Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program (PRMRP)

Presented by

Kathryn Argue, PhD
Deputy Program Manager





Transforming Healthcare through Innovative and Impactful Research



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.

Outline



- 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





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	

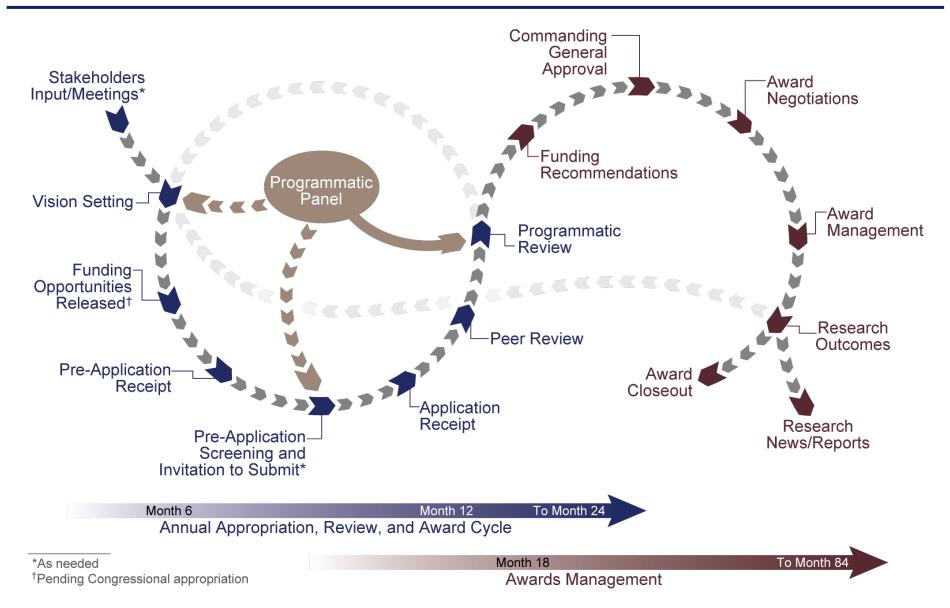


CDMRP Program Cycle and Review Process



Program Cycle





Goal of the Two-Tier Review Process

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



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

PARTNERSHIP **Programmatic** Peer Review Review

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



Peer Review Participants

FY22 Peer Review Participants (pdf)

Previous Years' Peer Review Participants



Prior year peer reviewer lists are available on the CDMRP website

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









^{*} All unique individuals

^{** 737} unique individuals



Peer Reviewed Medical Research Program (PRMRP)



UNCLASSIFIED 13

Peer Reviewed Medical Research Program (PRMRP)



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

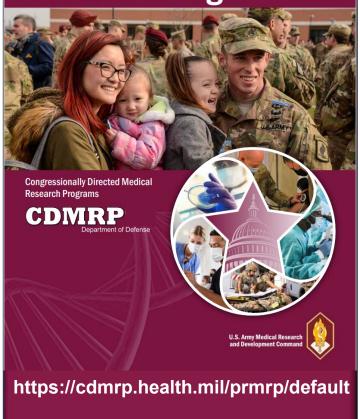
Mission: Encourage, identify, select and manage medical research projects of clear scientific merit that lead to impactful advances in health care of Service Members, Veterans, and beneficiaries

◆ 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

Peer Reviewed Medical Research Program



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





Autoimmune Disorders and Immunology

- Celiac Disease
- Eczema
- · Food Allergies
- · Guillain-Barre Syndrome
- · Inflammatory Bowel Disease
- Neuroinflammatory Responses to Emerging Viral Diseases
- Proteomics
- · Rheumatoid Arthritis
- Scleroderma



Cardiovascular Health

- · Familial Hypercholesterolemia
- Hypercholesterolemia
- Proteomics
- Vascular Malformations



Infectious Diseases

- · Hepatitis B
- Malaria
- Neuroinflammatory Responses to Emerging Viral Diseases
- Proteomics
- Tuberculosis



Hemorrhage Control

- Proteomics
- Trauma



Internal Medicine

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



Orthopaedic Medicine

- Arthritis
- Proteomics

Hemorrhage

Control and

Blood Products

- Orthopaedics
- Trauma



Respiratory Health

- Proteomics
- Pulmonary Fibrosis
- Respiratory Health
- Trauma



Neuroscience

- Eating Disorders
- Maternal Mental Health
- Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome
- Neuroactive Steroids
- Neuroinflammatory Responses to Emerging Viral Diseases

- Non-Opioid Therapy for Pain Management
- Peripheral Neuropathy
- Proteomics
- Sleep Disorders and Restriction
- Suicide Prevention
- Trauma



Rare Diseases and Conditions

- Dystonia
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- Fibrous Dysplasia/ McCune-Albright Syndrome
- Fragile X
- Frontotemporal Degeneration

- · Hereditary Ataxia
- Hydrocephalus
- · Mitochondrial Disease
- Myotonic Dystrophy
- Proteomics
- Sickle-Cell Disease
- Von Hippel-Lindau Syndrome Benign Manifestations

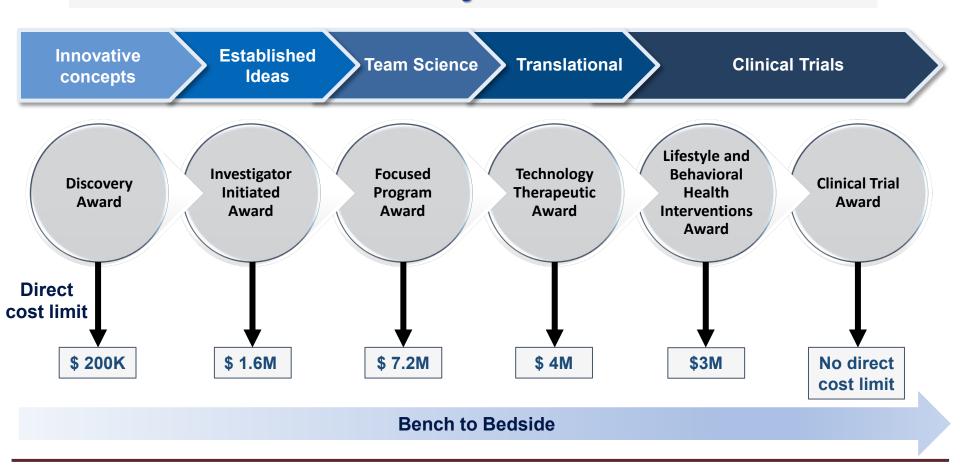
16

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: Pls 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

Direct cost max: \$2.0M

(FL1)/\$4.0M (FL2)

POP: 4 years

Eligibility: Pls 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

UNCLASSIFIED 18

FY23 PRMRP Funding Opportunities Available



Focused Program

Direct cost max: \$7.2M

POP: 4 years

Eligibility: Pls 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

<u>Direct cost max</u>: \$500K (PP)/no limit (full trial)

POP: 18months (PP)/ 4 years full

Eligibility: Pls 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



20

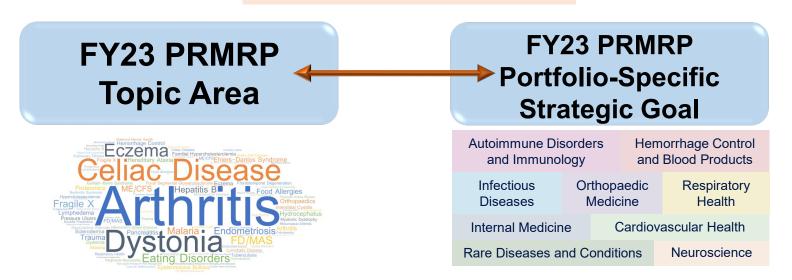
Military Health Statement

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.

Proposals must address one:



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



Example: Rare Diseases and Conditions Portfolio Strategic Goals

Foundational Studies

 Identify biological mechanisms underlying disease onset, disease progression, or phenotype/symptomatic heterogeneity

Diagnosis

- Identify and validate biomarkers to predict onset or progression of disease
- Develop and validate improved diagnostic criteria and screening tools for early detection or to track disease progression

Treatment

- Develop and test novel treatments or improve upon existing treatment regimens, especially those ready to progress rapidly to the clinic; may include repurposing existing drugs or non-prescription treatment options
- Develop and test tissue engineering, gene therapy, or protein replacement strategies for associated diseases and conditions

Epidemiology

- Population-based studies to identify risk or protective factors that influence onset, progression, and/or outcomes of associated diseases and conditions
- Conduct natural history/longitudinal studies to understand incidence, prevalence, and progression of associated diseases and conditions

Topic Areas

- Dystonia
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- FD/McCune Albright Syndrome
- Fragile X
- FTD
- Hereditary Ataxia
- Hydrocephalus
- Mitochondrial Diseases
- Myotonic Dystrophy
- Sickle Cell
 Disease
- VHL Syndrome Benign Manifestations

UNCLASSIFIED 21

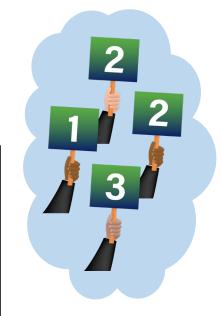
Peer Review Criteria – Listed in the Funding Opportunities



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:

Example Peer Review Criteria							
Scored	Unscored						
Research Strategy and Feasibility	Environment						
Impact	Budget						
Transition Plan and Regulatory Strategy	Application Presentation						



Impact

Personnel

- 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.
- To what extent the proposed research has potential for impact, both short-term and long-term, on the field of study and/or patient care.

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:
 - o Adherence to the intent of the award mechanism
 - o Relevance to the FY23 PRMRP Topic Areas
 - o Relevance to the FY23 PRMRP Strategic Goals
 - o Relevance to military health
 - o Program portfolio composition

Programmatic Panel membership lists are available on the CDMRP website





Programmatic Panels

FY23 Programmatic Panel

Previous Years'
Programmatic
Panels



PRMRP Submission Deadlines



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

UNCLASSIFIED



Additional Tips, Resources, and Strategies for Success



UNCLASSIFIED 2

Applying for Funding



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:

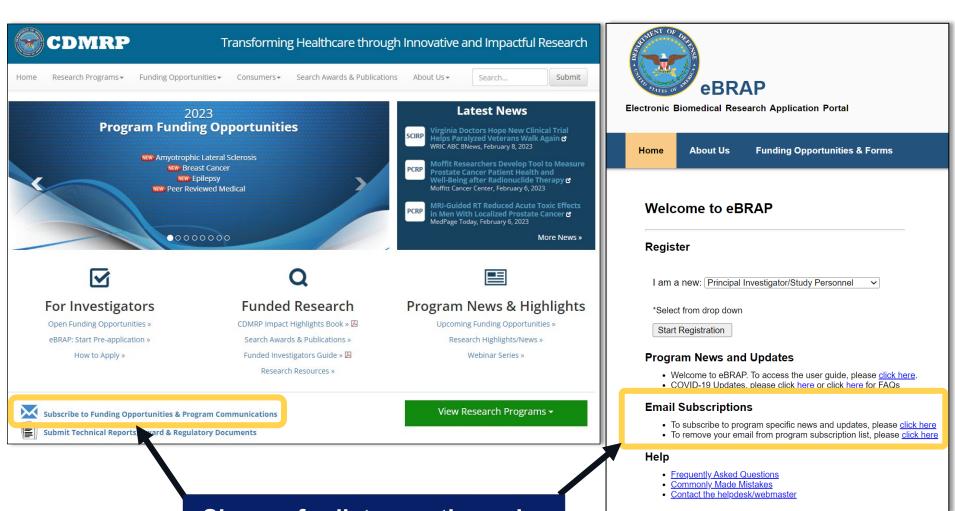
- Program pages
 - ➤ Strategic Plans
 - ➤ Program booklets, summary sheets, information papers, etc.
 - ➤ Other program-specific resources
- Pre-announcements and Funding Opportunities
- Research and Consumer Highlights
- Search awards
- Annual reports
- Webinar series and videos
- Other guides and resources

cdmrp.health.mil

Subscribe to Email Notifications



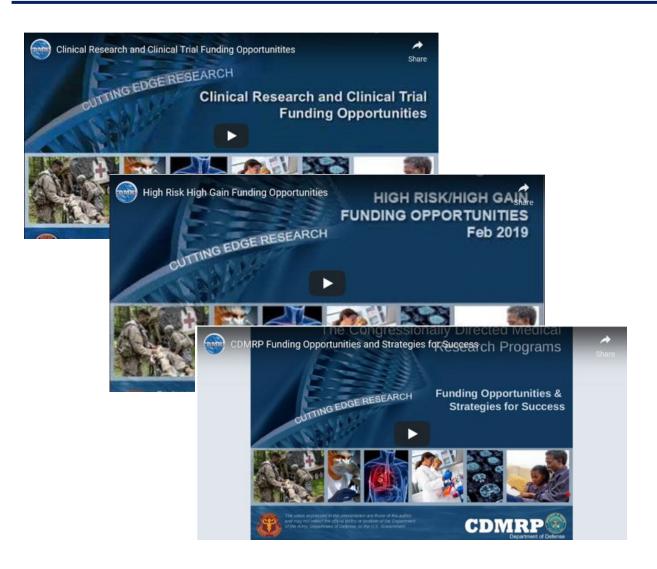
30



Sign up for listserve through CDMRP website or in eBRAP

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

UNCLASSIFIED 31

Questions? For more information, please visit:



