Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program (PRMRP)

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Webinar to PKD Foundation March 21, 2023

Transforming Healthcare through Innovative and Impactful Research



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- Overview of CDMRP
- Program Cycle and Review Process
- Peer Reviewed Medical Research Program (PRMRP)
- Funding Opportunities and How to Apply
- Additional Resources and Strategies for Success

Vision and Mission





Vision

Transforming healthcare through innovative and impactful research

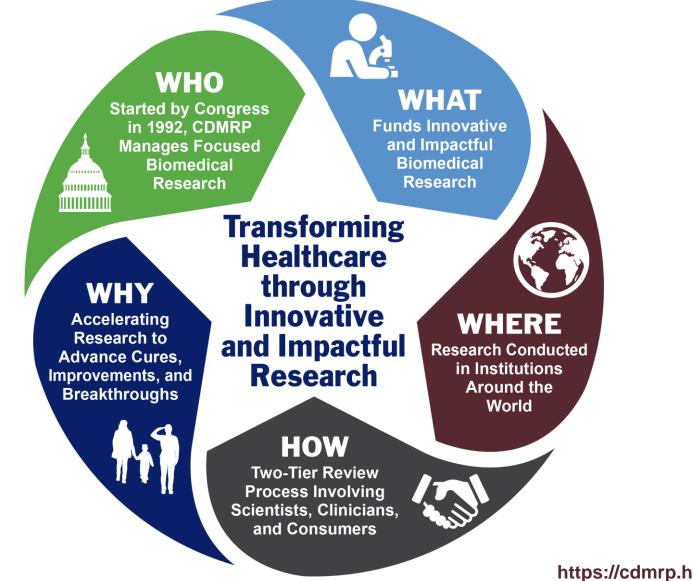


Mission

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

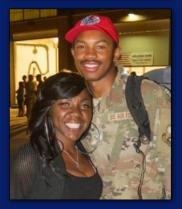
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Hallmarks









- Congress adds targeted research funds to the DOD budget
- Funds high-impact innovative research
- Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- Funding opportunities publicly announced and competed
- Follows the National Academy of Medicine-recommended model for application review
- Consumers participate throughout the process and are the "True North" and foundation of the programs
- Annually adapts each program's vision and investment strategy allowing rapid response to changing needs
- Funding flexibility
 - Funds obligated up-front; limited out-year budget commitments
 - No continuation funding
 - No "pay line" funding recommendations are based on portfolio composition, adherence to mechanism intent, relative impact, and technical merit
- Transparency and accountability to stakeholders
- Low management costs maximize research dollars

CDMRP FY23 Appropriations



Research Program	FY23 \$M	Research Program	FY23 \$M
Alcohol and Substance Use Disorders	\$4.0	Orthotics and Prosthetics Outcomes	\$15.0
Amyotrophic Lateral Sclerosis	\$40.0	Ovarian Cancer	\$45.0
Autism	\$15.0	Pancreatic Cancer	\$15.0
Bone Marrow Failure	\$7.5	Parkinson's	\$16.0
Breast Cancer	\$150.0	Peer Reviewed Alzheimer's	\$15.0
Chronic Pain Management	\$15.0	Peer Reviewed Cancer (20 Topics)	\$130.0
Combat Readiness Medical	\$5.0	Peer Reviewed Medical (50 Topics)	\$370.0
Duchenne Muscular Dystrophy	\$10.0	Peer Reviewed Orthopaedic	\$30.0
Epilepsy	\$12.0	Prostate Cancer	\$110.0
Hearing Restoration	\$5.0	Rare Cancers	\$17.5
Joint Warfighter Medical	\$25.0	Reconstructive Transplant	\$12.0
Kidney Cancer	\$50.0	Spinal Cord Injury	\$40.0
Lung Cancer	\$25.0	Tick-Borne Disease	\$7.0
Lupus	\$10.0	Toxic Exposures	\$30.0
Melanoma	\$40.0	Traumatic Brain Injury and Psychological Health	\$175.0
Military Burn	\$10.0	Tuberous Sclerosis Complex	\$8.0
Multiple Sclerosis	\$20.0	Vision	\$20.0
Neurofibromatosis	\$25.0	TOTAL = \$1.52B	



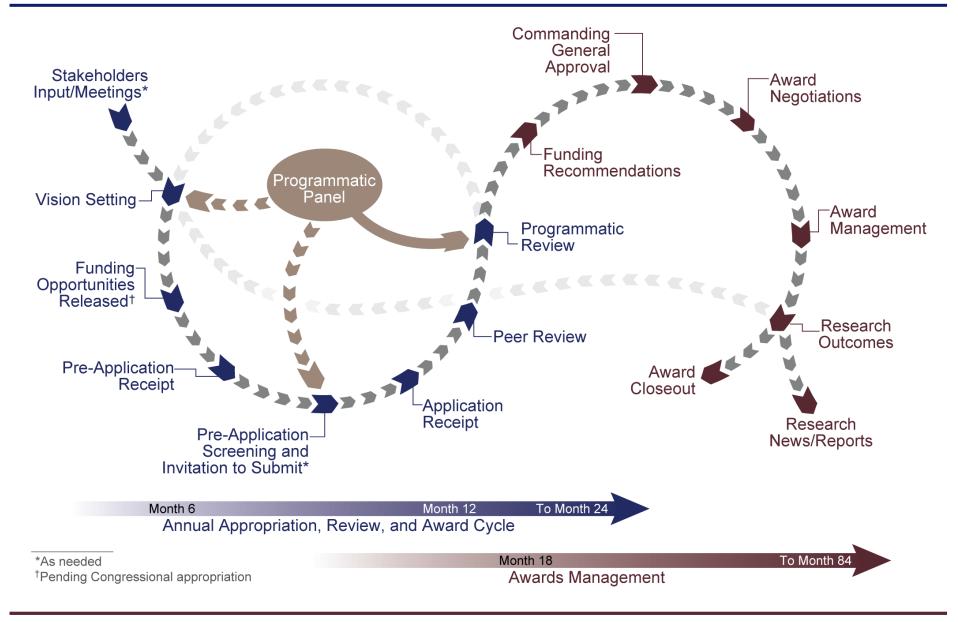
CDMRP Program Cycle and Review Process

Transforming Healthcare through Innovative and Impactful Research



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





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

Peer Review

Participants

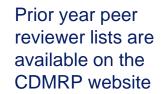
FY22 Peer Review

Participants (pdf)

Previous Years' Peer Review Participants

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 and may include specialists
 - Identities are unknown to applicants; contact between applicants, reviewers, and program staff are not permitted





Outcome: Summary Statements



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Second Tier: Programmatic Review

- How the evaluation process works
 - Comparison among proposals of high scientific merit
 - Adherence to award mechanism's intent
 - Relative innovation and/or impact
 - Relevance to program goals
 - Consideration of portfolio composition
 - No "pay line" (portfolio balance)
 - 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



Consumers are the "True North" and Foundation of the CDMRP



CDMRP includes consumers – patients, survivors, family members, and/or caregivers – in every aspect of the program lifecycle.

Consumers serve as full voting members on peer review and programmatic panels. Through their lived experiences with the target disease, disorder, or injury, consumers represent their respective communities and add valuable perspectives and a sense of urgency to the program mission, investment strategy, and research focus.



PROGRAM LIFECYCLE

Stakeholder Meeting Vision Setting

Pre-App Screening

> Peer Review

Programmatic Review Funding

Recommendations

Award Execution - -

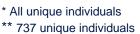
Awards Management/ Closeout

FY22 Consumer Involvement

80 consumers* were assigned to Programmatic Panels as members and ad hoc reviewers representing
65 consumer advocacy organizations, active-duty Service Members, or Veterans

855 consumer reviewers**
were assigned to Peer
Review Panels representing
415 consumer advocacy
(nominating) organizations

Consumer advocates also - participate on research teams for funded projects















Peer Reviewed Medical Research Program (PRMRP)

Transforming Healthcare through Innovative and Impactful Research



Peer Reviewed Medical Research Program (PRMRP)



Vision: Improve the health, care, and wellbeing of all military Service Members, Veterans, and beneficiaries

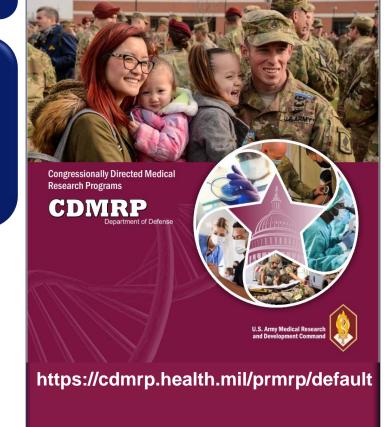
Peer Reviewed Medical Research Program

Mission: Encourage, identify, select and manage medical research projects of clear scientific merit that lead to impactful advances in health care of Service Members, Veterans, and beneficiaries

History

Initiated in 1999 to address diseases and conditions with relevance to military health

◆ Direction from congress to support research of "clear scientific merit" and "direct relevance to military health" in specified topic areas (shall be devoted only to the purposes listed) → Congressional language



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FY23 Topic Areas (50 total) for Peer Reviewed Medical Research Program

- Arthritis
- Celiac Disease*
- Dystonia
- Eating Disorders
- Eczema*
- Ehlers-Danlos Syndrome
- Endometriosis
- Epidermolysis Bullosa
- Familial Hypercholesterolemia
- Fibrous Dysplasia/McCune Albright Syndrome
- Focal Segmental Glomerulosclerosis
- Food Allergies
- Fragile X
- Frontotemporal Degeneration
- Guillain-Barre Syndrome
- Hemorrhage Control
- Hepatitis B
- Hereditary Ataxia *
- Hydrocephalus
- Hypercholesterolemia
- Inflammatory Bowel Diseases
- Interstitial Cystitis
- Lymphatic Disease *
- Lymphedema*
- Malaria
- Maternal Mental Health*

- Mitochondrial Disease
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- Myotonic Dystrophy
- Nephrotic Syndrome
- Neuroactive Steroids*
- Neuroinflammatory Response to Emerging Viral Diseases*
- Non-opioid Therapy for Pain Management
- Orthopaedics*
- Pancreatitis
- Peripheral Neuropathy
- Polycystic Kidney Disease
- Pressure Ulcers
- Proteomics*
- Pulmonary Fibrosis
- Respiratory Health
- Rheumatoid Arthritis
- Scleroderma**
- Sickle-Cell Disease*
- Sleep Disorders and Restriction
- Suicide Prevention
- Trauma
- Tuberculosis**
- Vascular Malformations
- Von Hippel-Lindau Syndrome Benign Manifestations*

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

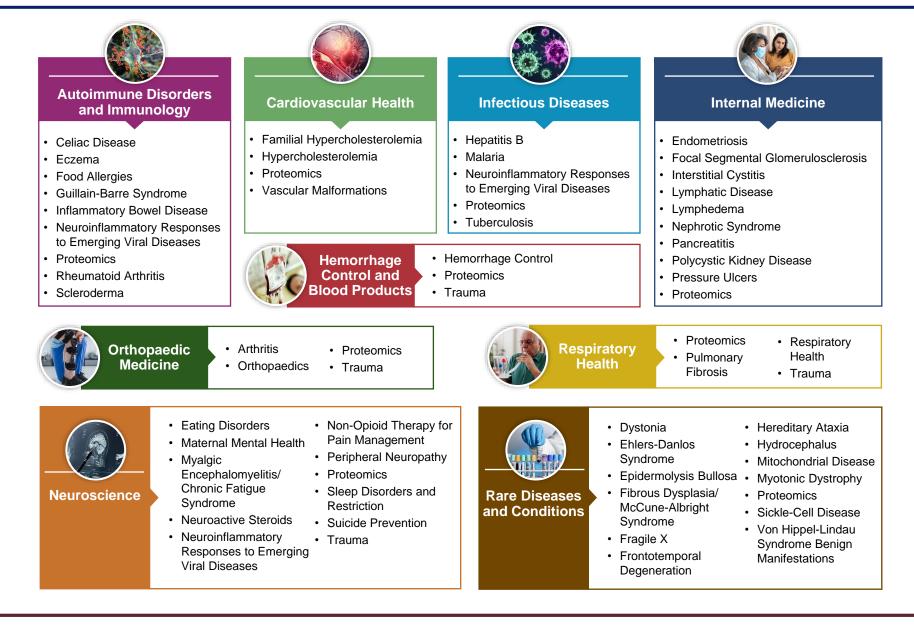


*New in FY23 ** Returning in FY23



PRMRP's FY23 Portfolio Driven Approach

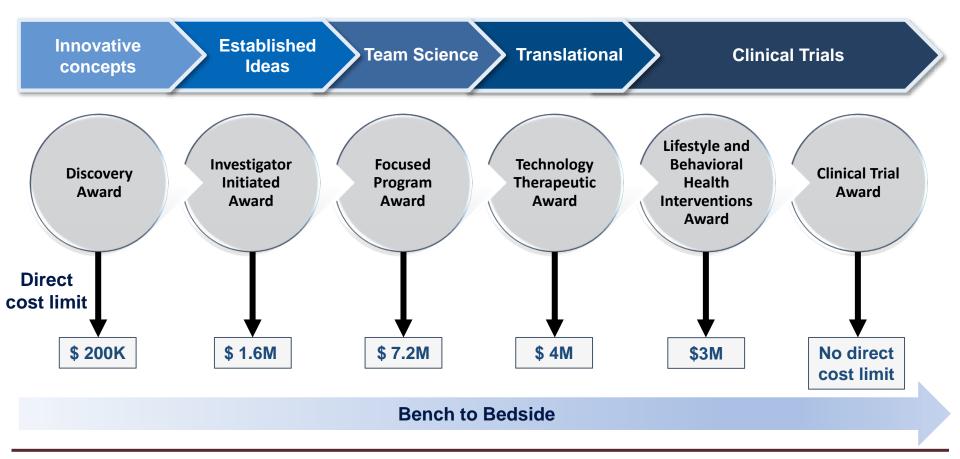




PRMRP Award Mechanisms Pipeline

Six Funding Opportunities offered in FY23

Applicants must address one Topic Area and one portfolio-specific Strategic Goal



FY23 PRMRP Funding Opportunities Available



Discovery

Direct cost max: \$200K POP: 2 years

Eligibility: Post-docs, clinical fellows and above

LOI/Invite: Letter of Intent

Supports the exploration of highly innovative concepts or untested theories

Investigator Initiated

Direct cost max: \$1.6M/ \$2.0M (PPIO) POP: 4 years

Eligibility: PIs at or above Assistant Professor

LOI/Invite: Letter of Intent

Supports basic through translational research that will improve and impact the field of research or patient care

Technology/Therapeutic

<u>Direct cost max</u>: \$2.0M (FL1)/\$4.0M (FL2) <u>POP</u>: 4 years

Eligibility: PIs at or above Assistant Professor

LOI/Invite: Letter of Intent

Supports translation of preclinical findings into impactful products for clinical application

Letter of intent is required for these mechanisms

FY23 PRMRP Funding Opportunities Available



Focused Program

Direct cost max: \$7.2M POP: 4 years

Eligibility: PIs at or above Full Professor

<u>LOI/Invite</u>: Pre-proposal submission is required; application submission is by invitation only

Supports synergistic, multidisciplinary research program of at least four distinct but complementary projects addressing an overarching goal

Clinical Trial

Direct cost max: \$500K (PP)/no limit (full trial) <u>POP</u>: 18months (PP)/ 4 years full trial)

<u>Eligibility</u>: PIs at or above Assistant Professor

<u>LOI/Invite</u>: Pre-proposal submission is required; application submission is by invitation only

Planning Phase: Supports regulatory costs for trial planning to include IND/IDE submission; must have FDA approval before trial may be funded

Clinical Trial: Supports rapid implementation of trials of novel interventions with the potential to have impact on patient care. May range from small through largescale Lifestyle and Behavioral Health Interventions

Direct cost max: \$3M POP: 4 years

Eligibility: PIs at or above Assistant Professor

LOI/Invite: Letter of Intent

Supports clinical research and/or clinical trials using a combination of scientific disciplines including behavioral health, psychology, psychometrics, biostatistics and epidemiology, surveillance, and public health

Pre-proposal submission is required; application submission is by invitation only

Letter of intent is required

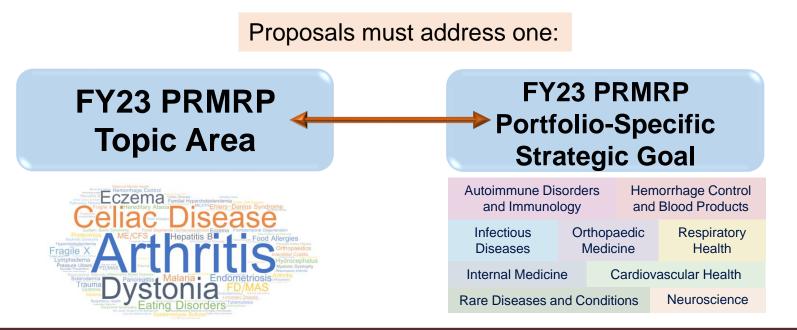
Required for all Funding Opportunities

Military Health Statement

Is the proposed research relevant to the healthcare needs of Service Members, Veterans, Military Beneficiaries, and/or the American Public?

EXAMPLES INCLUDE:

- ✓ Dual-use capacity to benefit the civilian population and a need related to military health
- ✓ Aspects of the target disease/condition with direct relevance to military heath
- ✓ Contribution to family readiness of Service Members (mission readiness)
- ✓ Support for the Warfighter and requirement for use in deployed setting



Application Requirements: Applications must address one Strategic Goal and one Topic Area



Example: Internal Medicine Portfolio Strategic Goals

Foundational Studies

 Improve understanding of long-term complications and comorbidities of associated diseases and conditions

Prevention

Develop and test strategies to prevent associated diseases or comorbidities

Diagnosis

- Develop tools or technologies for early detection, accurate diagnosis, or tracking of disease progression, including non-invasive methods, of associated diseases and conditions
- Develop tools to reduce time between presentation of symptoms and required specialized care for associated disease or condition management

Endometriosis

Topic Areas

- Focal Segmental Glomerulosclerosis
- Interstitial Cystitis
- Lymphatic Disease
- Lymphedema
- Nephrotic
 Syndrome
- Pancreatitis
- Polycystic Kidney
 Disease
- Pressure Ulcers
- Proteomics

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Application Requirements: Applications must address one Strategic Goal and one Topic Area



Example: Internal Medicine Portfolio Strategic Goals

Treatment

 Develop and test novel treatments, and/or improve upon existing treatments for associated diseases and conditions, which may include lifestyle interventions to improve psychosocial functioning and quality of life

Epidemiology

- Elucidate factors (e.g., medication toxicity, genetic predisposition, infections) that influence development, progression, and outcomes (including psychosocial functioning and quality of life) of associated diseases and conditions
- Develop surrogate endpoints to accelerate approval of new treatments for associated diseases and conditions
- Conduct patient-centered research to decrease disease burden for military families

Topic Areas

- Endometriosis
- Focal Segmental Glomerulosclerosis
- Interstitial Cystitis
- Lymphatic Disease

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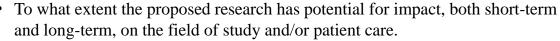
- Lymphedema
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 Syndrome
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 Disease
- Pressure Ulcers
- Proteomics

Peer Review Criteria – Listed in the Funding Opportunities

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:

Scored		Unscored				
Research Strategy and Feasibility		Environment				
Impact		Budget				
Transition Plan and Regulatory Strategy		Application Presentation				
	 Impact To what extent the project impacts a critical problem or question in one of the FY23 PRMRP Topic Areas. To what extent the proposed research project addresses one of the FY23 PRMRP Strategic Goals. How the proposed research project, if successful, will make important scientific advances in the relevant field of research. 					







Programmatic Review Criteria – Listed in the Funding Opportunities

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 PRMRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Relevance to the FY23 PRMRP Topic Areas
 - Relevance to the FY23 PRMRP Strategic Goals
 - Relevance to military health
 - Program portfolio composition

Programmatic Panel membership lists are available on the **CDMRP** website









Award Mechanism	LOI	Pre-Proposal	Dates	Invitation to submit	Full Application Deadline
Discovery Award (DA)	\checkmark	*	29 March 23		26 April 23
Investigator-Initiated Research Award (IIRA)	\checkmark	*	19 April 23		31 May 23
Technology/Therapeutic Development (TTDA)		×	19 April 23	*	31 May 23
Lifestyle and Behavioral Health Interventions (LBIRA)		X	19 April 23		31 May 23
Focused Program Award (FPA)	×	\checkmark	12 April 23	17 June 22	19 July 23
Clinical Trial (CTA)	*	\checkmark	12 April 23	17 June 22	19 July 23



Additional Tips, Resources, and Strategies for Success

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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

Strategies for Success



✓ 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

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 Website



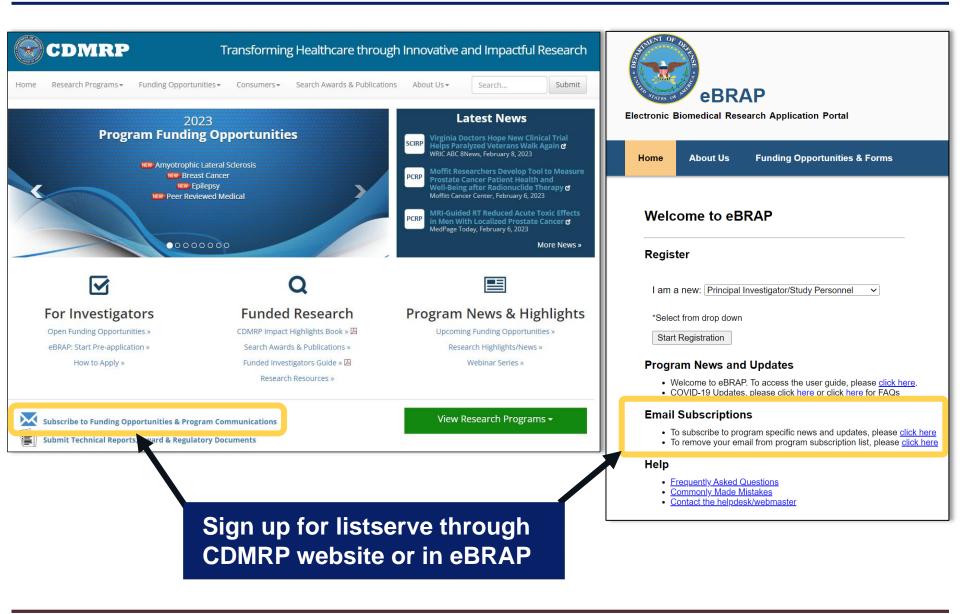
Information available:

- Program pages
 - ► Strategic Plans
 - ► Program booklets, summary sheets, information papers, etc.
 - Other program-specific resources
- Pre-announcements and Funding Opportunities
- Research and Consumer Highlights
- Search awards
- Annual reports
- Webinar series and videos
- Other guides and resources

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