦ Key Points for Success

- ◆ Impact → the point is to change the lives of patients with cancer, beyond only treatment!
- Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges
- **◆** Career Development Plan
 - Show involvement of Career Guide
 - Logical progression of career
 - Milestones to further career
 - Networking and collaboration
 - Workshops, training, and courses



Funding Opportunity Documents

Program Announcement

Peer Reviewed Cancer Research Program

Behavioral Health Science Award

Announcement Type: [Initial]

Funding Opportunity Number: W81XWH-21-PRCRP-BHSA

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), July 29, 2021
- Application Submission Deadline: 11:59 p.m. ET, August 18, 2021
- End of Application Verification Period: 5:00 p.m. ET, August 25, 2021
- Peer Review: October 2021
- Programmatic Review: December 2021

General Application Instructions

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Version 601
Department of Defense

Congressionally Directed Medical Research Programs

Table of Content

Table of Contents	
I. HELPFUL INFORMATION A. Tips for Success B. Applicant Organizations C. Current Funding Opportunities D. Receiving Emails from CDMRP, eBRAP, and Grants.gov E. Agency Contacts F. Application Submission Overview	2 2 2
II. eBRAP REGISTRATION AND PRE-APPLICATION SUBMISSION	4
III. APPLICATION SUBMISSION FOR EXTRAMURAL ORGANIZATIONS A. Grants.gov Application Package Components B. Submission to Grants.gov	10 26 26
IV. APPLICATION SUBMISSION FOR INTRAMURAL ORGANIZATIONS A. eBRAP Application Package Components	27
APPENDIX 2 REPORTING REQUIREMENTS AND ADMINISTRATIVE INFORMATION	
APPENDIX 3 QUALIFICATION AND RESTRICTIONS INFORMATIONAPPENDIX 4 FORMATTING GUIDELINESAPPENDIX 5 NATIONAL POLICY REQUIREMENTS	49
APPENDIX 6 ACRONYM LIST	53

Single most important tip: Read both documents carefully



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 is not permitted



Outcome: Summary Statements

Example of Peer Review Criteria

To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

Research Strategy and Feasibility

- Whether the stated hypothesis or the objective is relevant to at least one of the FY21 PRCRP Topic Areas in Section II.A.1.
- To what degree the study design, proposed methods, and analyses are appropriate to test the hypothesis and/or reach the final objective.
- If applicable, for retrospective or prospective recruitment studies whether the application defines the type of study (e.g., descriptive, correlational, field experimental, metaanalyses).
- If applicable, whether study populations are defined.
- To what degree the application addresses potential problem areas and potential pitfalls and presents alternative methods and approaches.
- To what extent the proposed study is innovative or is a high reward concept in at least one of the three areas of survivorship.

Answer ALL of the questions Peer Reviewers evaluate!



Second Tier: Programmatic Review

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



John Kuttesch, M.D., Ph.D. (FY20-21 Chair) University of New Mexico

Dan Dixon, Ph.D. (Chair Emeritus) University of Kansas Medical Center

Clark Chen, M.D., Ph.D. University of Minnesota

LCDR Alden Chiu

Walter Reed National Military Medical Center

Paul Doetsch, Ph.D.

NIH/NIEHS

LCDR Michelle Gage M.D.

Walter Reed National Military Medical Center

Adam Hayden (Consumer)

National Brain Tumor Society

Lt Col Della Howell, M.D.

Brooke Army Medical Center

Brant Inman, M.D.

Duke University

Aaron Mansfield, M.D.

The Mayo Clinic

Robert Mesloh (Consumer-Veteran)

Lymphoma Research Foundation

Lopa Mishra, M.D.

George Washington University

Col (ret) Thomas Newton M.D. (Veteran)

Inova Schar Cancer Institute

Kenneth Tanabe, M.D.

Harvard University

Chiaojung Jillian Tsai, M.D., Ph.D.

Memorial Sloan Kettering Cancer Center

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 FY21 PRCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio balance and composition
 - Programmatic relevance to the FY21 PRCRP Military Health Focus Areas
 - Programmatic relevance to the <u>FY21 PRCRP Overarching Challenges</u>
 - Relative impact]
 - 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



◆ Plan Ahead

- Deadlines are important!
- ◆ Coordinate your efforts → bring the team together early

◆ Grantsmanship

- ◆ The Ted Talk → state your idea upfront, then back it up!
- ◆ Clear voice, forget the jargon → not a competition to see how many abbreviations included
- ◆ Review your documents prior to submission → use the verification period!

♦ What's the Intent

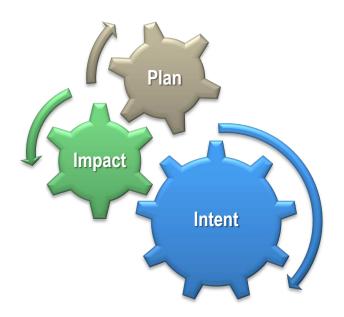
- ◆ How do you fit in → Ted Talk again!
- Make your case to how your research aligns with the intent

◆ Impact

- ◆ Cool science is good → Impactful science is great!
- ◆ Show how it is impactful, important to patients

◆ 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



- ◆ 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



FY21 PRCRP Timeline



Pre-proposal Mechanisms Deadlines

Idea Award and Impact Award

- ◆ Pre-Application Submission Deadline: 5 pm ET, 20 May 2021
- ◆ Invitation to Submit an Application: 8 July 2021
- ◆ Application Submission Deadline: 11:59 pm ET, 8 September 2021
- ◆ End of Application Verification Period: 5 pm ET, 15 September 2021
- ◆ Peer Review: November 2021
- ◆ Programmatic Review: February 2022
- **♦** Pre-application → the preproposal 2 pages.
- ◆ The pre-proposal is reviewed!
- ◆ You need an invitation to submit!

Letter of Intent Mechanisms Deadlines

Translational Team Science Award, Behavioral Health Science Award, and Career Development Award-Fellow

- Pre-Application Submission Deadline: 5 pm ET, 29 July 2021
- ◆ Application Submission Deadline: 11:59 pm ET, 18 August 2021
- ◆ End of Application Verification Period: 5 pm ET, 25 August 2021
- ◆ Peer Review: October 2021
- ◆ Programmatic Review: December 2021
- ◆ Pre-application → Letter of Intent
- A letter stating you intend to apply. It is NOT reviewed!
- **♦ You DO NOT need an invitation to submit!**



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











