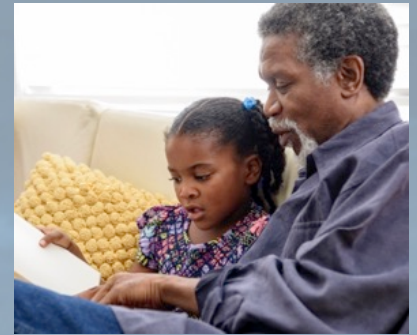


The Congressionally Directed Medical Research Programs

**FY20 Peer Reviewed
Cancer Research Program
Funding Opportunities**

CUTTING EDGE RESEARCH

**Donna M. Kimbark, Ph.D.
Program Manager
Peer Reviewed Cancer Research Program**



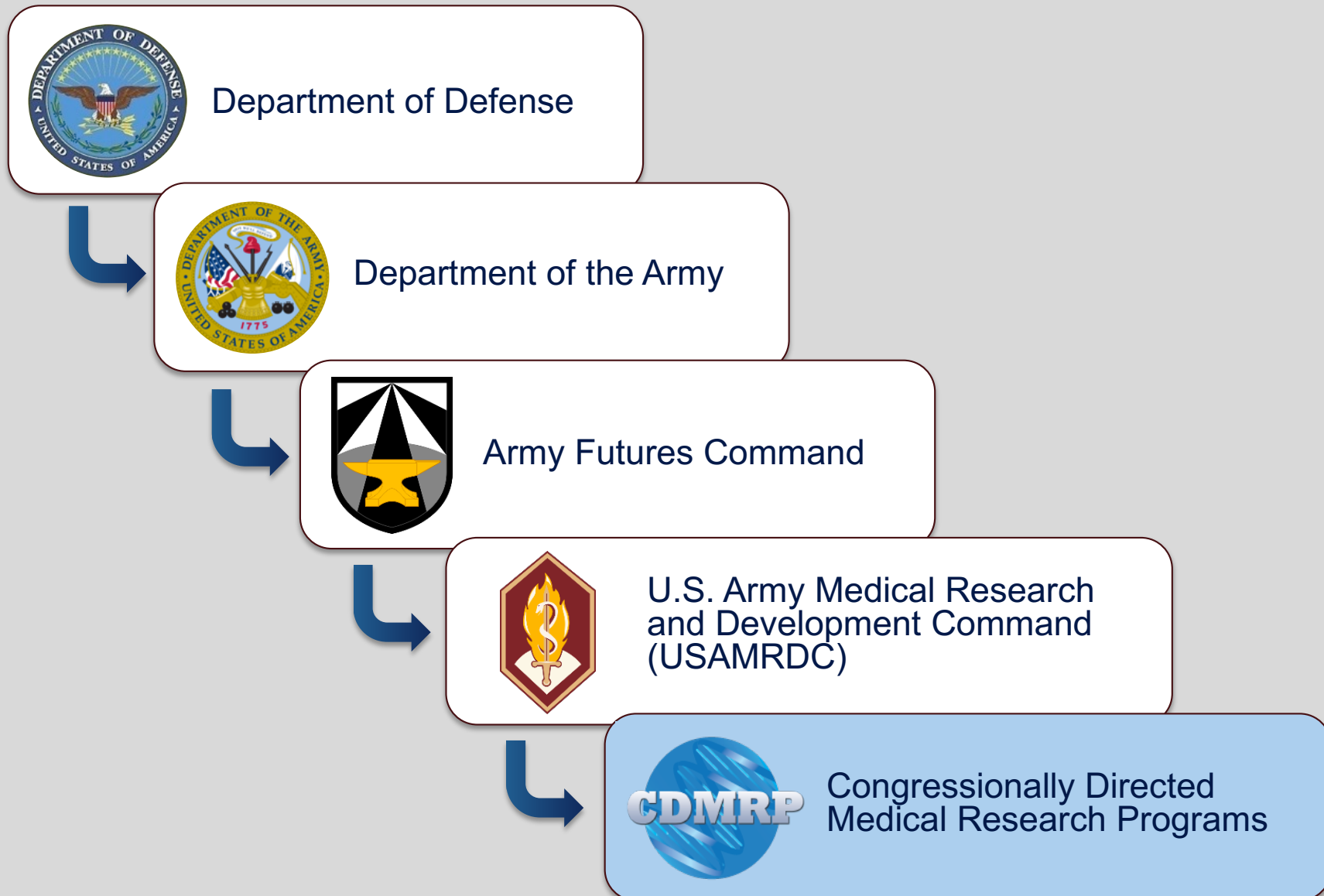
The views expressed in this presentation are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government

CDMRP

Department of Defense



WHO is the CDMRP?



About CDMRP

◆ CONGRESSIONAL PROGRAMS

- ❖ Manages extramural research programs directed by Congress
- ❖ Started in 1992 with a focus on breast cancer research; currently includes over 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



FY20 PROGRAMS:

- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Breast Cancer Semipostal
- Combat Readiness
- Chronic Pain
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness
- Hearing Restoration
- Joint Warfighter Medical
- Kidney Cancer
- Lung Cancer
- Lupus
- Melanoma
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Orthotics and Prosthetics Outcomes
- Ovarian Cancer
- Pancreatic Cancer
- Neurotoxin
- Exposure Treatment Parkinson's

- Peer Reviewed Alzheimer's
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Rare Cancers
- Reconstructive Transplant
- Scleroderma
- 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
Service Members and the
American public
through innovative and
impactful research**

FUNDING GROUNDBREAKING, HIGH-IMPACT RESEARCH

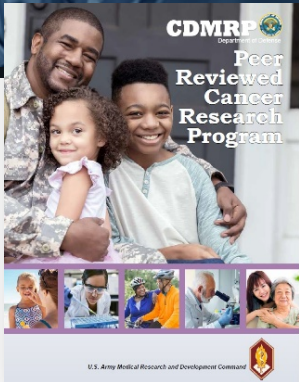
Mission

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

Unique Partnerships



Background PRCRP



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

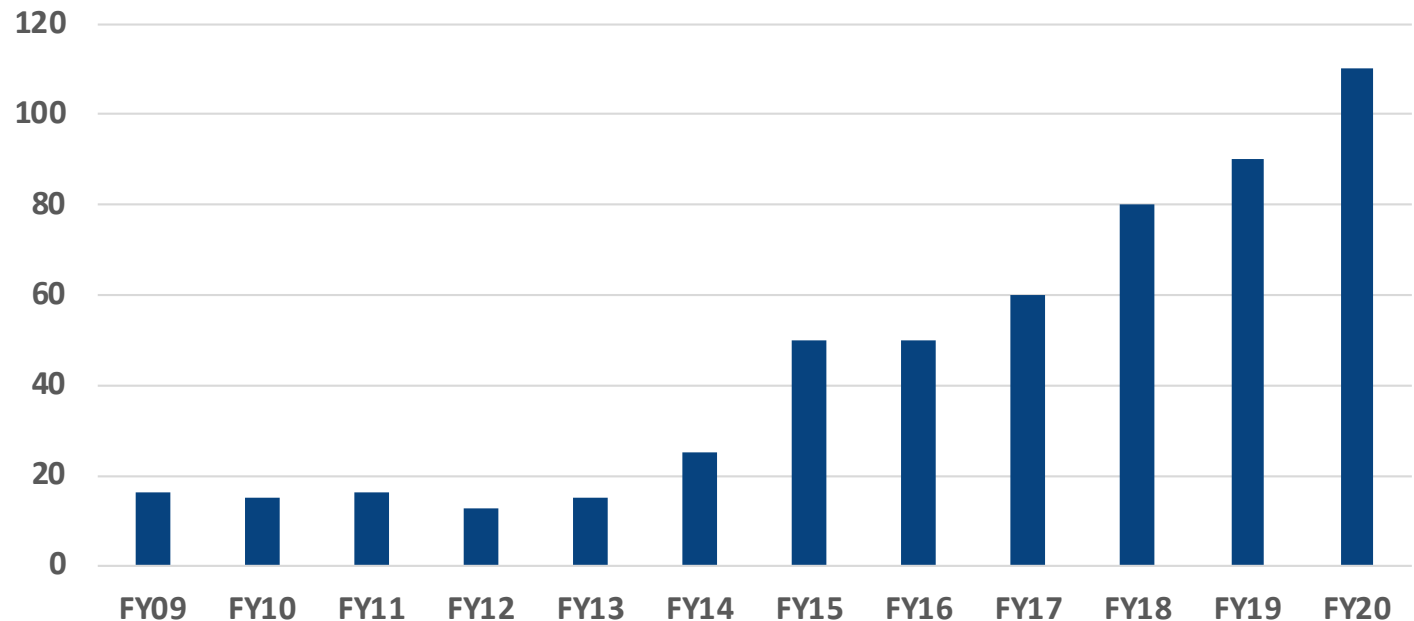
Mission: To successfully promote high-impact research for cancer prevention, detection, treatment, and survivorship

- 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

- FY09-FY19 PRCRP: \$429.8M funded 729 awards

- FY09-FY19 Over 25 Topic Areas have been included in the Congressional Language for PRCRP

FY09-FY20 PRCRP Congressional Appropriation



Strategic Guidance

Congressional Language: FY20 Topic Areas

FY20 Topic Areas

- Bladder cancer
- Blood cancers
- Brain cancer
- Colorectal cancer
- Esophageal cancer
- Head and Neck cancers
- Immunotherapy
- Liver cancer
- Mesothelioma
- Metastatic cancers
- Neuroblastoma
- Pediatric, adolescent, and young adult cancers
- Pediatric Brain Tumors
- 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, 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 progress should be relevant to Service members and their families

FY20 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)



Environmental Exposures

- ◆ **Mission Readiness**

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



Mission Readiness

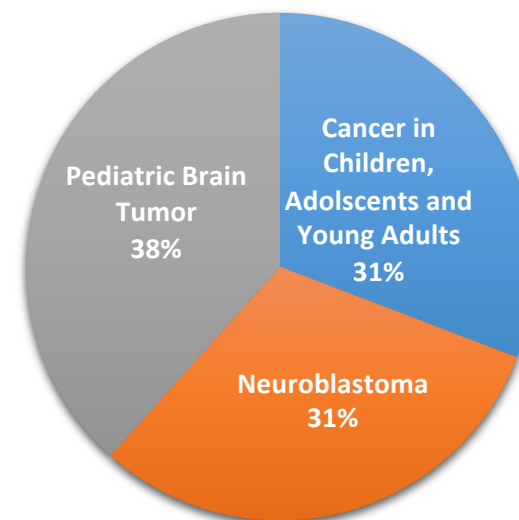
For more information: <https://youtu.be/g3TiEf97Ch0>

PRCRP Investment in Pediatric Cancers

12% Portfolio

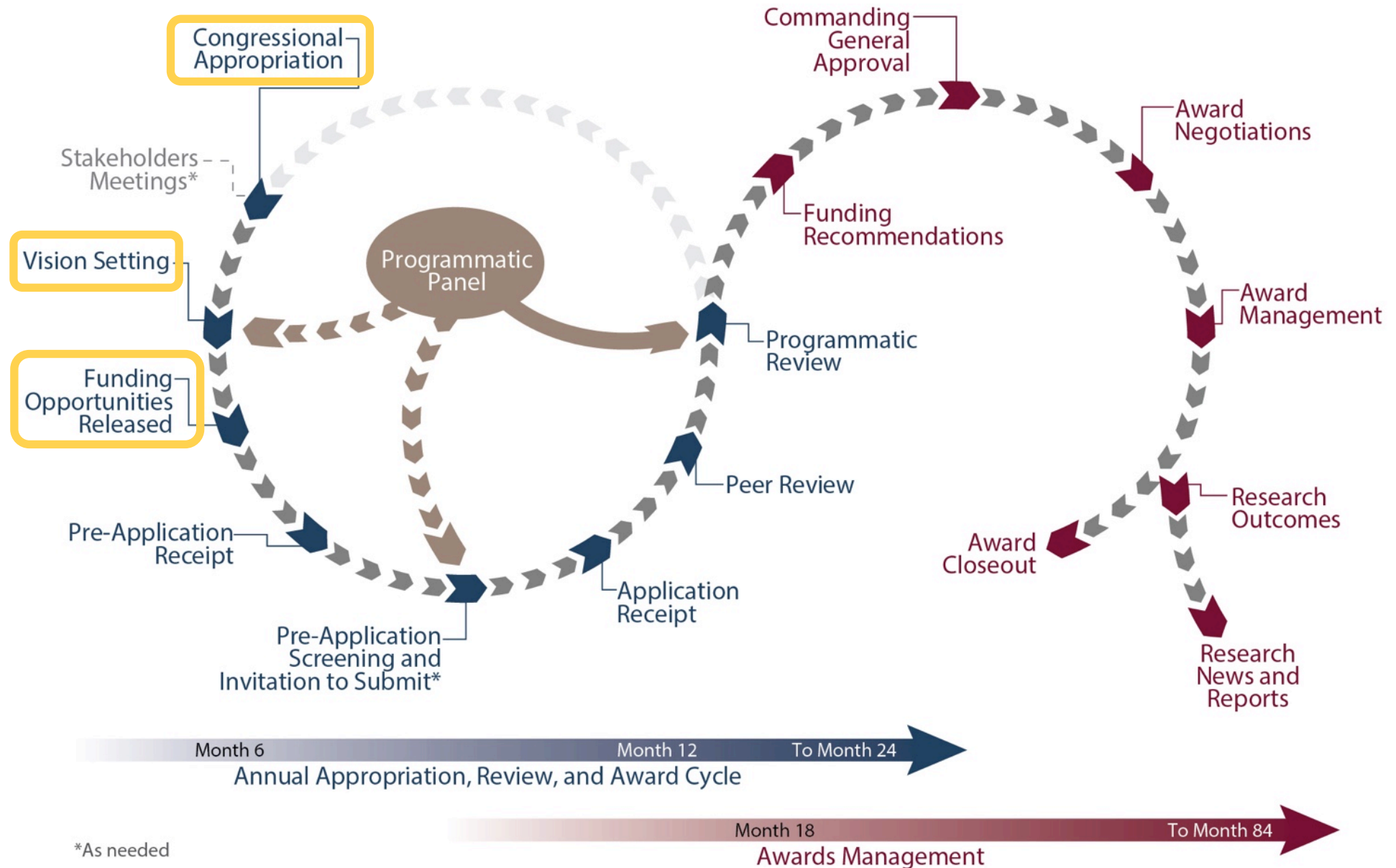
Topic Area*	Fiscal Year (FY) included under PRCRP	Total Funding per Topic Area Through FY19*
Cancers in Children, Adolescents and Young Adults	FY17-FY20	\$16.3M
Neuroblastoma	FY13-FY20	\$16.3M
Pediatric Brain Tumors	FY09-FY10, FY12-FY14, FY16-FY20	\$20.3M
Total		\$52.9M

PRCRP Investment in Pediatric Cancers



*Investments dependent on FY19 final negotiation due 30 September 2020

Program Cycle



FY20 PRCRP Funding Opportunities

Preproposal Required

Idea Award	Impact Award
<ul style="list-style-type: none">• All researchers with faculty level appointment eligible• Supports innovative, high-risk/high gain research• <u>1 page pre-proposal</u>• Invitation to Submit full application• Emphasis on innovation• Preliminary data not required• Direct costs - \$500k up to 3 yrs.	<ul style="list-style-type: none">• 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 FY20 PRCRP Topic Areas• <u>2 page pre-proposal</u>• Invitation to Submit full application• Clinical Trial support• Preliminary data required• Direct costs - \$1M over 3 yrs.

FY20 PRCRP Funding Opportunities

Letter of Intent

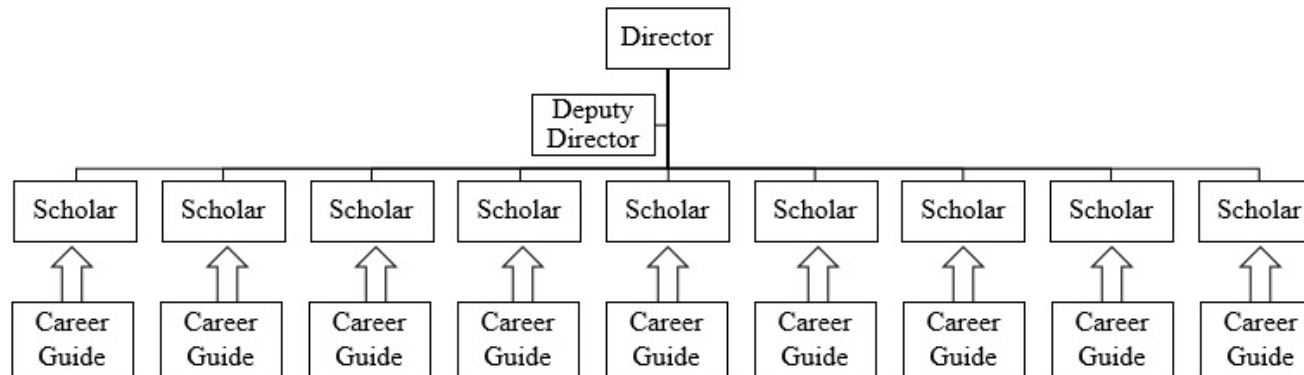
Translational Team Science Award

- Assistant Professor or above eligible
- 2-3 PIs partner
- Supports correlative studies associated with an ongoing, completed trial
- Areas of Emphasis:
 - Interventions to improve QoL
 - Cancer prevention or early detection
- Clinical Trial support
- New for FY20: Letter of Intent → letter with topic area stating intent to apply
- No invitation needed to apply to full application solicitation
- Preliminary data required
- Direct costs - \$1.5M amongst the partners over 4 yrs.

Behavioral Health Science Award

- New for FY20
- Independent investigator with a faculty-level appointment (or equivalent).
- Supports innovative research
- Prevention, survivorship, QoL, psychosocial effects related to cancer
- Supports Pilot Clinical Trial support
- Letter of Intent → letter with topic area stating intent to apply
- No invitation needed to apply to full application solicitation
- Preliminary data required for applications proposing a pilot clinical trial
- Direct costs - \$1M over 4 yrs.

FY20 Virtual Cancer Center Award



- ◆ Letter of Intent required
- ◆ Extraordinary opportunity for a Director and Deputy Director
- ◆ Oversee Virtual Cancer Center of early-career investigators (Scholars) and their designated Career Guides, facilitate regular interactive communication among all members, and assess research progress and career progression of the Scholars
- ◆ Establish a Virtual Cancer Center → foster the next generation of independent cancer researchers across the spectrum of cancers included under the PRCRP
- ◆ Goals → seek cancer commonalities and discover cogent solutions through an interactive network
- ◆ Funds for development, workshops, biennial meetings
- ◆ \$1.25M up to 4 years
- ◆ Letter of Intent → letter with topic area stating intent to apply; No invitation needed to apply to full application solicitation

Scholars with Career Guide apply to separate funding opportunity

Virtual Cancer Center Director

- ◆ Cancer Center focused on early career investigators
- ◆ Opportunity to shape the next generation of cancer researchers
- ◆ Change the future of cancer through a Vision and Mission
- ◆ Build the infrastructure for a network
- ◆ Build lasting collaborations to bring cancer research through the next decade
- ◆ Put together an advisory board of career guides and prominent leaders in the field
- ◆ Annual meetings, grant workshops



FY20 Career Development Award Fellow or Scholar Options

◆ Fellow

- ◆ Independent investigators at or above the level of 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
- ◆ Preliminary data not required
- ◆ Letter of Intent → letter with topic area stating intent to apply
- ◆ No invitation needed to apply to full application solicitation
- ◆ Direct costs - \$400k over 3 yrs.

◆ VCC Scholar

- ◆ Independent investigators at or above the level of Assistant Professor or Instructor (or equivalent) and within 7 years after completion of their terminal degree
- ◆ Career Guide at level of Associate Professor
- ◆ Supports Scholars in the unique, interactive virtual cancer center focused on fostering the next generation of independent cancer researchers
- ◆ Candidate should demonstrate an outstanding level of productivity and potential
- ◆ Provides intensive mentoring, national networking, and a peer group for junior faculty
- ◆ Opportunity to network across different cancers, different research disciplines
- ◆ Letter of Intent → letter with topic area stating intent to apply
- ◆ No invitation needed to apply to full application solicitation
- ◆ Direct costs - \$800k over 4 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

Virtual Cancer Center Director Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-PRCRP-VCCDA

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 30, 2020
- Application Submission Deadline: 11:59 p.m. ET, August 20, 2020
- End of Application Verification Period: 5:00 p.m. ET, August 27, 2020
- Peer Review: October 2020
- Programmatic Review, Stage 1: December 2020
- Invitation for Oral Presentation: December 2020
- Programmatic Review, Stage 2: February 2021

General Application Instructions

General Application Instructions

Version 501

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

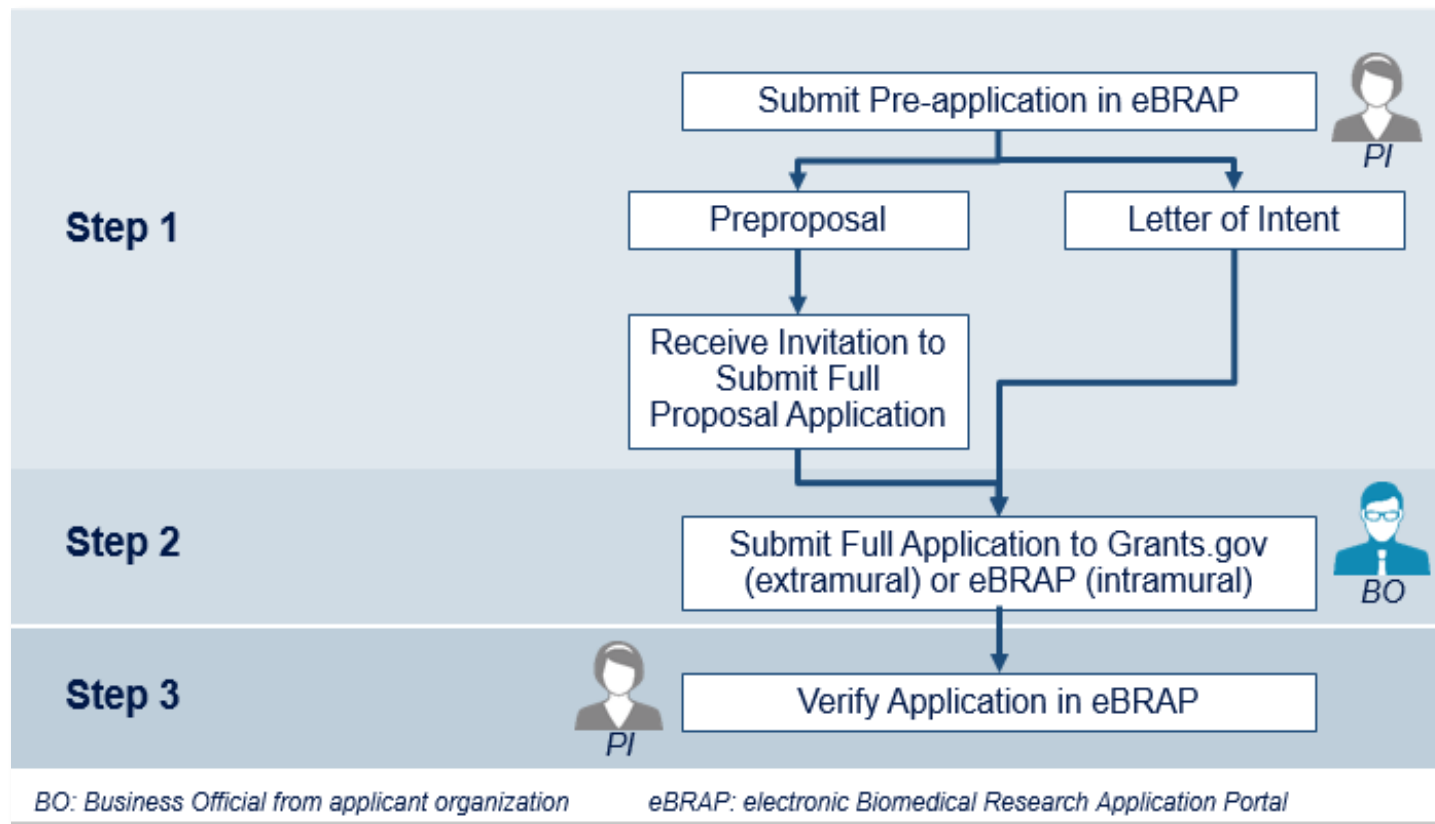
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Single most important tip:
Read both documents carefully

Submission Information

CDMRP utilizes a standard submission process



All PAs use a two-step 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 1-2 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**

Idea Award
Impact award

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

Virtual Cancer Center Award, Behavioral
Health Science Award, Translational Team
Science 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

- ◆ 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

Partnership



Programmatic Review

- ◆ 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**

Example of Peer Review Criteria

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:

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

- **Research Strategy and Feasibility**

- How well the proposed research addresses an important critical scientific or clinical issue relevant to at least one of the FY20 PRCRP Topic Areas in [Section II.A.1](#).
- How well the rationale is described for the study in terms of clinical research gap or patient outcome gap.
- To what degree the experimental design and methodology is appropriate to test the hypothesis and reach the final objectives of the proposed research. Whether the included preliminary data reconciles with the objectives of the research proposed.
- If applicable, to what extent the human subject population described is appropriate for the study and there is clear demonstration of access to the designated population.
- To what degree the statistical plan with appropriate power analysis is appropriate and whether the power analysis supports the sample size.
- How well the application acknowledges potential problems and potential pitfalls, and addresses alternative approaches.
- Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.

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 Chair Elect)
University of New Mexico

Jonathan Brody, Ph.D.
Thomas Jefferson University

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

LCDR Alden Chiu
Walter Reed National Military Medical Center

Dan Dixon, Ph.D.
University of Kansas Medical Center

Paul Doetsch, Ph.D.
NIH/NIEHS

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)
Lymphoma Research Foundation

Lopa Mishra, M.D.
University of Texas MD Anderson Cancer Center

Col Thomas Newton
Walter Reed National Military Medical Center

Nancy Roach
Fight Colorectal Cancer

Kenneth Tanabe, M.D.
Harvard University

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 FY20 PRCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio balance and composition
 - Relevance to the FY20 PRCRP Military Health Focus Areas
 - 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

✓ 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**

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

FY20 PRCRP Summary

FY20 Funding Opportunity	Intent/Funding
Idea Award	High Risk/High Gain \$500k
Career Development Award	Early Career Investigators Fellow Option \$400K Scholar Option \$800K
Virtual Cancer Center Award	Director/Deputy Director oversee a virtual network tying together all cancers \$1.25M
Impact Award	Near term clinical impact \$1M
Translational Team Science Award	Correlative Studies clinic informs the research \$1.5M
Behavioral Health Science Award	Study of survivorship and patient outcomes \$1M

FY20 PRCRP Timeline

◆ Pre-proposal Mechanisms Deadlines

- ◆ Pre-Application Submission Deadline: 5 pm ET, 14 May 2020
- ◆ Invitation to Submit an Application: 16 June 2020
- ◆ Application Submission Deadline: 11:59 pm ET, 27 August 2020
- ◆ End of Application Verification Period: 5 pm ET, 3 September 2020
- ◆ Peer Review: November 2020
- ◆ Programmatic Review: February 2021
- ◆ Pre-application refers to the preproposal 1-3 pages.
- ◆ The pre-proposal is reviewed!
- ◆ This is for Idea and Impact Award funding opportunities only!
- ◆ You need an invitation to submit!

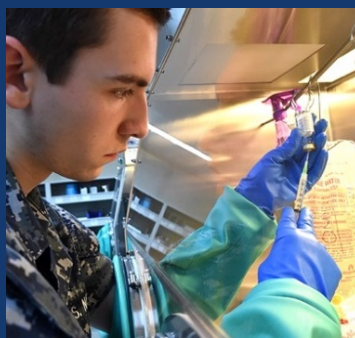
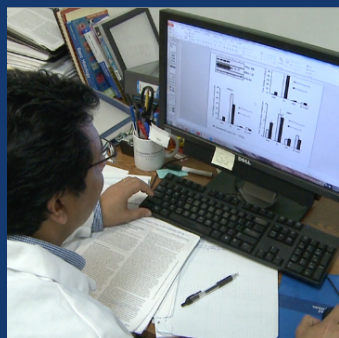
◆ Letter of Intent Mechanisms Deadlines

- ◆ Pre-Application Submission Deadline: 5 pm ET, 30 July 2020
- ◆ Application Submission Deadline: 11:59 pm ET, 27 August 2020
- ◆ End of Application Verification Period: 5 pm ET, 3 September 2020
- ◆ Peer Review: October/November 2020
- ◆ Programmatic Review: December 2020/February 2021
- ◆ Pre-application refers to Letter of Intent which is a letter stating you intend to apply. It is NOT reviewed!
- ◆ This is for all other funding opportunities TTSA, CDA, BHSA, VCCDA!
- ◆ 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



A Proud Consumer Legacy

