The Congressionally Directed Medical Research Programs

Funding Medical Research - What You Need to Know

UNCLASSIFIED

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Congressionally Directed Medical Research Programs (CDMRP)
U.S. Army Medical Research and Materiel Command (USAMRMC)
6 March 2017

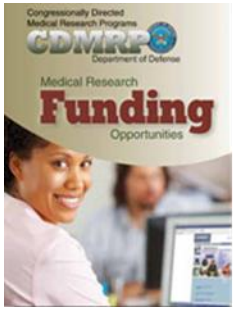
Disclaimer

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

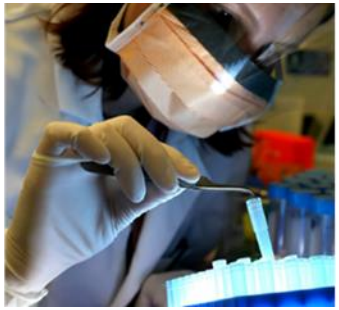
Outline

- Overview of the CDMRP
- CDMRP Funding Process
- Strategies for Success

Overview of the CDMRP






Who is the CDMRP?

Department of Defense

Department of the Army

Army Medical Command

Medical Research and Materiel Command

Congressionally Directed Medical Research Programs

Vision and Mission

Vision

Transform healthcare for Service Members and the American public through innovative and impactful research

Mission

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

About the CDMRP

- **CONGRESSIONAL PROGRAMS:**
  - Manages extramural research programs directed by Congress
  - Started in 1992 with Breast Cancer, now 27 programs
  - Congress specifies disease area, CDMRP determines research strategy and competitively selects the best projects
  - Unique public/private partnership encompassing 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:**
  - Provide support to Program Area Directorates (PADs) / Joint Program Committees (JCPs) for managing extramural and intramural research portfolios to advance their missions
- **DIRECTOR:**
  - Col Wanda Salzer

- Alcohol and Substance Abuse Disorders
- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness
- Joint Warfighter Medical
- Lung Cancer
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Orthotics and Prosthetics Outcomes
- Ovarian Cancer
- Parkinson's
- Peer Reviewed Alzheimer's
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Reconstructive Transplant
- Spinal Cord Injury
- Tick-Borne Disease
- Trauma Clinical
- Tuberous Sclerosis Complex
- Vision

Additional Supported DoD Programs

- Defense Medical R&D
- Defense Medical R&D Restoral
- Psychological Health and Traumatic Brain Injury

Fiscal Year 2016 (FY16) Funding

Program	$M		Program	$M
Alcohol and Substance Abuse Disorders	$4.0		Peer Reviewed Alzheimer's	$15.0
Amyotrophic Lateral Sclerosis	$7.5		Peer Reviewed Cancer (13 Topics)	$50.0
Autism	$7.5		Peer Reviewed Medical (39 Topics)	$278.7
Bone Marrow Failure	$3.0		Peer Reviewed Orthopaedic	$30.0
Breast Cancer	$120.0		Prostate Cancer	$80.0
Breast Cancer Research Semipostal	$0.2		Reconstructive Transplant	$12.0
Duchenne Muscular Dystrophy	$3.2		Spinal Cord Injury	$30.0
Epilepsy	$7.5		Tick-Borne Disease	$5.0
Gulf War Illness	$20.0		Trauma Clinical	$10.0
Joint Warfighter Medical (1)	$50.0		Tuberous Sclerosis	$6.0
Lung Cancer	$12.0		Vision	$10.0
Military Burn	$8.0		Additional Supported DoD Programs: (1)	
Multiple Sclerosis	$6.0		Centers of Excellence	$3.1
Neurofibromatosis	$15.0		Defense Medical R&D	$120.5
Orthotics and Prosthetics Outcomes	$10.0		Defense Medical R&D Restoral	$31.6
Ovarian Cancer	$20.0		Psychological Health and Traumatic Brain Injury	$69.6
Parkinson's	$16.0		Small Business Innovation Fund	$3.6

(1) Approximate funding to be managed on behalf of others

TOTAL = $1.1B

A Major Funder

- **The CDMRP is THE leading U.S. funder for neurofibromatosis research**
- **The CDMRP is the 2nd largest U.S. funder for research in:**
  - Breast cancer
  - Gulf War illness
  - Lung cancer
  - Ovarian cancer
  - Prostate cancer
  - Tuberous sclerosis complex

FY16 Topic Areas for PRMRP*

1. Acute Lung Injury
2. Antimicrobial Resistance
3. Chronic Migraine and Post-Traumatic Headache
4. Congenital Heart Disease
5. Constrictive Bronchiolitis
6. Diabetes
7. Dystonia
8. Emerging Infectious Diseases
9. Focal Segmental Glomerulosclerosis
10. Fragile X Syndrome
11. Hepatitis B
12. Hereditary Angioedema
13. Hydrocephalus
14. Inflammatory Bowel Disease
15. Influenza
16. Integrative Medicine
17. Interstitial Cystitis
18. Lupus
19. Malaria
20. Metals Toxicology
21. Mitochondrial Disease
22. Nanomaterials for Bone Regeneration
23. Non-Opioid Pain Management
24. Pancreatitis
25. Pathogen-Inactivated Dried Plasma
26. Polycystic Kidney Disease
27. Post-Traumatic Osteoarthritis
28. Psychotropic Medications
29. Pulmonary Fibrosis
30. Respiratory Health
31. Rett Syndrome
32. Rheumatoid Arthritis
33. Scleroderma
34. Sleep Disorders
35. Tinnitus
36. Tuberculosis
37. Vaccine Development for Infectious Disease
38. Vascular Malformations
39. Women's Heart Disease

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

* Peer-Reviewed Medical Research Programs

Consumers

Grassroots consumers heightened political awareness of breast cancer, which led to increased funding for cancer research and the 1992 creation of the CDMRP. The voices and experiences of consumers continue to play a pivotal role in the establishment and growth of research programs.

Over 2,100 consumers representing over 1,000 organizations have served on Peer Review and Programmatic Review panels

Additional DoD Supported Programs

- As directed by the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency (DHA) Research and Development Directorate (J9) oversees the Defense Health Programs (DHP) Research, Development, Test, and Evaluation appropriations
  - **Vision of Research and Development Directorate :** Advance collaborative, innovative medical research and development to improve military community health and save lives on and off the battlefield
  - **Joint, integrated focus includes Army, Navy, and Air Force**
- **The CDMRP provides program and award management support to the DHA through the USAMRMC**
  - **DHP Congressional Special Interest Medical Research Programs**
  - **Six DHP core research areas** (CDMRP Defense Medical Research and Development)

DHP Core Research Areas

Joint Program Committees (JPCs)

- **Medical Simulation and Information Sciences (JPC-1)**
  - Medical Modeling, Simulation, and Training
  - Health Information Technology and Informatics
- **Military Infectious Diseases (JPC-2)**
  - Bacterial Diseases
  - Viral Diseases
  - Diagnostics Development
- **Military Operational Medicine (JPC-5)**
  - Musculoskeletal Injury
  - Cognitive Health and Performance
  - Psychiatry and Clinical Psychology Disorders
  - Behavioral Health, Wellness, and Resilience
  - Warfighter Physical Performance
  - Nutrition and Weight Balance
  - Sensory Performance, Injury, and Protection
  - Millennium Cohort Study
  - Environmental Toxicant Exposure
  - Aircrew Health and Performance
- **Combat Casualty Care (JPC-6)**
  - Damage Control Resuscitation
  - Neurotrauma, Neuroprotection, and Neurodiagnostics
  - Patient Movement/En Route Combat Casualty Care
  - Extremity Trauma
  - Systems of Critical Care Delivery
  - Burn Injury
  - Maxillofacial Trauma and Combat Dentistry
  - Pre-Hospital Tactical Combat Casualty Care
  - Military Medical Photonics
- **Radiation Health Effects (JPC-7)**
  - Radiation Medical Countermeasures Development
- **Clinical & Rehabilitative Medicine (JPC-8)**
  - Neuromusculoskeletal Rehabilitation
  - Pain Management
  - Regenerative and Rehabilitative Medicine
  - Sensory Systems (Vision, Hearing, and Balance)

Coordinate Partnerships

Consumers

- Demonstrate need
- Participate at all levels
- Passion and perspective

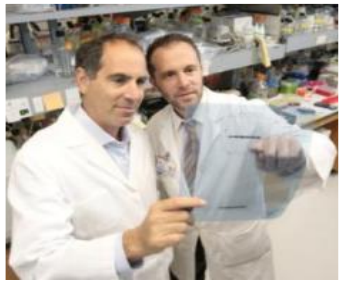
Congress

- Add funds to budget
- Targeted guidance

IMPROVE HEALTH OUTCOME

Researchers

- Innovation and gaps
- Risk/benefit
- Product-oriented

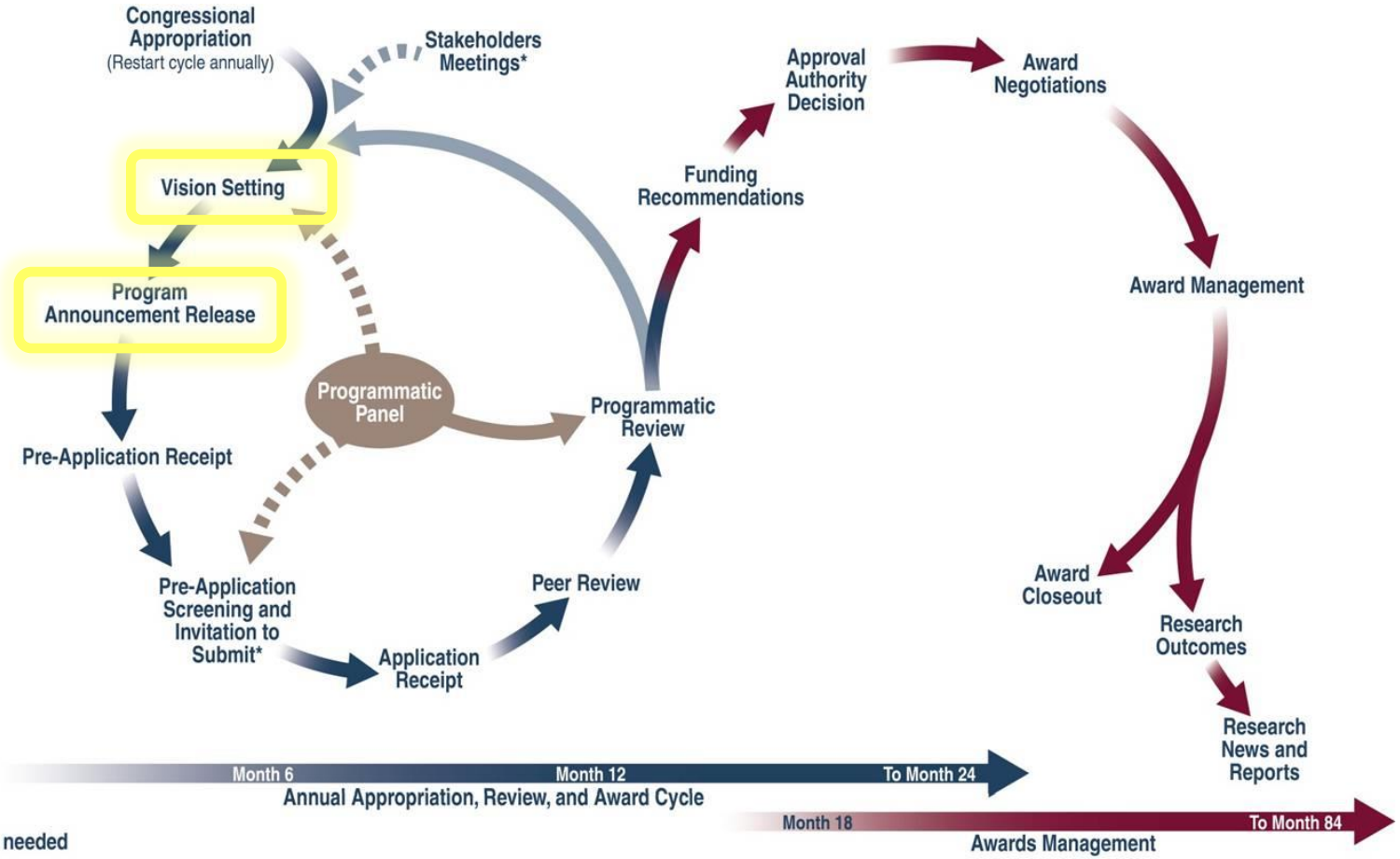


DoD

- Program management
- Contracting actions
- Regulatory requirements

CDMRP Funding Process

Program Cycle



Vision Setting

Each year, the Programmatic Panel recommends an investment strategy, considering factors such as:

- **Congressional language**
- **Current research landscape**
- **Emerging technologies**
- **Research gaps**
- **Impact**
- **Portfolio composition**

Award Mechanisms Pipeline

Career Development

Funding for all career stages

Predoctoral → Postdoctoral → Physician Scientist → New Investigator → Established Investigator

Initial Concepts → Early Ideas → Clinical/ Translational → Team Science → Clinical Trials

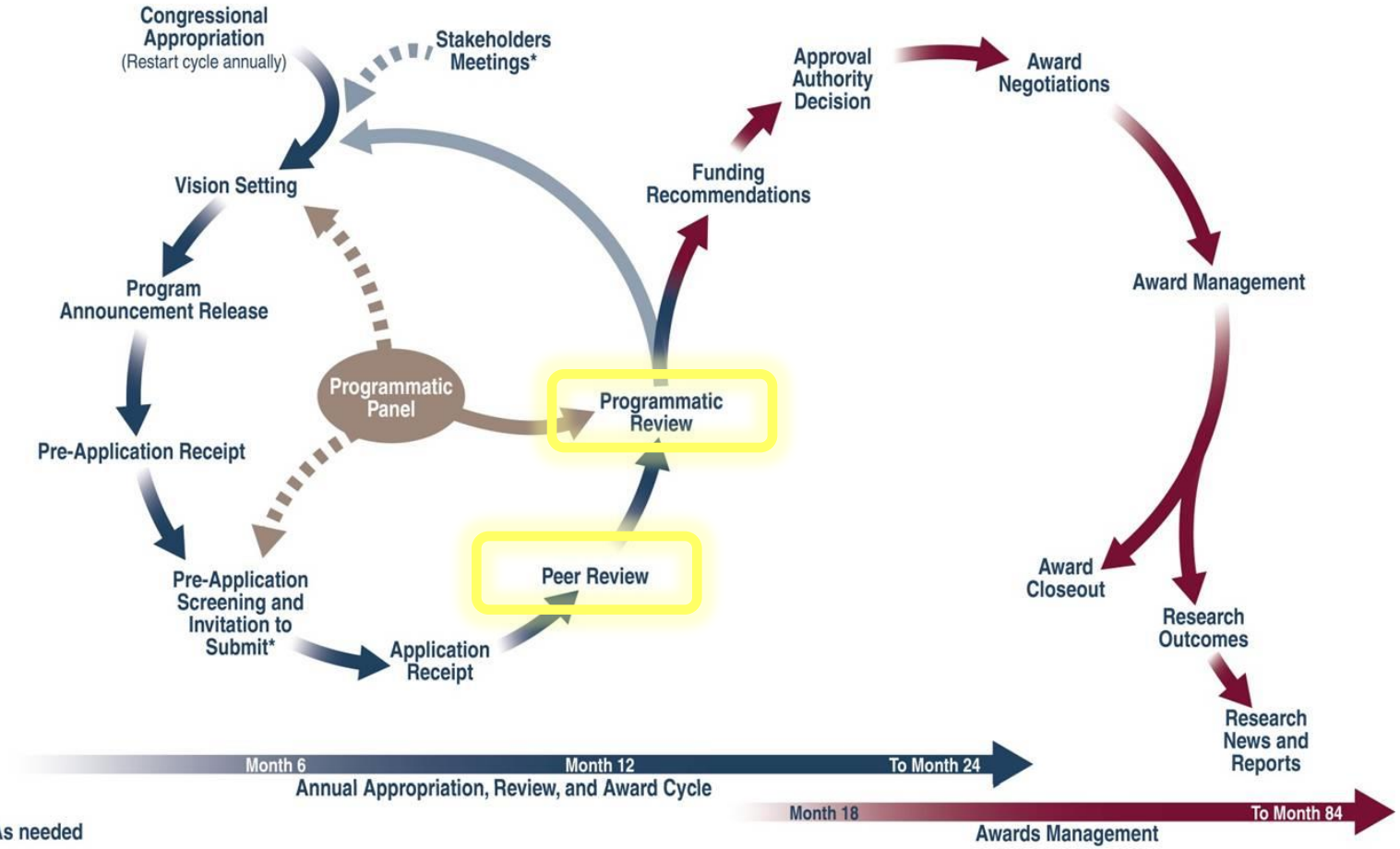
Research Awards

Closing gaps in research through innovative and impactful research

Funding Opportunities

- **Numerous types of award mechanisms**
  - Tailored to the goals of each program
  - May vary from year to year
- **Each funding opportunity is made available through a Program Announcement (PA) or program-specific Broad Agency Announcement (BAA)**
- **Pre-announcement release**
  - CDMRP website and email blast
- **Funding Opportunity Postings**
  - Grants.gov
  - CDMRP electronic Biomedical Research Application Portal (eBRAP) system
  - CDMRP website
  - FedBizOpps.gov (BAA)

Program Cycle



Two-Tier Review Process Goal

CDMRP Mission

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

Peer Review	Partnership	Programmatic Review

- **Criterion-based evaluation of full proposal**
- **Determination of "absolute" scientific merit**
- **Outcome: Written critique and scores for individual criteria and overall merit**
  - ❖No standing peer review panels
  - ❖No contact between reviewers and applicants

- **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; no out-year budget commitments (but milestones imposed)
  - ❖No continuation funding

First Tier: Peer Review

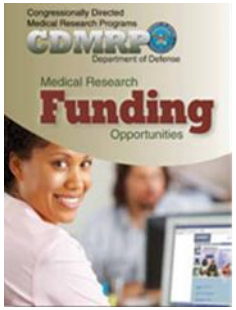
- **How the evaluation process works**
  - Technical merit assessment based on an ideal application
  - Criteria-based evaluation of entire application
- **Peer Reviewers**
  - Panels composed of scientific and consumer reviewers
  - No standing panels
  - Reviewers recruited based on expertise needed
  - Identities are not made known to applicants; contact between applicants and reviewers not permitted
- **Outcome: Summary Statement**

Second Tier: Programmatic Review

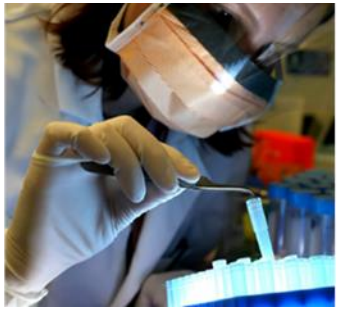
- **How the evaluation process works**
  - Comparison-based
  - Strong scientific merit
  - Adherence to award mechanism's intent
  - Potential for impact
  - Program relevance
  - Consideration of portfolio composition
- **Programmatic reviewers**
  - Programmatic Panel (or equivalent)
  - Ad hoc reviewers
- **Outcome: Funding recommendations**

Strategies for Success

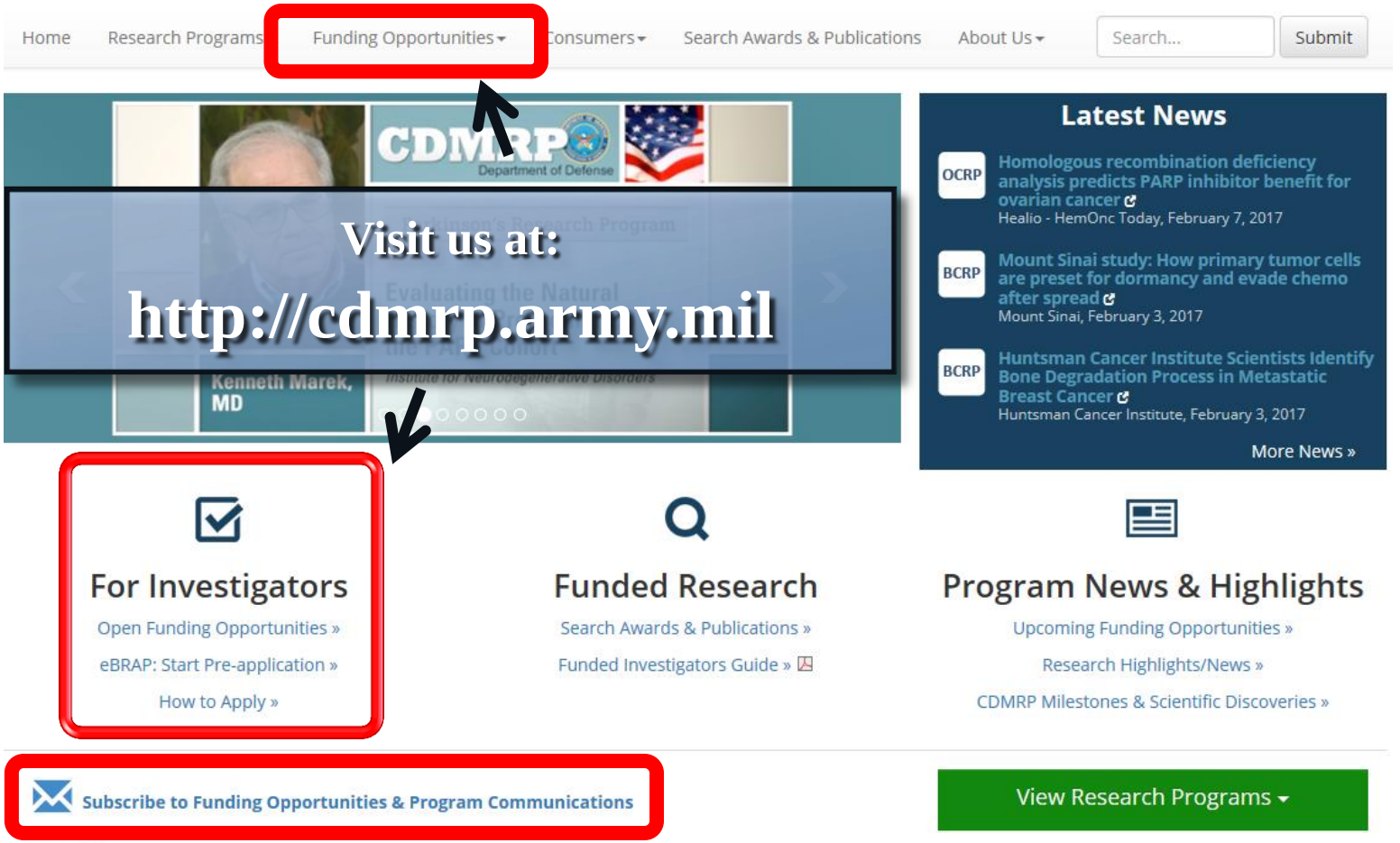
Finding the Announcement



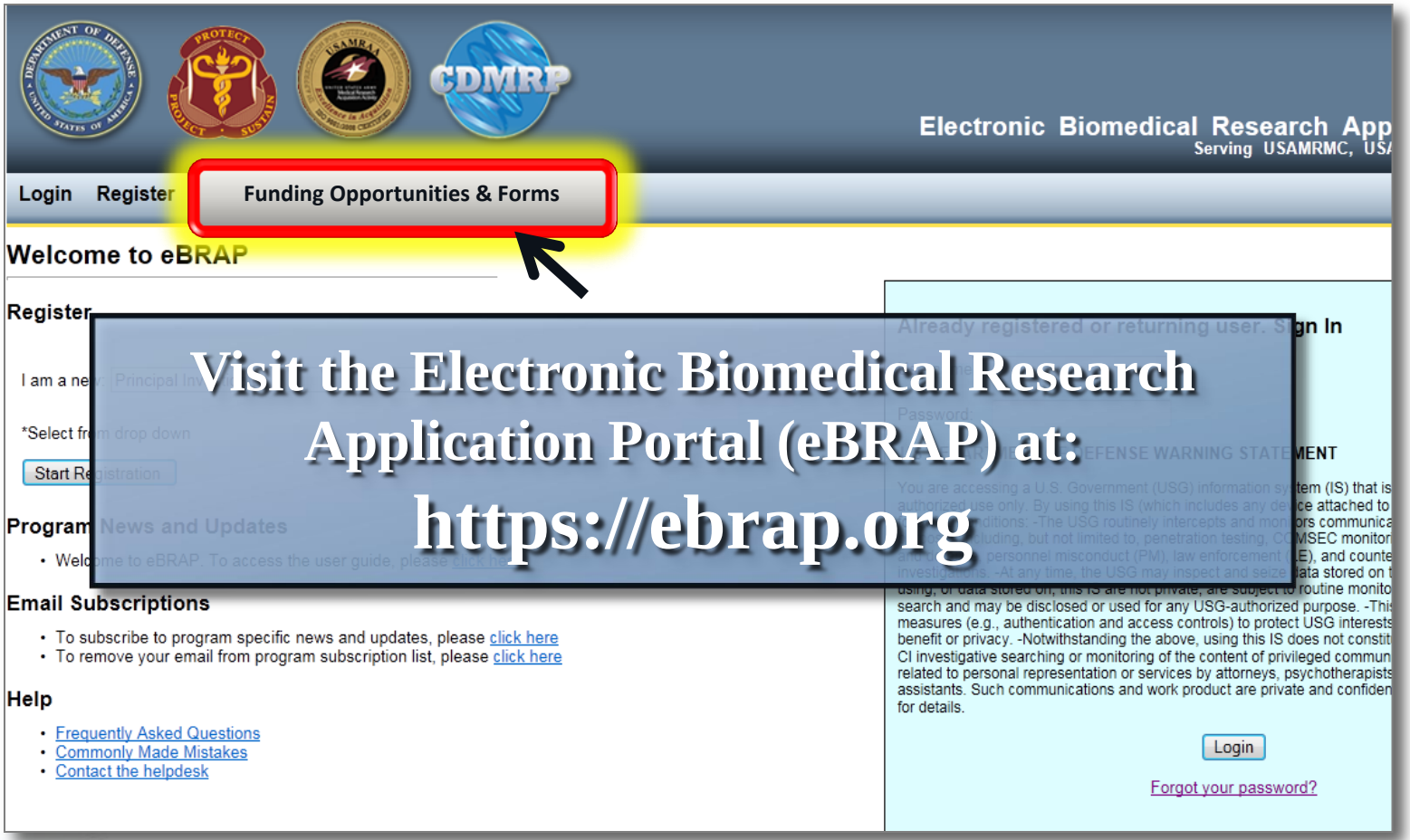



Funding Opportunities: CDMRP Website



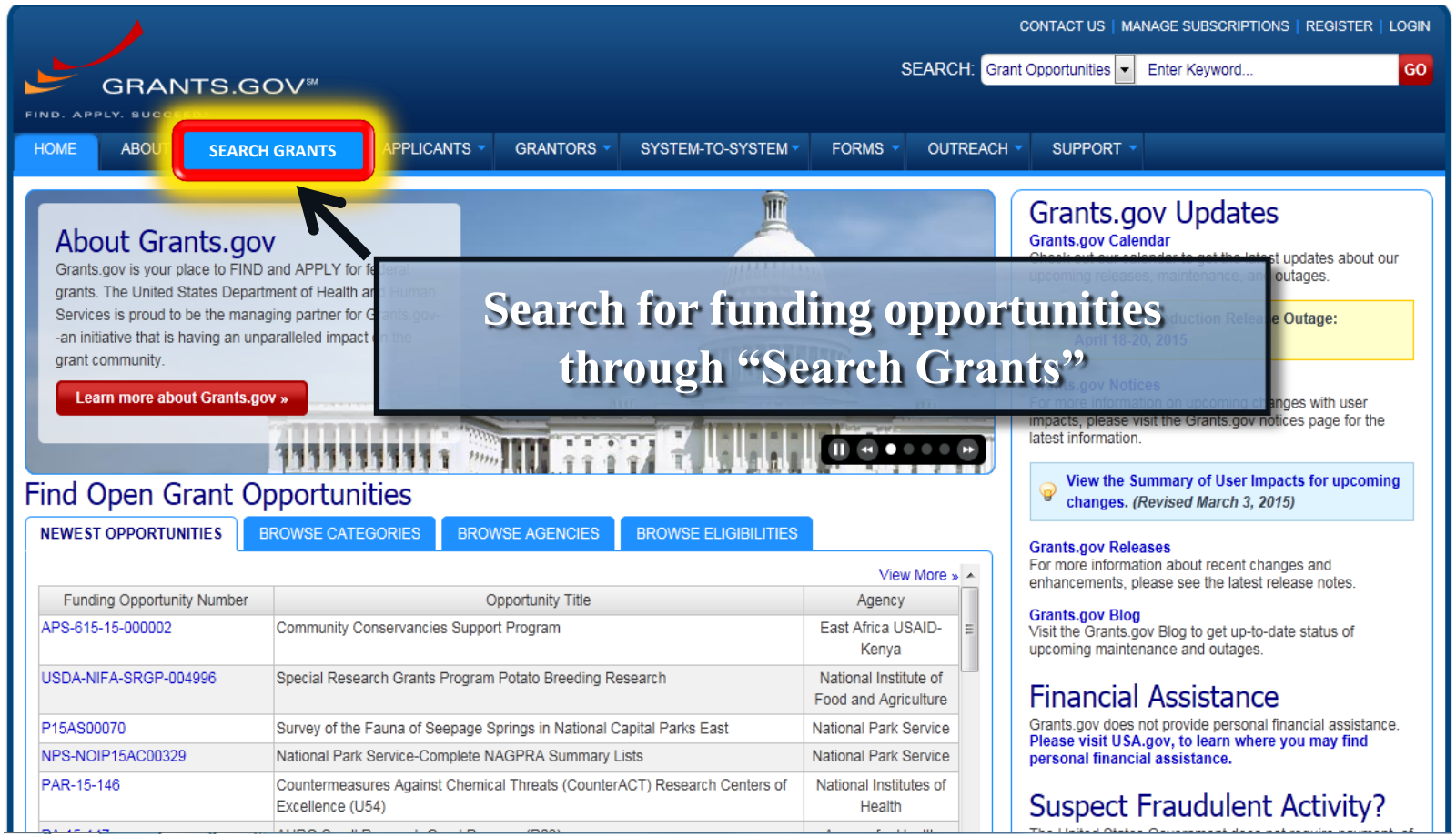
Funding Opportunities: eBRAP



Visit the Electronic Biomedical Research Application Portal (eBRAP) at:

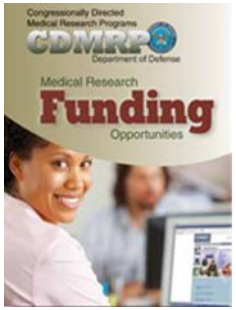
https://ebrap.org

Funding Opportunities: Grants.gov

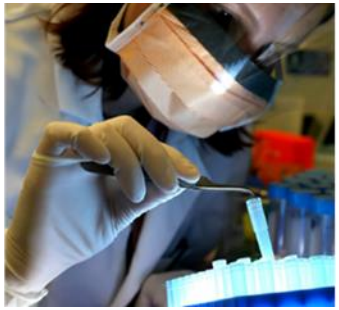


Strategies for Success

Which Announcement is Best?






Synopses of Program Award Mechanisms

DEPARTMENT OF DEFENSE - CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

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CDMRP

Transforming Healthcare through Innovative and Impactful Research

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Funding Opportunities

Program Announcements

All pre-applications must be submitted electronically to the Electronic Biomedical Research Application Portal (eBRAP) https://ebrap.org. Full applications must be submitted electronically to the Grants.gov website http://grants.gov.

Fiscal Year 2016/2017 (FY16/17) Defense Medical Research and Development Program

- Fiscal Year 2016/2017 (FY16/17) Defense Medical Research and Development Program (DMRDP) is currently accepting applications for four award mechanisms.
  Full details for submission:
  DMRDP Funding Opportunities | Synopsis of DMRDP Award Mechanisms

Synopses of Program Award Mechanisms

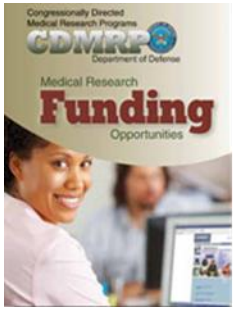
Provides a brief description and key elements of the current award mechanisms offered

Fiscal Year 2016-2017 Defense Medical Research and Development Program
Reference Table of Award Mechanisms and Submission Requirements

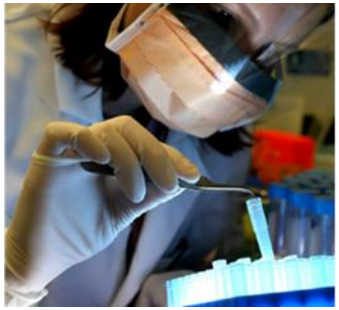
Award Mechanism	Program	Eligibility	Key Mechanism Requirements	Funding	Submission Deadline
FY17 Developing Models for Military Medical Training from Field Data Collected from Sensors (MATADOR) Award • *Extramural* Investigators and organizations must apply through **Grants.gov.** • *Intramural* investigators and organizations must apply through **CDMRP eBRAP** Go to: Extramural Program Announcement and General Application Instructions Intramural Program Announcement and Application Instructions **Grants.gov Funding Opportunity Number:** W81XWH-16-DMRDP-MSIS-MAT	JPC-1/Medical Simulation and Information Sciences (MSIS) Research Program	• Independent investigators at all academic levels (or equivalent). • An **extramural investigator** is defined as all those not included in the definition of intramural investigator below. • An **intramural investigator** is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center.	• Seeks to support research for the development and preliminary validation of a conceptual predictive model with the ability to rapidly collect, analyze, and weigh sensor and/or biosurveillance data collected directly from the field (not be limited to a particular type of field environment) via a variety of sensors and/or biosurveillance systems. • Creates standards, specifications, format, and storage of the collected data/information as appropriate to the initial stages of the proposed working model. • Preliminary data are required. • **Pre-application is required; application is by invitation only.**	• Maximum funding of **$750,000** in total costs (direct plus indirect costs) • Period of performance should not exceed 2 years.	**Pre-Application:** November 14, 2016 5:00 p.m. Eastern Time (ET) **Extramural Application:** March 1, 2017 11:59 p.m. ET **Extramural Application Verification Period:** March 6, 2017 5:00 p.m. ET **Intramural Application:** March 6, 2017 5:00 p.m. ET Pre-application submission is required. Application submission is by invitation only.

Strategies for Success

Components of a Successful Application





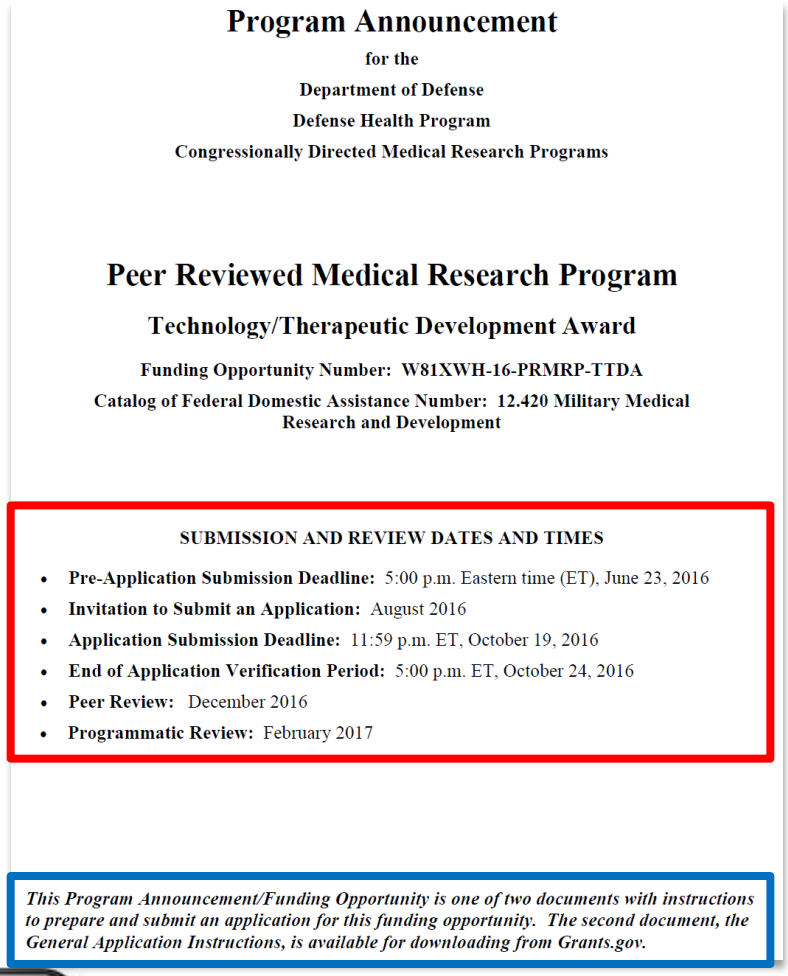

About the Grant Application

Understanding the intent of the award mechanism and review criteria is critical for a successful grant application

Review of the Program Announcement

- Single most important tip for CDMRP funding: *Read the PA*
- The PA contains information on:
  - Program Goals
  - Focus Areas
  - Award Intent
  - Required Elements, Eligibility, and Funding
  - Review Criteria
  - Deadlines

Review of the Program Announcement



Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Technology/Therapeutic Development Award

Funding Opportunity Number: W81XWH-16-PRMRP-TTDA

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), June 23, 2016
- **Invitation to Submit an Application:** August 2016
- **Application Submission Deadline:** 11:59 p.m. ET, October 19, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, October 24, 2016
- **Peer Review:** December 2016
- **Programmatic Review:** February 2017

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

- These dates are critical
- There is *no grace period* for late submissions
- **Start early**—do not leave until the last day
- Use the application *verification period*

- The **Program Announcement** and the **General Application Instructions** - *read both*

Review of the Program Announcement

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Peer Reviewed Medical Research Program (PRMRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The PRMRP was initiated in 1999 to provide support for military health-related research of exceptional scientific merit. Appropriations for the PRMRP from FY99 through FY15 totaled $1.092 billion. The FY16 appropriation is $278.7 million (M).

The vision of the FY16 PRMRP is to improve the health and well-being of all military Service members, Veterans, and beneficiaries. The PRMRP challenges the scientific and clinical communities to address at least one of the FY16 Topic Areas with original ideas that foster new directions along the entire spectrum of research and clinical care. The program seeks applications in laboratory, clinical, behavioral, epidemiologic, and other areas of research to advance knowledge in disease etiology, improve prevention, detection, diagnosis, treatment, and quality of life for those affected by a relevant disease or condition, and to develop and validate clinical care or public health guidelines.

Review of the Program Announcement

B. FY16 PRMRP Topic Areas

All applications for PRMRP funding must specifically address at least one of the Topic Areas as directed by Congress and must be directly relevant to the healthcare needs of military Service members, Veterans, and/or beneficiaries. If the proposed research does not specifically address at least one of the FY16 PRMRP Topic Areas, the Government will administratively withdraw the application. The Government reserves the right to reassign the application's Topic Area if submitted under an inappropriate Topic Area. The FY16 PRMRP Topic Areas are listed below.

- Acute Lung Injury
- Antimicrobial Resistance
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Emerging Infectious Diseases
- Focal Segmental Glomerulosclerosis
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- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Tinnitus
- Tuberculosis
- Vaccine Development for Infectious Disease
- Vascular Malformations
- Women's Heart Disease

Review of the Program Announcement

1. **Fluid Resuscitation Studies (Human)**

   Fluid Resuscitation: Through multicenter prospective observational studies (retrospective or prospective), demonstrate the impact of various fluid resuscitation rates and techniques, as well as various adjunctive therapies (e.g., high-dose/low-dose vitamin C, albumin timing, etc.) on clinically relevant outcomes during acute burn resuscitation.

Some **Focus Areas** include *detailed specifications*

(from FY15 Military Burn PA)

3. In addition to the required focus areas above, it is highly encouraged that applications to the FY16 OPORP OORA address one or more of the following areas of encouragement:
   - Longitudinal studies that include short- and long-term outcomes.
   - Compare the effectiveness of different patient care approaches (i.e., orthotic devices and associated treatments and rehabilitation strategies) to enhance patient-centered clinical decision making.
   - Provide information on quality of life, reintegration, and/or return to duty/return to work as it pertains to those patients who use an orthotic device due to limb impairment.
   - Compare the effectiveness of orthotic devices, associated treatments, and rehabilitation issues unique to underserved populations (i.e., women, minorities, etc.).

Some PAs include both **Focus Areas** (*mandatory*) and **Areas of Encouragement**

(from FY15 Orthotics and Prosthetics Outcomes PA)

Review of the Program Announcement

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- Nanomaterials for Bone Regeneration
- Non-Opioid Pain Management
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- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Psychotropic Medications
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
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Applicants must address at least one of the Topic Areas as directed by Congress

Review of the Program Announcement

Research relevant to one or more FY16 PRMRP Topic Areas may be considered for funding. ***Applicants should select the FY16 PRMRP Funding Opportunity most appropriate to the stage of the proposed research.*** Areas of Encouragement related to the FY16 PRMRP Topic Areas have been identified by the Department of Defense (DoD), the Department of Veterans Affairs (VA), and other [illegible]keholders (Appendix 1). Applicants are urged to read and consider these Are[illegible] ***not ex[illegible] applicat*** ***Are[illegible]ncouragement on***

Applications addressing any of the FY16 PRMRP Topic Areas are of interest to the program. ***Any aspect of research relevant to one or more FY16 PRMRP Topic Areas may be considered for funding.*** Areas of encouragement related to the FY16 PRMRP Topic Areas have been identified by the DoD, VA, and other relevant stakeholders. Applicants are urged to read and consider these areas of encouragement before preparing their applications. ***The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an area of encouragement in this list.***

Acute Lung Injury

- Research on the etiology and prevention of acute respiratory distress syndrome (ARDS) caused by the immune system's responses to infectious disease.
- Preventive techniques, novel detection technologies, and therapeutics to reduce the incidence and/or severity of ARDS and/or other lung injury secondary to trauma, transfusion, burns, hemorrhagic shock, and/or oxygen exposure.
- Development of clinical laboratory-based device for manufacturing/amplification of stem cells to treat acute lung injury/ARDS due to inhalation injury or due to single or polytrauma.
- Clinical studies to test cellular therapies in the treatment of acute lung injury/ARDS due to inhalation injury or due to single or polytrauma.
- Metrics to associate health outcomes of acute lung injury with physiological and physical performance of military Service members.
- Strategies to support the safe transport of patients with lung injury in order to optimize therapeutic interventions.

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C. Award Information

The PRMRP Technology/Therapeutic Development Award is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical applications, including prevention, detection, diagnosis, treatment, or quality of life, in at least one of the Congressionally directed FY16 PRMRP Topic Areas. Products in development should be responsive to the healthcare needs of military Service members, Veterans, and/or beneficiaries.

- **Definitions**: "Knowledge Product," "Clinical Trial," "Proof of Concept"
- **Requirements**:
  - Must include preliminary data
  - May not be used to conduct clinical trials
  - Military relevance is a key feature of the award
  - Requirements for use of active-duty military or Veteran populations, research involving human subjects, human cadavers, animals
  - Investigational New Drug/Investigational Device Exemption
- Examples of the **types of research** supported

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PAs may have **funding limits** on Direct Costs or Total Costs (Direct + Indirect), so *be sure to check*

Mistakes here can put your budget over the limit

E. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **$3M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$3M** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that has a period of performance less than the maximum **3** years.

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II. SUBMISSION INFORMATION

Submission of applications that are essentially identical or propose essentially the same research project to different Funding Opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

All PAs use a *two-step submission process*:
Pre-apps (Preproposal or Letter of Intent) via eBRAP
Full apps via grants.gov

Familiarize yourself (and your Business Official [BO]) with eBRAP and grants.gov requirements in advance

Use the Verification Period!

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B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. **During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.**

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

Tab 1—Application Information, e.g., Topic Area
Tab 2—Application Contacts, PI, and BO
Tab 3—Collaborators and Key Personnel
Tab 4—Conflicts of Interest
Tab 5—Pre-Application Files
Tab 6—Submit Pre-Application

Preproposal Narrative
- Topic Area
- Technology/Therapeutic Development Product
- Research Strategy
- Personnel
- Impact/Military Relevance

Pre-Application Supporting Documents
- References Cited
- List of Abbreviations
- Key Personnel Biosketches

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Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PRMRP, pre-applications will be screened based on the following criteria:

  - **Technology/Therapeutic Development Product:** How well the pre-application defines a product (e.g., drug, device, clinical guidelines) that will address an unmet need. Whether the project is based on promising preclinical findings, sound scientific rationale, and demonstrated proof-of-concept.
  - **Research Strategy:** How well the specific aims and proposed methodology support the research hypothesis and/or objectives and the development of the product.
  - **Personnel:** How the personnel's background and expertise are appropriate to accomplish the proposed research.
  - **Impact:** Whether the potential immediate and long-range outcome(s)/product(s) (intellectual and/or materiel) of the proposed research, if successful, will impact a central critical problem or question in the field of research and/or patient care in the FY16 PRMRP Topic Area(s) addressed.
  - **Programmatic Relevance:** Whether the proposed research idea supports the objectives of the PRMRP. How well the research will address a healthcare issue relevant to military Service members, Veterans, and/or beneficiaries.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

Pre-application screening is typically done by the Programmatic Panel *according the criteria in the PA*

Applicants *do not* receive additional feedback here **Applicants must be invited to submit a full application**

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VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Military Relevance Statement: Upload as Attachment 7 with file name "MilRel.pdf."	
	8	Transition Plan: Upload as Attachment 8 with file name "Transition.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	

The Project Narrative and the Budget ***cannot*** be changed during the verification period in eBRAP

Detailed guidance is provided in the PA for the contents of these sections

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Project Narrative	Impact Statement	Military Relevance Statement	Transition Plan and Regulatory Strategy
• Background • Hypothesis/Objective • Specific Aims • Research Strategy	• Relevance to a Topic Area • Short-term impact • Long-term impact	• Relevance to health care needs of military Service Members, Veterans and/or beneficiaries • Involvement of military populations • Alignment with DoD and Department of Veterans Affairs areas of research interest	• Methods and strategies to move the product or knowledge outcomes to the next phase of development

Review of the Program Announcement

B. Application Review Process

1. 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:

Pe
Scored
Research Strategy and Feasibility
Impact
Transition Plan and Regulatory Strategy
Personnel

- **Transition Plan and Regulatory Strategy**
  - Whether the identified next level of development and/or commercialization is realistic.
  - Whether the funding strategy described to bring the product(s) to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
  - How the regulatory strategy and the development plan to support the proposed product label, if applicable, are appropriate and well described.
  - If applicable, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.
  - Whether the schedule and milestones for bringing the anticipated product(s) to the next level of development (clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable. Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

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2. **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:

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the DHP and FY16 PRMRP, as evidenced by the following:**

      - Adherence to the intent of the award mechanism
      - Military relevance
      - Program portfolio composition
      - Relative impact

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A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

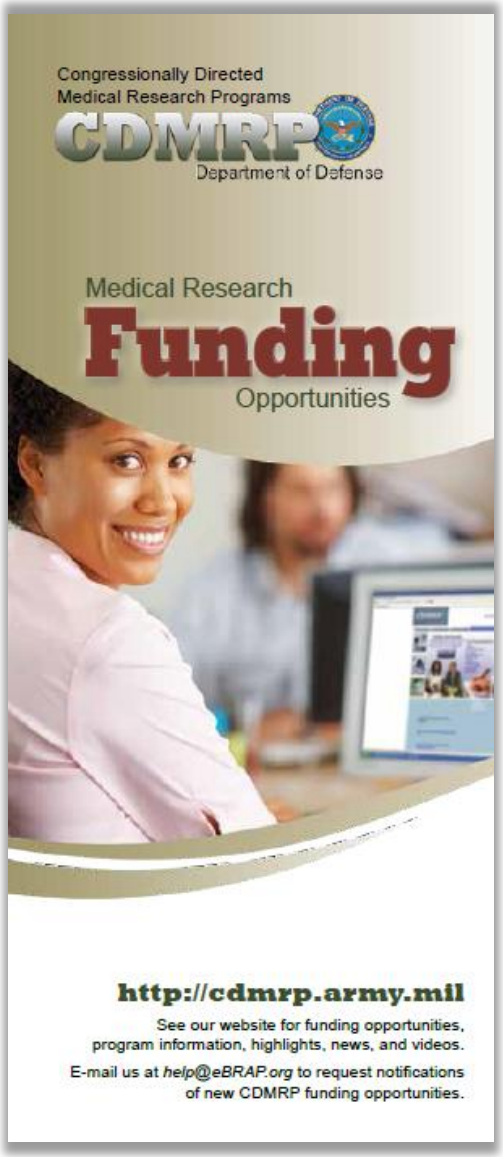
B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research project is not relevant to any of the Congressionally directed FY16 PRMRP Topic Areas.
- If a clinical trial is proposed, the application will be withdrawn.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

http://cdmrp.army.mil



More information on how to apply, funding opportunities, and CDMRP programs will be available during the Round Robin Discussions and at the CMDRP table in the foyer


Thank you