Transforming Healthcare through Innovative and Impactful Research

Peer Reviewed Medical Research Program (PRMRP)

Presented by
Kathryn Argue, PhD
Deputy Program Manager

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For more information, visit cdmrp.health.mil
Outline

● Overview of CDMRP

● Program Cycle and Review Process

● Peer Reviewed Medical Research Program (PRMRRP)

● Funding Opportunities and How to Apply

● Additional Resources and Strategies for Success
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

WHO
Started by Congress in 1992, CDMRP manages focused biomedical research.

WHAT
Funds innovative and impactful biomedical research.

WHERE
Research conducted in institutions around the world.

HOW
Two-tier review process involving scientists, clinicians, and consumers.

WHY
Accelerating research to advance cures, improvements, and breakthroughs.

Transforming healthcare through innovative and impactful research.

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

Stakeholders Input/Meetings*

Vision Setting

Funding Opportunities Released†

Pre-Application Receipt

Pre-Application Screening and Invitation to Submit*

Programmatic Panel

Application Receipt

Commanding General Approval

Funding Recommendations

Award Negotiations

Programmatic Review

Peer Review

Award Management

Research Outcomes

Award Closeout

Research News/Reports

Month 6

Annual Appropriation, Review, and Award Cycle

Month 12 To Month 24

*As needed

†Pending Congressional appropriation

Month 18 To Month 84

Awards Management
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.

PARTNERSHIP

Peer Review

Programmatic Review

Video and additional information available at: [https://cdmrp.health.mil/about/2tierRevProcess](https://cdmrp.health.mil/about/2tierRevProcess)
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

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.

<table>
<thead>
<tr>
<th>PROGRAM LIFECYCLE</th>
<th>FY22 Consumer Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholder Meeting</td>
<td>80 consumers* were assigned to Programmatic Panels as members and ad hoc reviewers representing</td>
</tr>
<tr>
<td>Vision Setting</td>
<td>65 consumer advocacy organizations, active-duty Service Members, or Veterans</td>
</tr>
<tr>
<td>Pre-App Screening</td>
<td></td>
</tr>
<tr>
<td>Peer Review</td>
<td>855 consumer reviewers** were assigned to Peer Review Panels representing</td>
</tr>
<tr>
<td>Programmatic Review</td>
<td>415 consumer advocacy (nominating) organizations</td>
</tr>
<tr>
<td>Funding Recommendations</td>
<td></td>
</tr>
<tr>
<td>Award Execution</td>
<td>Consumer advocates also participate on research teams for funded projects</td>
</tr>
<tr>
<td>Awards Management/ Closeout</td>
<td></td>
</tr>
</tbody>
</table>

* All unique individuals
** 737 unique individuals
Peer Reviewed Medical Research Program (PRMRP)

Transforming Healthcare through Innovative and Impactful Research
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
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

Autoimmune Disorders and Immunology
- 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
- Orthopaedics
- Proteomics
- 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

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

Orthopaedic Medicine
- Proteomics
- Trauma

Respiratory Health
- Pulmonary Fibrosis
- Trauma
Six Funding Opportunities offered in FY23

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

- **Innovative concepts**
  - Discovery Award
    - Direct cost limit: $200K
- **Established Ideas**
  - Investigator Initiated Award
    - Direct cost limit: $1.6M
- **Team Science**
  - Focused Program Award
    - Direct cost limit: $7.2M
- **Translational**
  - Technology Therapeutic Award
    - Direct cost limit: $4M
- **Clinical Trials**
  - Lifestyle and Behavioral Health Interventions Award
    - Direct cost limit: $3M
  - Clinical Trial Award
    - No direct cost limit

Bench to Bedside
### FY23 PRMRP Funding Opportunities

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Direct cost max</th>
<th>POP</th>
<th>Eligibility</th>
<th>LOI/Invite</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discovery</strong></td>
<td>$200K</td>
<td>2 years</td>
<td>Post-docs, clinical fellows and above</td>
<td>Letter of Intent</td>
<td>Supports the exploration of highly innovative concepts or untested theories</td>
</tr>
<tr>
<td><strong>Investigator Initiated</strong></td>
<td>$1.6M/$2.0M (PPIO)</td>
<td>4 years</td>
<td>PIs at or above Assistant Professor</td>
<td>Letter of Intent</td>
<td>Supports basic through translational research that will improve and impact the field of research or patient care</td>
</tr>
<tr>
<td><strong>Technology/Therapeutic</strong></td>
<td>$2.0M/$4.0M (FL1)/$4.0M (FL2)</td>
<td>4 years</td>
<td>PIs at or above Assistant Professor</td>
<td>Letter of Intent</td>
<td>Supports translation of preclinical findings into impactful products for clinical application</td>
</tr>
</tbody>
</table>

Letter of intent is required for these mechanisms.
## FY23 PRMRP Funding Opportunities Available

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Direct Cost Max</th>
<th>POP</th>
<th>Eligibility</th>
<th>LOI/Invite</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focused Program</strong></td>
<td>$7.2M</td>
<td>4y</td>
<td>PIs at or above Full Professor</td>
<td>Pre-proposal submission is required; application submission is by invitation only</td>
<td>Supports synergistic, multidisciplinary research program of at least four distinct but complementary projects addressing an overarching goal</td>
</tr>
</tbody>
</table>
| **Clinical Trial**                  | $500K (PP) / No limit (full trial) | 1y / 4y | PIs at or above Assistant Professor | 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 large-scale |
| **Lifestyle and Behavioral Health Interventions** | $3M             | 4y  | PIs at or above Assistant Professor | Letter of Intent is required | 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 |
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 health
✓ Contribution to family readiness of Service Members (mission readiness)
✓ Support for the Warfighter and requirement for use in deployed setting

Proposals must address one:

FY23 PRMRP Topic Area

FY23 PRMRP Portfolio-Specific Strategic Goal

- Autoimmune Disorders and Immunology
- Hemorrhage Control and Blood Products
- Infectious Diseases
- Orthopaedic Medicine
- Respiratory Health
- Internal Medicine
- Cardiovascular Health
- Rare Diseases and Conditions
- Neuroscience
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
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:

<table>
<thead>
<tr>
<th>Scored</th>
<th>Unscored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Strategy and Feasibility</td>
<td>Environment</td>
</tr>
<tr>
<td>Impact</td>
<td>Budget</td>
</tr>
<tr>
<td>Transition Plan and Regulatory Strategy</td>
<td>Application Presentation</td>
</tr>
<tr>
<td>Personnel</td>
<td></td>
</tr>
</tbody>
</table>

**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.
- 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.
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.
## PRMRP Submission Deadlines

<table>
<thead>
<tr>
<th>Award Mechanism</th>
<th>LOI</th>
<th>Pre-Proposal</th>
<th>Dates</th>
<th>Invitation to submit</th>
<th>Full Application Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery Award (DA)</td>
<td>✓</td>
<td>X</td>
<td>29 March 23</td>
<td>X</td>
<td>26 April 23</td>
</tr>
<tr>
<td>Investigator-Initiated Research Award (IIRA)</td>
<td>✓</td>
<td>X</td>
<td>19 April 23</td>
<td>X</td>
<td>31 May 23</td>
</tr>
<tr>
<td>Technology/Therapeutic Development (TTDA)</td>
<td>✓</td>
<td>X</td>
<td>19 April 23</td>
<td>X</td>
<td>31 May 23</td>
</tr>
<tr>
<td>Lifestyle and Behavioral Health Interventions (LBIRA)</td>
<td>✓</td>
<td>X</td>
<td>19 April 23</td>
<td>X</td>
<td>31 May 23</td>
</tr>
<tr>
<td>Focused Program Award (FPA)</td>
<td>X</td>
<td>✓</td>
<td>12 April 23</td>
<td>17 June 22</td>
<td>19 July 23</td>
</tr>
<tr>
<td>Clinical Trial (CTA)</td>
<td>X</td>
<td>✓</td>
<td>12 April 23</td>
<td>17 June 22</td>
<td>19 July 23</td>
</tr>
</tbody>
</table>
Additional Tips, Resources, and Strategies for Success

Transforming Healthcare through Innovative and Impactful Research
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
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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- 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

Questions?
For more information, please visit: cdmrp.health.mil