

Peer Reviewed Cancer Research Program Funding Opportunities

Presented by
Julia Huiberts, MS
Program Manager, PRCRP

April 2024



*Transforming Healthcare through Innovative and **Impactful** Research*

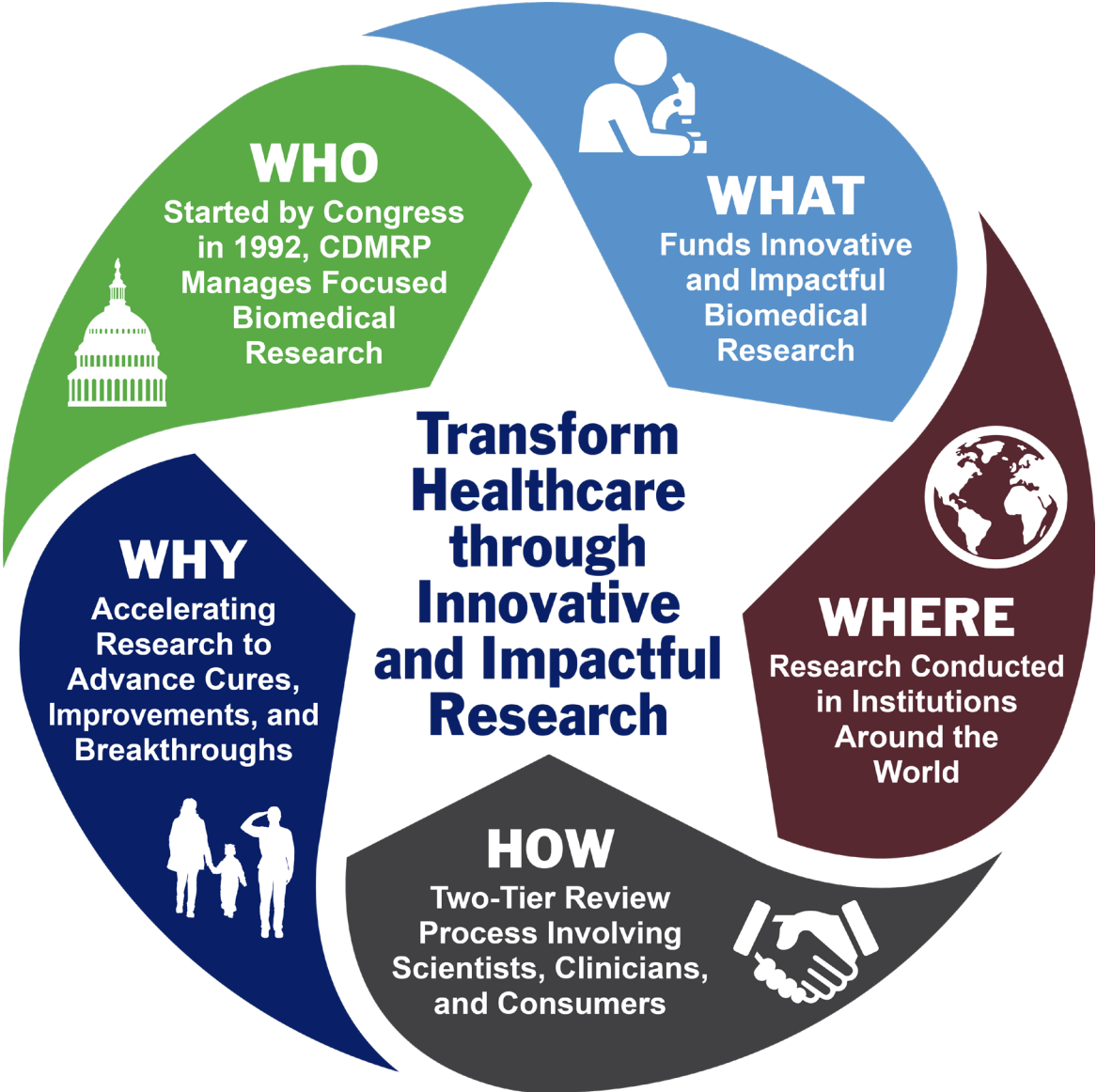


CDMRP
DEPARTMENT OF DEFENSE
**CONGRESSIONALLY DIRECTED
MEDICAL RESEARCH PROGRAMS**

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. Future use of this presentation does not constitute, express, or imply endorsement of the user by the Department of the Army.

UNCLASSIFIED

For more information, visit cdmrp.health.mil



<https://cdmrp.health.mil>



Vision

Transforming healthcare through innovative and impactful research

Mission

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



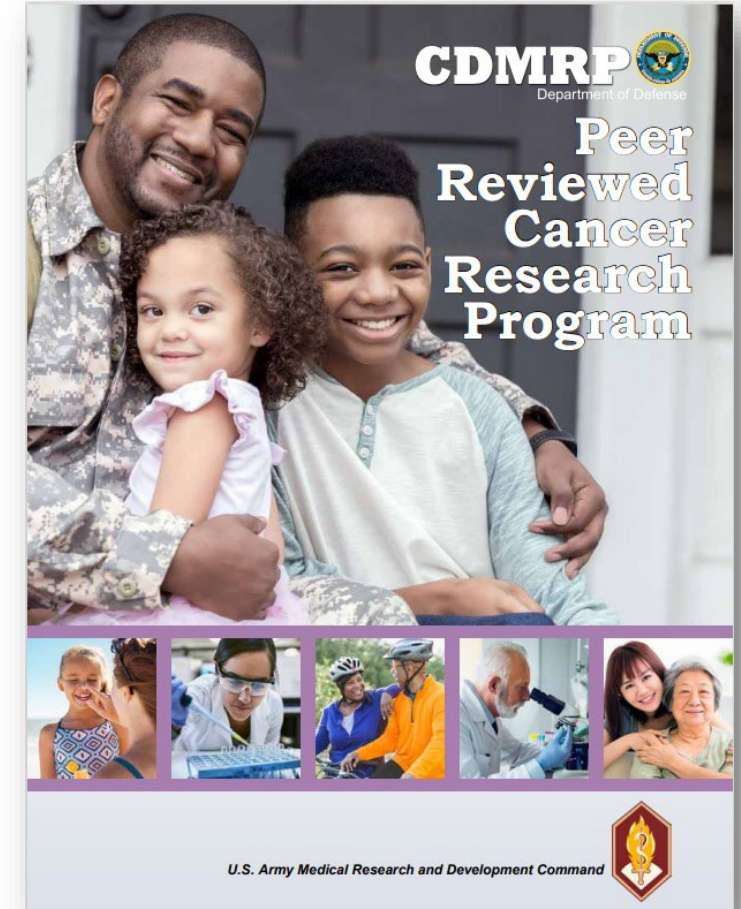
CDMRP FY24 Appropriations



Research Program	FY24 \$M	Research Program	FY24 \$M
Alcohol and Substance Use Disorders	\$4.0	Neurofibromatosis	\$25.0
Amyotrophic Lateral Sclerosis	\$40.0	Ovarian Cancer	\$45.0
Arthritis (<i>New for FY24</i>)	\$10.0	Pancreatic Cancer	\$15.0
Autism	\$15.0	Parkinson's	\$16.0
Bone Marrow Failure	\$7.5	Peer Reviewed Alzheimer's	\$15.0
Breast Cancer	\$150.0	Peer Reviewed Cancer (18 Topics)	\$130.0
Combat Readiness Medical	\$5.0	Peer Reviewed Medical (42 Topics)	\$370.0
Duchenne Muscular Dystrophy	\$10.0	Peer Reviewed Orthopaedic	\$30.0
Epilepsy	\$12.0	Prostate Cancer	\$110.0
Glioblastoma (<i>New for FY24</i>)	\$10.0	Rare Cancers	\$17.5
Hearing Restoration	\$5.0	Reconstructive Transplant	\$12.0
Joint Warfighter Medical	\$20.0	Spinal Cord Injury	\$40.0
Kidney Cancer	\$50.0	Tick-Borne Disease	\$7.0
Lung Cancer	\$25.0	Toxic Exposures	\$30.0
Lupus	\$10.0	Traumatic Brain Injury and Psychological Health	\$175.0
Melanoma	\$40.0	Tuberous Sclerosis Complex	\$8.0
Military Burn	\$10.0	Vision	\$20.0
Multiple Sclerosis	\$20.0		
		TOTAL = \$1.51B	

About PRCRP

- **History** – Established in Fiscal Year (FY) 2009 with an appropriation of \$16 Million (M) and Congressional language directing four topic areas to be funded.
 - FY24: \$130M, 18 Topic Areas, TBD awards
 - FY09-FY23: \$914.8 M, 35 Unique Topic Areas, 1,112 awards
- **Vision** – To advance mission readiness of U.S. military members affected by cancer.
- **Mission** – To successfully promote high-impact research in cancer prevention, detection, treatment, quality of life, and survivorship for Service Members, their families, Veterans, and the American public.



FY24 Congressional Language: Topic Areas

- Bladder Cancer
- Blood Cancers
- Brain Cancer (excluding glioblastoma)
- Colorectal Cancer
- Endometrial Cancer
- Esophageal Cancer
- Germ Cell Cancers
- Liver Cancer
- Lymphoma
- Mesothelioma
- Metastatic Cancers
- Myeloma
- Neuroblastoma
- Pediatric, Adolescent, and Young Adult Cancers
- Pediatric Brain Tumors
- Sarcoma
- Stomach Cancer
- Thyroid Cancer

*excludes subtypes of FY24 Topic Areas that are rare by definition

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

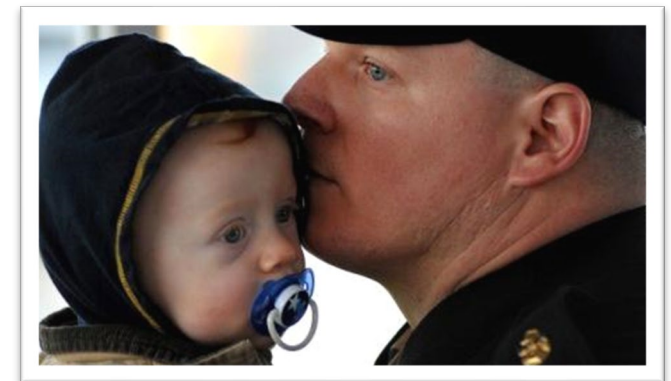
Funds may not be used for research into breast, kidney, lung, ovarian, pancreatic, prostate, rare cancers*, glioblastoma, or melanoma



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

All submissions must define how the research is relevant to Service Members and their families.

- Environmental and/or occupational exposure risk factors associated with cancer
 - Factors that are relevant to activities specific to the military, such as deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.)
- Mission Readiness and Gaps in Cancer Research
 - Service Members are not mission ready if they or family members are impacted by cancer
 - Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment
 - Gaps in quality of life and/or survivorship



- Applications to the PRCRP must address one of the seventeen FY24 Overarching Challenges

Prevention	Diagnostics/ Prognostics	Therapeutics	Patient Well Being and Survivorship	Disparities
<ul style="list-style-type: none">• Investigate primary, secondary, and tertiary prevention interventions/strategies to decrease cancer burden• Determine the risk factors, etiology, or mechanisms underlying cancer development to improve prevention interventions	<ul style="list-style-type: none">• Identify approaches to predict treatment, 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	<ul style="list-style-type: none">• Transform Cancer Treatment• Improve current therapies including systemic and local• Evaluate disease progression and/or treatment response over time• Leverage the mechanisms of cancer development to improve treatment methods for all communities	<ul style="list-style-type: none">• Study methods to address survivorship issues• Reduce short- and long-term treatment toxicities• Investigate ways to bridge gaps between treatment and survivorship• Understand and address the immediate and enduring burdens on caregivers, families, and communities	<ul style="list-style-type: none">• Improve prevention, diagnosis, treatment, and outcomes for patients in underserved, under recognized populations• Study methods to improve accessibility to care and address survivorship• Advance health equity and reduce disparities in cancer care through research• Develop strategies to understand barriers to and improve communication amongst provider, patient, and care network.

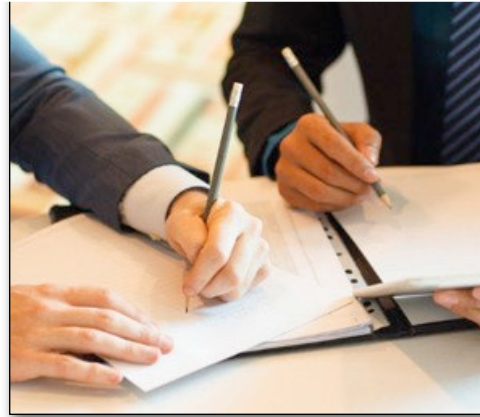
Goal of the Two-Tier Review Process

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>

Congressional Special Interest (CSI) versus DOD Core funding

- 
- CDMRP's CSI funds are ***directed by Congress*** and appropriated through the DOD budget – obligated up-front because there is ***no guarantee of out year funding***
 - Core funds are ***planned through specific budgeting processes*** and appropriated yearly in response to the President's DOD budget request – projects can be incrementally funded in out-years

FY24 PRCRP Funding Mechanisms*

Promising Ideas	Mature Research	Translational and Clinical	Collaborative Team Science
Idea Award	Impact Award	Clinical Trials Award	Convergent Science Consortium Award
	Career Development Award, Scholar Option	Patient Well-being and Survivorship Award	Virtual Cancer Center Director Award

- **Idea Award:** Innovative, basic research of untested ideas, no preliminary data required, **\$400K**
- **Impact Award:** Hypothesis-driven, high-impact research with the potential to make a critical impact, **\$1M⁺**
- **Clinical Trial Award:** Pilot/Phase 0 – Phase 3, therapeutics, devices, clinical guidance, or technologies, **\$3M⁺**
- **Patient Well-being and Survivorship Award:** QOL, symptom management and psychosocial issues, **\$1M⁺**
- **Convergent Science Consortium Award:** Coordinating center and research projects at three sites, **\$20M⁺**
- **Virtual Cancer Center (VCC) Director:** Supports leaders with a strong record of mentoring, **\$1.75M**
- **Career Development Award, Scholar:** Early-career PIs who will join the VCC Cohort, **\$800K**

* Funding levels are Maximum Direct Costs

⁺Allows Clinical Trials



Promising Ideas

Idea Award

- **Direct Costs:** \$400K (2 Years)
- **Eligibility:** Faculty-level appointment or equivalent
- **Supports basic research** that is innovative, untested, high-risk/potentially high-reward
- **Preliminary data is discouraged**
- Applicants can only be named as **PI** on one Idea Award
- Clinical Trials not allowed
- One-page pre-application followed by invitation to submit full application

Mature Research

Impact Award

- **Direct Costs:** \$1M (3 years)
- **Eligibility:** Independent investigators at or above the level of Assistant Professor
- **Supports mature research** focused on critical scientific and clinical issues that, if successful, have the potential to make a near-term, major impact
- **Preliminary data required**
- Clinical Trials are allowed
- One-page pre-application followed by invitation to submit full application

Advancing Cancer Care through Clinical Trials Award

- **Direct Costs:** \$3M (4 Years)
- **Eligibility:** Faculty-level appointment or equivalent
- Supportive preclinical data is required; **no animal work allowed**
- May evaluate pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and technologies
- Projects may range from small Pilot/Phase 0 trials to large Phase III efficacy studies
- Application must demonstrate access to suitable patient population
- **Trial expected to be open and recruit at least two subjects within the first 12 months**
- Three-page pre-application followed by invitation to submit full application

Patient Well-being and Survivorship Award

- **Direct Costs:** \$1M (3 years)
- **Eligibility:** Independent investigators at or above the level of Assistant Professor
- **Only eight of 17 Overarching Challenges** in the Disparities and Patient Well Being and Survivorship categories are permitted
- Supports studies in preservation of physical function, quality-of-life, symptom management, resilience, relief from neurocognitive deficits, and support for psychosocial issues
- Must demonstrate how the research will transform outcomes related to the FY24 Topic Areas
- **Basic laboratory studies are not appropriate**
- Pilot clinical trials are allowed
- Pre-application requires only a Letter of Intent for planning purposes

Convergent science* *“is a means of solving vexing research problems, in particular, complex problems... It entails integrating knowledge, methods, and expertise from different disciplines and forming novel frameworks to catalyze scientific discovery and innovation.”*

There are three independent PRCRP mechanisms with a convergent science focus:

Mechanism	Description	VCC Participant
Virtual Cancer Center (VCC) Director Award	Develop and oversee a multidisciplinary, multi-institutional research community capable of proposing convergent solutions to a variety of topic areas	✓
Career Development Award, Scholar Option	Early-career independent investigators (Scholars) interested in professional development in convergent science	✓
Convergent Science Consortium Award	Supports a Coordinating Center (to include a Research Site) and Research Sites at two other organizations	

Virtual Cancer Center Director Award

- **Direct Costs:** \$1.75M (4 years)
- **Eligibility:** level of associate professor or equivalent
- Brings together **two established investigators** to interrogate the commonalities of cancer with **Scholars** (separate mechanism)
- **Director and Deputy Director** must study different cancer disciplines, be at different institutions, have current and past cancer funding, and mentorship and convergent science experience
- VCC Directors will provide **intensive mentoring** and national networking, to junior faculty Scholars in a **collaborative research** and career development environment
- Host annual workshop, encourage multi-disciplinary, convergent, collaborative research via subawards to collaborating Scholars
- Application may require a live, virtual presentation
- **Two-page pre-application followed by invitation to submit full application**

Career Development Award, Scholar Option

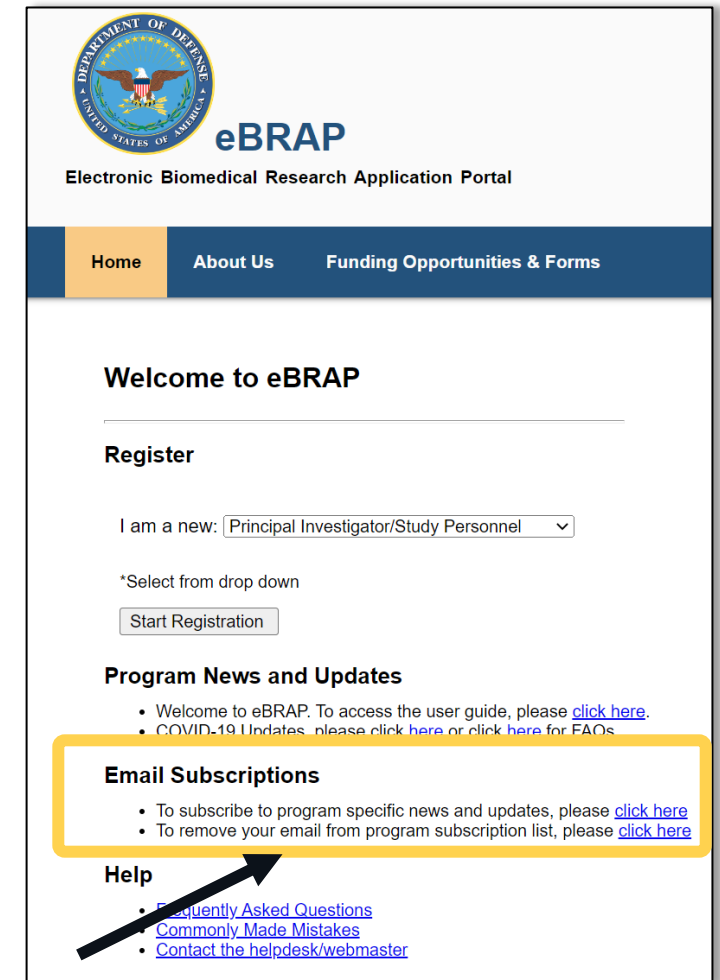
- **Direct Costs:** \$800K (4 years)
- **Eligibility:** Early-career **researcher or physician-scientist within 7 years of completion of terminal degree** at application deadline
 - Excludes time spent in residency, clinical training, or on family medical leave; postdoctoral fellowship is not excluded
- Scholar must be in a **tenure-track or equivalent position and have independent laboratory space**; Postdoctoral Fellows are not eligible
- Scholar must name an experienced cancer researcher as a **Career Guide**
- **Career Development Plan:** clearly articulated strategy for acquiring the necessary skills, competence, further independence
- Requires participation in the PRCRP **Convergent Science Virtual Cancer Center**
- Preliminary data are not required
- Clinical trials are not allowed
- Pre-application is only a Letter of Intent

Convergent Science Cancer Consortium Award

- **Direct Costs:** \$20M (4 years)
- **Eligibility:** level of associate professor or equivalent
- Supports a **Coordinating Center** (one Research Site) and **two additional Research Sites** at separate organizations (three research projects, minimum)
- PI (Coordinating Center Director) must commit minimum of 10% Level of Effort
- PI or a Co-I must demonstrate **experience in convergent science theory**
- Coordinating Center will serve as a **planning nexus and provide support services** (e.g., administrative, operational, and/or data management support)
- PI and Co-I's should be from **different disciplines and different cancers**
- **Research projects** should be based on the principles of convergent science and address at least **three different FY24 PRCRP Topic Areas**
- Consortium **focal point** should originate from the FY24 Overarching Challenges
- Application may require a live, virtual presentation
- **Three-page pre-application followed by invitation to submit full application**

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)



**Sign up for listserve through
CDMRP website or in eBRAP**

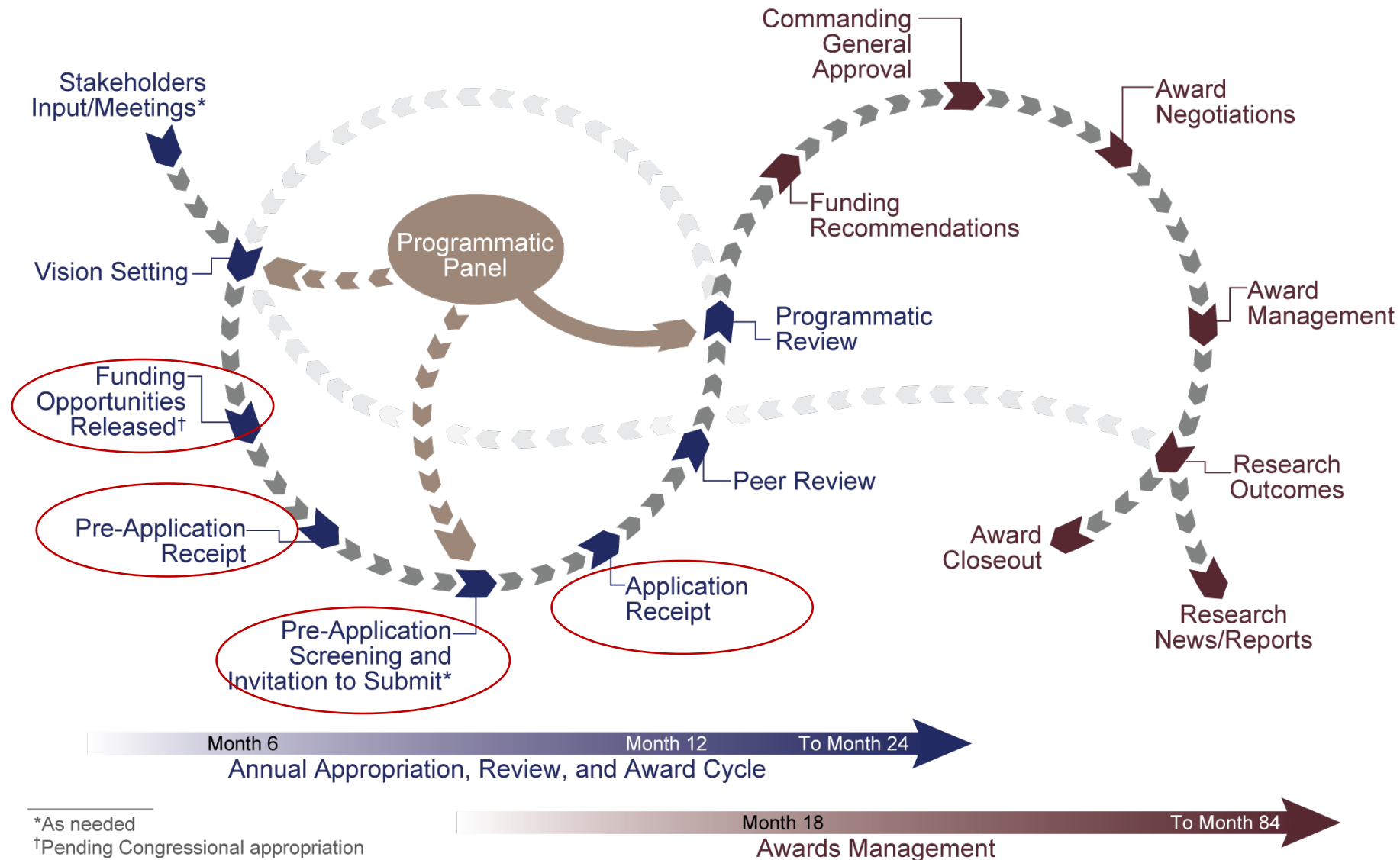
Understanding the *goals of the program, intent of the award mechanism, and review criteria* is critical for a successful application



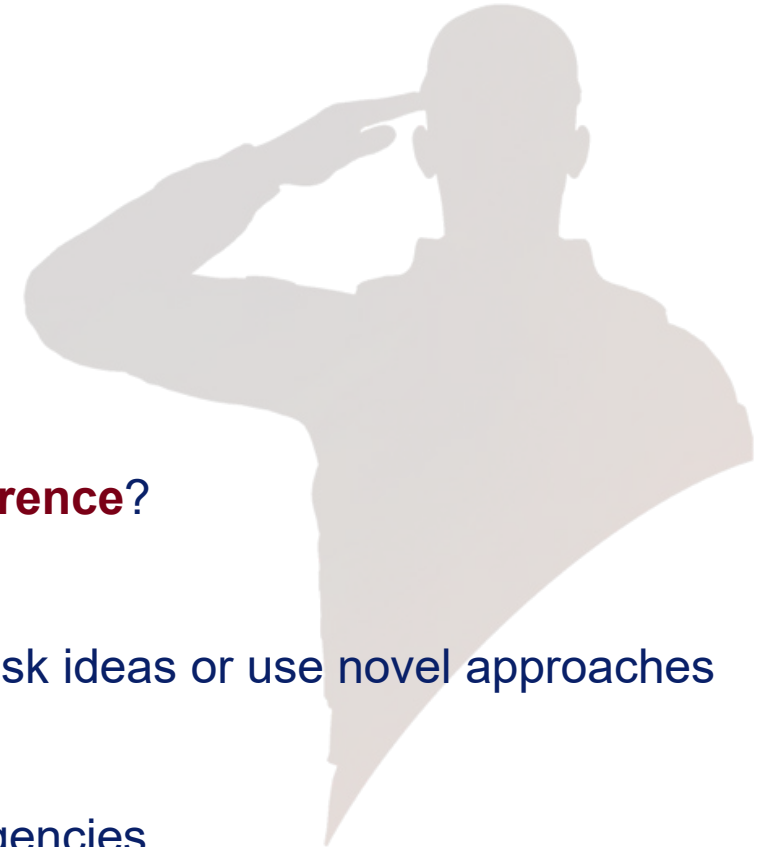
- The funding opportunity announcement contains information on:
 - Program Goals
 - Focus Areas/Topics
 - Award Intent
 - Required Elements, Eligibility, and Funding
 - Review Criteria
 - Deadlines

Single most important tip:
Read the announcement carefully

Program Cycle



- ✓ **Relevance**
 - Address program-specific goals
 - **Align** the proposed work with specific guidance from the announcement
- ✓ **Impact**
 - Propose **solutions** to important problems or gaps
 - Clearly articulate translatability – how will this work **make a difference**?
- ✓ **Innovation**
 - Provide clear rationale if proposing to test new, potentially high-risk ideas or use novel approaches
- ✓ **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



✓ 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**



Funding Opportunities Webinar Series



Webinar Title
Funding Opportunities and Strategies for Success
High Risk/High Gain Funding Opportunities
Team Science Funding Opportunities
Clinical Research and Clinical Trial Funding Opportunities
Funding Opportunities for the Development of Technology and/or Resources
Funding Opportunities for Early Career Investigators
Consortium-Type Funding Opportunities



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

Questions?
For more information, please visit:



cdmrp.health.mil



CDMRP

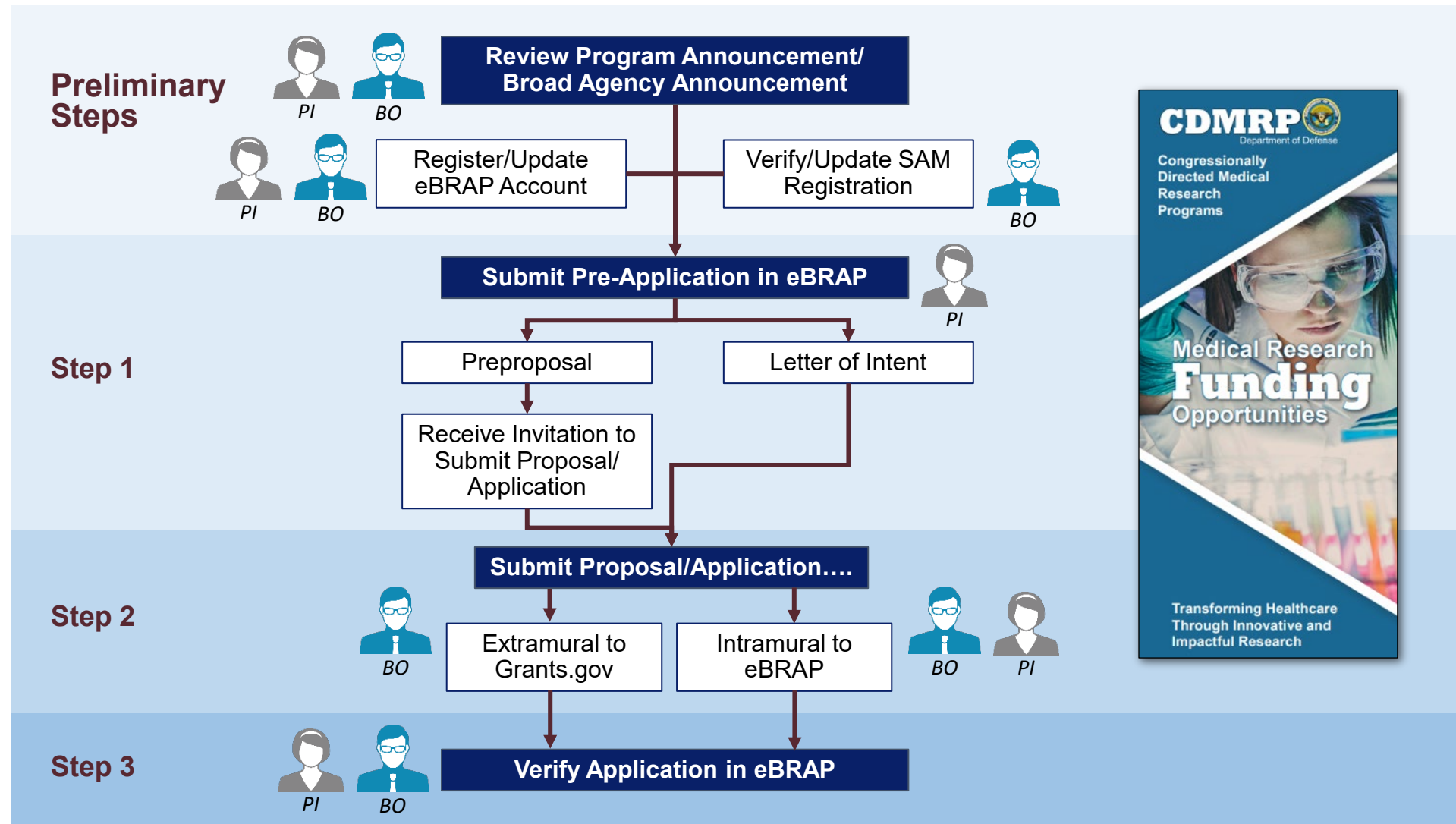
DEPARTMENT OF DEFENSE

**CONGRESSIONALLY DIRECTED
MEDICAL RESEARCH PROGRAMS**

Additional Slides



Application Process Overview



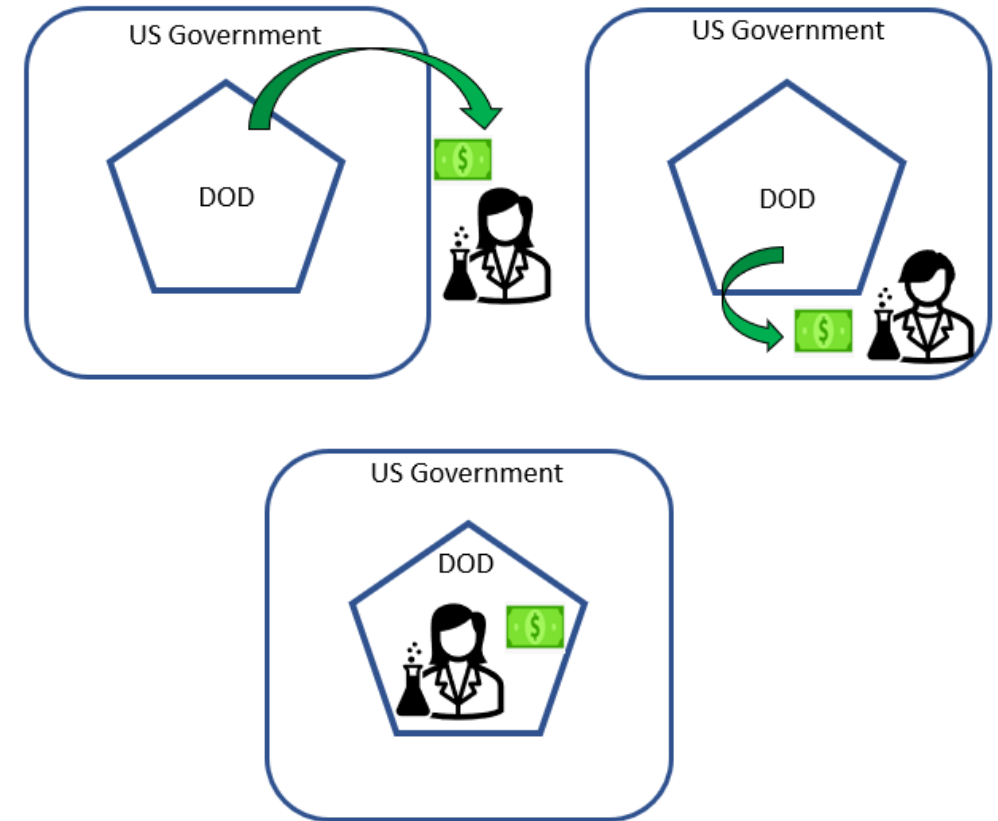
BO: Business Official from applicant organization
PI: Principal Investigator from applicant organization

eBRAP: electronic Biomedical Research Application Portal
SAM: System of Award Management



- CDMRP funds a wide variety of research at extramural and intramural organizations to accomplish its mission

- **Extramural** – funds awarded primarily to private institutions (academia, industry, foundations, etc.) through grants and cooperative agreements
 - Non-DoD federal government organizations are also considered extramural and may be funded through support agreements and direct transfers of funds
- **Intramural** – funds awarded by reimbursing other DoD organizations using support agreements and direct transfers of funds



- Some projects involve collaborations between **both** extramural and intramural

Inclusion of Women and Minorities

- CDMRP requires that women and individuals from minority groups be included as subjects in all CDMRP-funded clinical research studies, unless there is a clear, justifiable rationale that it is inappropriate with respect to the health of the subjects or the purpose of the research
- Policy implemented in October 2020
 - Policy and Frequently Asked Questions document available at <https://ebrap.org/eBRAP/public/Program.htm>
- In all clinical research applications, investigators are required to provide a strategy for inclusion of women and minorities
- Maximizes generalizability and impact of study results





- Active-duty military or Veteran patient populations and resources (databases, specimens, etc.)
 - Clearly define DOD or VA collaborator role: conducting research may require higher level approval
 - Key collaborators should be research partners and publication co-authors
 - Plan for IRB review
 - Create a contingency plan if PI is military (many move every few years)
 - Know what legal instruments are available for collaborative research
 - e.g., Cooperative Research and Development Agreement (CRADA), Memorandum of Understanding (MOU), Material Transfer Agreement (MTA)
 - Know the requirements and timelines for human or animal subjects research approvals and consult early when planning collaboration

References:

- Conducting DOD Funded Human Research with Military Populations
(https://cdmrp.health.mil/pubs/pdf/Conducting%20Research%20Military%20Pop%20DoD_funded_7NOV2022.pdf)
- “Expanding Use of Technology Transfer Mechanisms Within the Army’s Medical Treatment Facilities” US Army Med Dep J. Jan-Mar 2012;32-6.

- 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, reviewers, and program staff are not permitted



Outcome:
Summary
Statements

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, researchers, and program staff from a wide variety of representative organizations
 - Ad hoc reviewers



Outcome:
Funding
Recommendations

- Every program aligns with CDMRP's overarching vision of transforming healthcare for Service Members (SMs), Veterans and the American public

Select examples of incidence in the military:

- Post-traumatic epilepsy affects >2,000 Iraq/Afghanistan War Veterans, with 5x higher mortality rate
- Female active duty SMs have a 20-40% higher incidence rate of breast cancer
- SMs are at a 50% greater risk for ALS
- Substance abuse responsible for ~30% of Army's suicide deaths
- Deployment associated with 1.8-fold increased risk of Parkinson's
- Risk of dementia is 2-4x higher in SMs; increases by 70% following a TBI



- Commitment to the health and wellbeing of DOD families also directly contributes to the readiness of Service Members by allowing them to focus on their military mission
 - Over 15,000 military dependents have a diagnosis of autism spectrum disorder
- CDMRP-funded research generates products that provide better preventions, novel diagnostics and prognostics, improved treatments and therapies, and more effective rehabilitation and restorative strategies – **to improve lives**

Questions?
For more information, please visit:



cdmrp.health.mil



CDMRP

DEPARTMENT OF DEFENSE

**CONGRESSIONALLY DIRECTED
MEDICAL RESEARCH PROGRAMS**