### The Congressionally Directed Medical Research Programs



### **CDMRP** Overview

#### Gayle Vaday, Ph. D. Program Manager, CDMRP





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





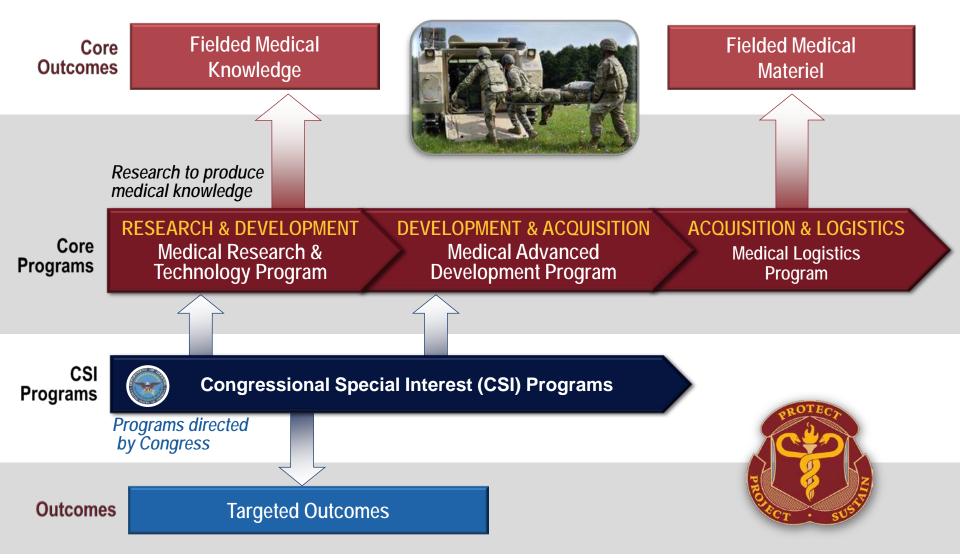
### WHO is the CDMRP?

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# USAMRMC Strategic Process



### **Vision and Mission**

# Vision

UTTING EDGE RESEARCH

Transform healthcare for FUNDING GROUNDBREAKING, HIGH-IMPACT RESEARCH

## **Mission**

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

### History

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1990

1996-





- Congress appropriated \$210M to the FY93 DoD budget for a new Breast Cancer Research Program (BCRP)
- The USAMRMC was directed to manage the BCRP
- The Army sought the advice of the National Academy of Medicine (previously the Institute of Medicine [IOM]), which resulted in:
  - A two-tier review process peer and programmatic reviews
  - A new research model incorporating consumers into program policy, investment strategy, and research focus
- Since 1996, additional research programs and topics have been added by Congress and administratively managed by the CDMRP



- Centers of Excellence\*
- Trauma Clinical Research Repository

- Prostate Cancer
- Peer Reviewed Alzheimer's
- Orthotics and Prosthetics Outcomes
- Multiple Sclerosis
- Lung Cancer
- Hearing Restoration
- Duchenne Muscular Dystrophy
- Combat Readiness

- Breast Cancer

F493.94

F195

8496

F197

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Millions (\$)

1600

1400

1200

1000

800

600

400

200

0

- Alcohol and Substance Abuse Disorders

5492

E499

F198

Amyotrophic Lateral Sclerosis Defense Women's Health

F100

Epilepsy

Lupus

Osteoporosis

- Breast Cancer Research Semipostal

Institutionally Based Programs

Myeloproliferative Disorders

Peer Reviewed Cancer

Reconstructive Transplant

Tuberous Sclerosis Complex

Defense Medical R&D\*

E102

8102

FYOA

Small Business Innovation Research/Small Business Technology Transfer\* 👘 Trauma Clinical\*

E403

FIOS

F106

F407

Autism

Melanoma

National Prion

Ovarian Cancer

Spinal Cord Injury

Vision

F108

Chronic Myelogenous Leukemia

Genetic Studies of Food Allergies

Deployment Related Medical

Joint Warfighter Medical

Peer Reviewed Medical

Defense Medical R&D CSI Restoral\*

F109

8120

FAIT

AN1

A13

FILA

FAIS

Bone Marrow Failure

Chronic Pain

DOD/VA Medical

Gulf War Illness

Kidney Cancer

Military Burn

Parkinson's

Neurofibromatosis

Tick-Borne Disease

Vision Prosthesis\*

Peer Reviewed Orthopaedic

Armed Forces Institute of Regenerative Medicine II\*

Psychological Health/Traumatic Brain Injury\*

F176

FUL

FY18\*

412

Additional Supported

DoD Programs/Projects

\*FY18/\*FY19 Approximate

funding of

**CDMRP** Funding History

CDMR

### **A Major Funder**

- The CDMRP is THE leading U.S. funder for Neurofibromatosis-specific research
- The CDMRP is the 2nd largest U.S. funder for research in:
  - Breast cancer

CUTTING EDGE RESEARCH

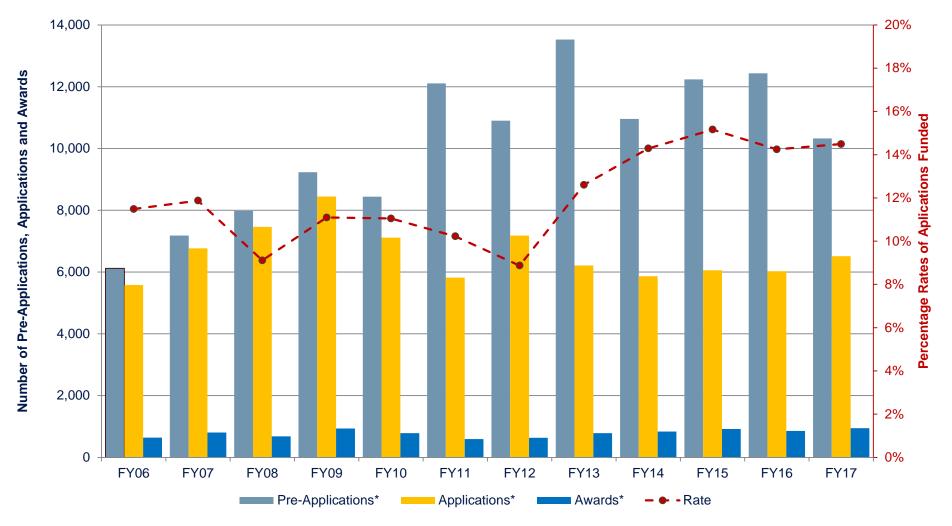
- Prostate cancer
- Ovarian cancer
- Lung cancer
- Gulf War Illness
- Tuberous Sclerosis
   Complex





### FY06 – FY17 Funding Rate

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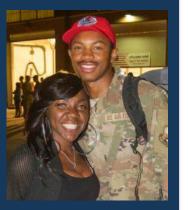


### Hallmarks



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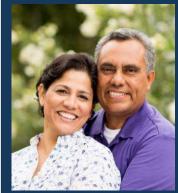
- Targeted research funds are added to the DoD budget by Congress
- Funds high-impact innovative research
- Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- Follows the National Academy of Medicinerecommended model for application review
- **Consumers participate throughout the process**
- 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 intent of mechanism, and relative impact, in addition to technical merit











### **Unique Partnerships**

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### Consumers



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Grassroots consumer efforts led to targeted research funding and the creation of the CDMRP. The voices and experiences of consumers plays a pivotal role in the growth of CDMRP research programs

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



### **FY19 Funding**

Program	\$M
Alcohol and Substance Abuse Disorders	\$4.0
Amyotrophic Lateral Sclerosis	\$10.0
Autism	\$7.5
Bone Marrow Failure	\$3.0
Breast Cancer	\$130.0
Breast Cancer Research Semipostal	\$0.6
Combat Readiness*	\$15.0
Chronic Pain"	\$10.0
Duchenne Muscular Dystrophy	\$3.2
Epilepsy	\$7.5
Gulf War Illness	\$22.0
Hearing Restoration	\$10.0
Joint Warfighter Medical	\$50.0
Kidney Cancer	\$20.0
Lung Cancer	\$14.0
Lupus	\$5.0
Melanoma*	\$10.0
Military Burn	\$8.0
Multiple Sclerosis	\$6.0
Neurofibromatosis	\$15.0

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Program	\$M
Orthotics and Prosthetics Outcomes	\$10.0
Ovarian Cancer	\$20.0
Parkinson's	\$16.0
Peer Reviewed Alzheimer's	\$15.0
Peer Reviewed Cancer (15 Topics)	\$90.0
Peer Reviewed Medical (49 Topics)	\$350.0
Peer Reviewed Orthopaedic	\$30.0
Prostate Cancer	\$100.0
Reconstructive Transplant	\$12.0
Spinal Cord Injury	\$30.0
Tick-Borne Disease	\$5.0
Tuberous Sclerosis Complex	\$6.0
Vision	\$20.0
Additional Supported DoD Programs/Proje	cts <sup>(1)</sup>
Armed Forces Institute of Regenerative Medicine II	TBD
Defense Medical R&D	\$299.2
Psychological Health and Traumatic Brain Injury	\$125.0
Small Business Innovation Research/Small Business Technology Transfer	TBD
Trauma Clinical	\$10.0

(\*) New for FY19 (1) Approximate funding of Additional Support DoD Programs/Projects

#### **TOTAL = \$1.4B**

CDI

Department of De

## CUTTING EDGE RESEARCH FY19 Topic Areas for CDI Peer Reviewed Cancer Research (15 total)

- Bladder Cancer
- Blood Cancer
- Brain Cancer
- Cancer in Children, Adolescents and Young Adults
- Colorectal Cancer
- Immunotherapy
- Listeria-based Regimens for Cancer
- Liver Cancer
- Lymphoma
- Mesothelioma
- Neuroblastoma
- Pancreatic Cancer
- Pediatric Brain Tumors
- Rare Cancers\*
- Stomach Cancer

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

Funds may not be used for research into breast, kidney, lung, ovarian, or prostate cancer

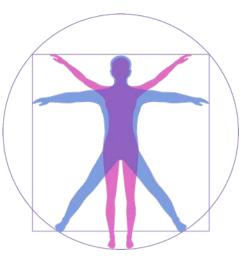
> Research programs must be relevant to Service Members, their Families, Veterans, and other military beneficiaries

## CUTTING EDGE RESEARCH FY19 Topic Areas for CDM Peer Reviewed Medical Research (49 total)

- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- Cardiomyopathy
- Cerebellar Ataxia
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Eating Disorders
- Emerging Infectious Diseases
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Frontotemporal Degeneration
- Guillain-Barre Syndrome
- Hemorrhage Control\*
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Immunomonitoring of Intestinal Transplants
- Inflammatory Bowel Disease
- Interstitial Cystitis

- Lung Injury\*
- Metals Toxicology
- Mitochondrial Disease
- Musculoskeletal Disorders
- Myotonic Dystrophy
- Nanomaterials for Bone Regeneration\*
- Nutrition Optimization
- Pancreatitis
- Pathogen-Inactivated Blood Products
- Polycystic Kidney Disease\*
- Post-Traumatic Osteoarthritis
- Pressure Ulcers
- Pulmonary Fibrosis
- Resilience Training\*
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Spinal Muscular Atrophy
- Tinnitus
- Tissue Regeneration
- Tuberculosis
- Vascular Malformations
- Women's Heart Disease

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



#### <sup>(\*)</sup> New for FY19

#### CUTTING EDGE RESEARCH FY19 Additional Supported DoD Programs/Projects Program Area Directorates/Joint Program Committees



#### Medical Simulation and Information Sciences

- Health Information Sciences
- Medical Modeling, Simulation, and Training
- Health Information Technology and Informatics

#### **Combat Casualty Care**

- Battlefield Resuscitation for Immediate Stabilization of Combat Causalities
- En Route Care
- Prolong Field Care
- Neurotrauma

#### **Military Infectious Diseases**

Bacterial Diseases

#### **Military Operational Medicine**

- Environmental Health and Protection
- Injury Prevention and Reduction
- Physiological Health and Performance
- Psychological Health and Resilience

#### **Radiation Health Effects**

 Biomedical Technology for Radiation Medical Countermeasures

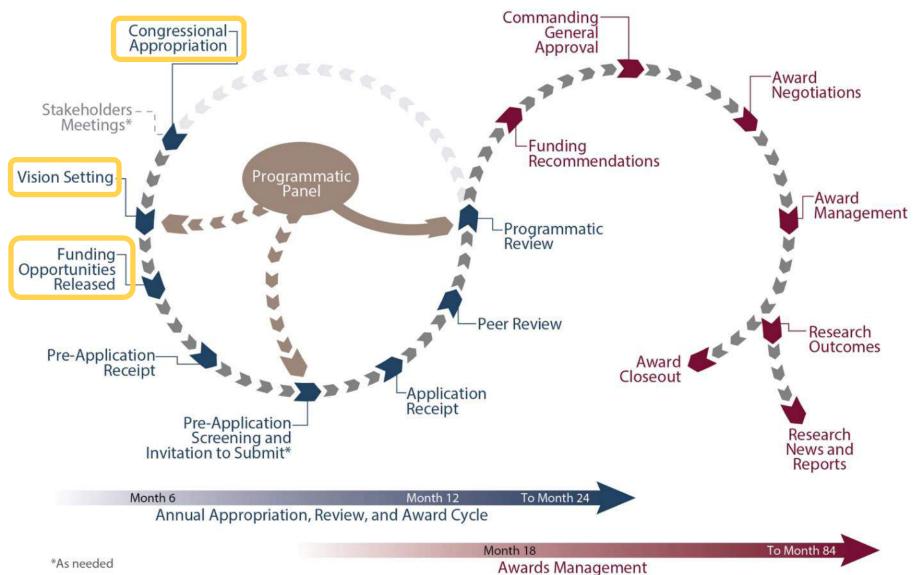
#### **Clinical and Rehabilitative Medicine**

- Neuromusculoskeletal Injury Rehabilitation
- Pain Management
- Regenerative Medicine
- Sensory System Traumatic Injury (visual, auditory and vestibular dysfunction)



### **Program Cycle**

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### **Vision Setting**

At 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

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 Portfolio composition







### **Award Mechanisms Pipeline**

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### **Research Awards**

#### **Closing gaps through innovative and impactful research**



### **Researcher Development**

Funding for all career stages



### **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

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- Panels comprised of scientific and consumer reviewers
- No standing panels
- Reviewers are recruited based on expertise needed
- Identities are unknown to applicants; contact between applicants and reviewers are not permitted



### Outcome: Summary Statements



# Second Tier: Programmatic Review

#### How the evaluation process works

- Comparison-based
- Strong scientific merit
- Adherence to award mechanism's intent
- Potential for impact
- Program relevance
- Consideration of portfolio composition

#### Programmatic reviewers

- Programmatic Panel members comprised of consumers, clinicians, and researchers
- Ad hoc reviewers



### Outcome: Funding Recommendations

### The Congressionally Directed Medical Research Programs

Panel 1: CDMRP Funding Opportunities/Lessons Learned

#### Angel Davey, Ph.D. Program Manager, CDMRP





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### **Funding Opportunities**

#### Numerous types of award mechanisms

- Tailored to the goals of each program
- May vary from year to year

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 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

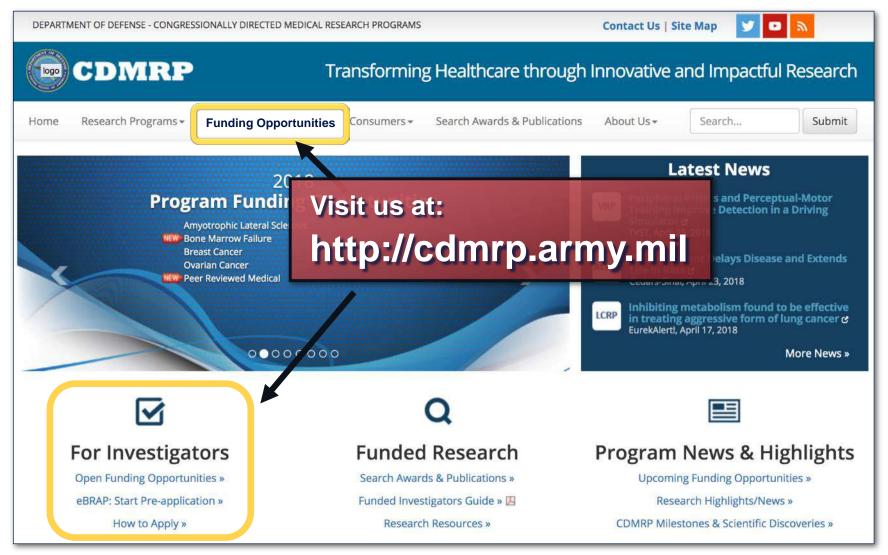
#### Funding opportunity postings

- Grants.gov (CFDA 12.420)
- electronic Biomedical Research Application Portal (eBRAP) system
- CDMRP website
- FedBizOps.gov (BAAs)





## CUTTING EDGE RESEARCH Funding Opportunities on the CDMRP Website





## CUTTING EDGE RESEARCH Synopses of Program Award Mechanisms

#### The CDMRP website provides a brief description and key elements of the current award mechanisms offered

Fiscal Year 2018 (FY18) Amyotrophic Lateral Sclerosis Research Program

 Fiscal Year 2018 (FY18) Amyotrophic Lateral Sclerosis Research Program (ALSRP) is currently accepting applications for two award mechanisms. Full details for submission:

ALSRP Funding Opportunities I Synopsis of ALSRP Award Mechanisms

#### Fiscal Year 2018 Department of Defense Amyotrophic Lateral Sclerosis Program **Reference Table of Award Mechanisms and Submission Requirements**

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadlines	
Therapeutic Development Award         Go to:         • Program Announcement         • General Application Instructions         Grants.gov Funding Opportunity         Number:         W81XWH-18-ALSRP-TDA	Independent investigators at all levels	<ul> <li>Pre-application is required; full application submission is by invitation only.</li> <li>Supports post-discovery, preclinical development of therapeutics for ALS</li> <li>Preliminary data, including identity and purity of an identified bioactive compound(s), are required</li> <li>Types of efforts that will be supported include: <ul> <li>Confirmation of candidate therapeutics obtained from screening or by other means</li> <li>Validation of lead pharmacological agents up to IND submission</li> <li>Optimization of potency and pharmacology, studies of formulation, stability, and production methods based on Good Manufacturing Practices</li> <li>Investigational New Drug (IND)-enabling studies</li> </ul> </li> </ul>	<ul> <li>Maximum period of performance is 2 years.</li> <li>Maximum funding of \$1,000,000 for direct costs for the standard award.</li> <li>Maximum funding of \$1,250,000 for direct costs for submissions under the Therapeutically Relevant Marker Option</li> <li>Indirect costs may be proposed in accordance with the institution's</li> </ul>	Pre-Application (Preproposal): June 22, 2018 5:00 p.m. Eastern time Preproposal is required; application submission is by invitation only. Application: October 11, 2018 11:59 p.m. Eastern Time	

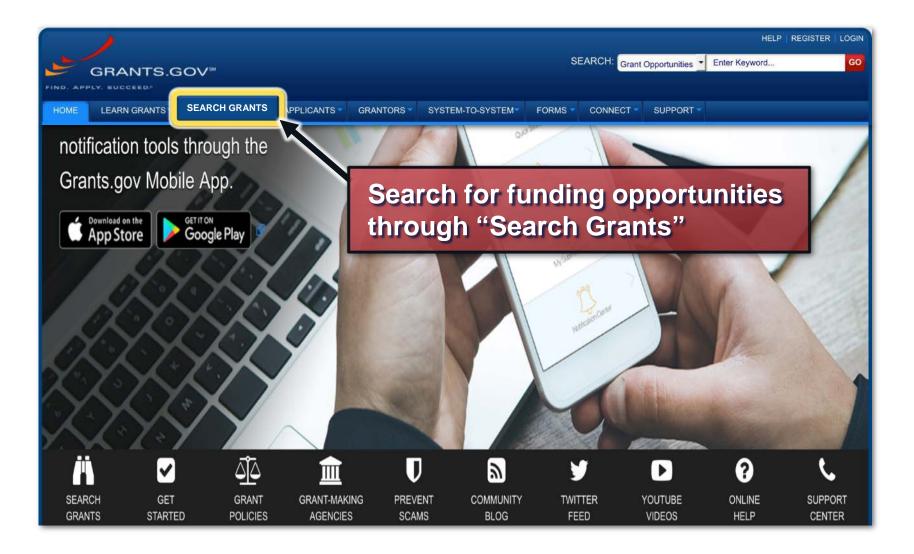


# Funding Opportunities on eBRAP

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Program News and Updates • Welcome to eBRAP. To access the user guide, please Email Subscriptions • To subscribe to program specific news and updates, pl • To remove your email from program subscription list, p Help	click here.       following conditions: -The USG r         click here.       purposes including, but not limited         defense, personnel misconduct       -At any time, the USG may inspective disclosed or used for any USG-a         lease click here       authentication and access control         blease click here       -Notwithstanding the above, usir         searching or monitoring of the corpersonal representation or service	authorized use only. By using this IS (which includes any device attached to this IS), you consent to the following conditions: -The USG routinely intercepts and monitors communications on this IS for purposes including, but not limited to, penetration testing, COMSEC monitoring, network operations a defense, personnel misconduct (PM), law enforcement (LE), and counterintelligence (CI) investigation -At any time, the USG may inspect and seize data stored on this ISCommunications using, or data stored on, this IS are not private, are subject to routine monitoring, interception, and search and may I disclosed or used for any USG-authorized purposeThis IS includes security measures (e.g., authentication and access controls) to protect USG interestsnot for your personal benefit or privacy. -Notwithstanding the above, using this IS does not constitute consent to PM, LE or CI investigative searching or monitoring of the content of privileged communications, or work product, related to personal representation or services by attorneys, psychotherapists, or clergy, and their assistants. Sur communications and work product are private and confidential. See User Agreement for details.				



# **Funding Opportunities on Grants.gov**



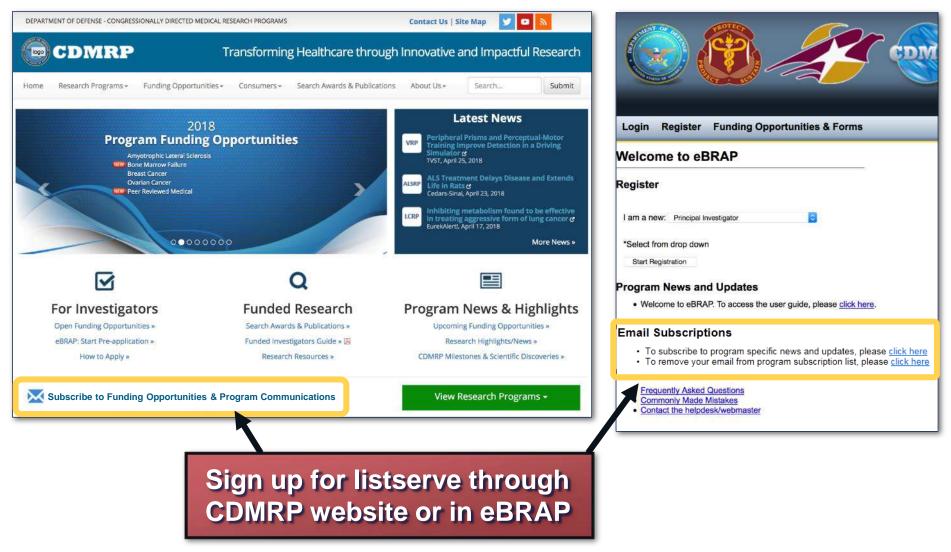
CUTTING EDGE RESEARCH Funding Opportunities on Grants.gov (cont.)

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Proc	curement Contract (2)		W81XWH18PRMRPIIRA	DoD PRMRP Investigator-Initiated Rese	earch Award	DOD- AMRAA	Posted	04/25/2018	09/20/2018
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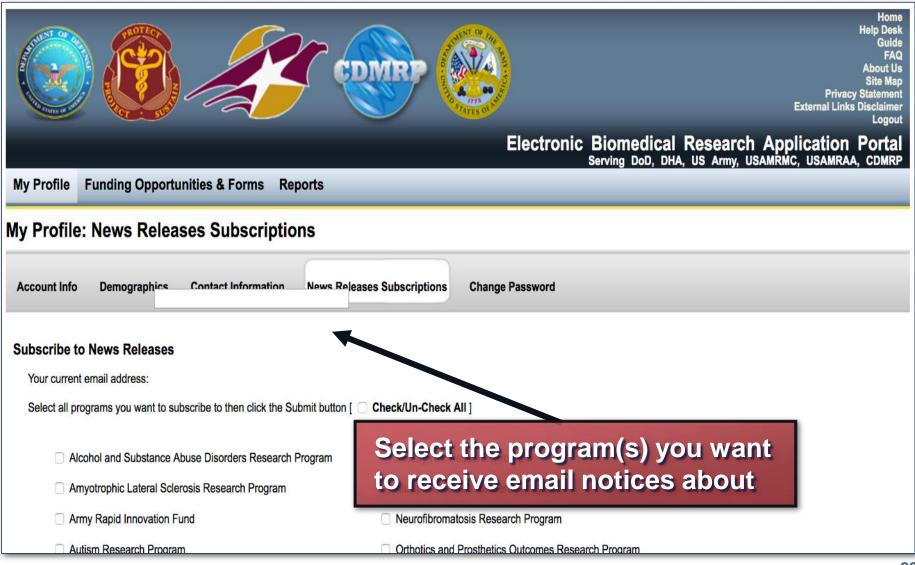


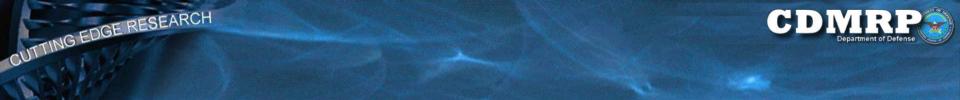
# Subscribe to Email Notifications





## CDI Subscribe to Email Notifications (cont.)





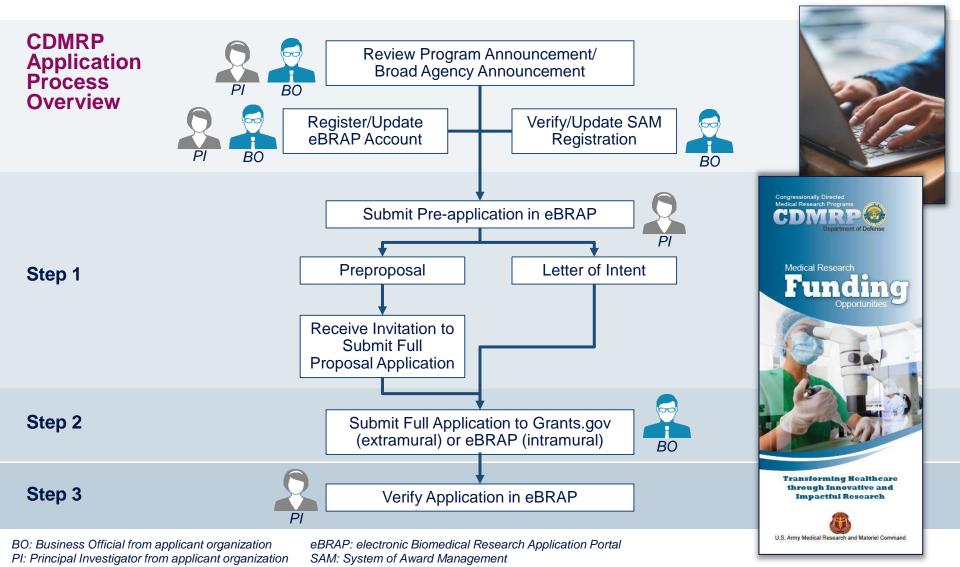
## **Lessons Learned**

### **Application Submission Process**





# Application Process Overview





### **Applying for Funding**

Understanding the <u>goals of the program</u>, <u>intent of the award mechanism</u>, and <u>review criteria</u> is critical for a successful grant application



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# The announcement (PA or BAA) contains information on:

- Program Goals
- Focus Areas
- Award Intent
- Required Elements, Eligibility, and Funding
- Review Criteria
- Deadlines

Single most important tip: <u>Read the announcement carefully</u>

### **Overview**



#### What is the timeline for submission?

#### I. OVERVIEW OF THE FUNDING OPPORTUNITY

#### Program Announcement for the Department of Defense

#### Defense Health Program

**Congressionally Directed Medical Research Programs** 

Peer Reviewed Medical Research Program

Technology/Therapeutic Development Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH18PRMRPTTDA

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 12, 2018
- Invitation to Submit an Application: July 2018
- Application Submission Deadline: 11:59 p.m. ET, September 20, 2018
- End of Application Verification Period: 5:00 p.m. ET, September 24, 2018
- Peer Review: November 2018

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• Programmatic Review: January 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20130329. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

1

DoD FY18 Peer Reviewed Medical Technology/Therapeutic Development Award

- 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

### **Program Description**

#### Does your research align with program goals?

#### **II.A.** Program Description

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Applications to the Fiscal Year 2018 (FY18) Peer Reviewed Medical Research Program (PRMRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement 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 FY17 totaled \$1.7 billion. The FY18 appropriation is \$330 million (M).

The vision of the FY18 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 FY18 PRMRP 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.

### **Topic/Focus Areas**



#### What type of research is being solicited?

#### Review the program's Topic Areas, Focus Areas, Areas of Encouragement, etc.

II.A.1. FY18 PRMRP Topic Areas

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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 FY18 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 FY18 PRMRP Topic Areas are listed below.

- "All applications for PRMRP funding must specifically address at least one of the Topic Areas..."
- "...and must be directly relevant to the healthcare needs of military Service members, Veterans, and/or beneficiaries."
- FY18 PRMRP: 53 Topic Areas spanning autoimmune disease & immunology, cardiovascular health, infectious disease, internal medicine, neurological & psychological health, orthopedic & regenerative medicine, and respiratory health



### **Topic/Focus Areas (cont.)**

**Device Development:** Develop offloading and stability devices (e.g., braces, casting) for ligamentous injuries, small extremity fractures, and/or other non-severe common battlefield musculoskeletal injuries for immediate return to duty.

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**FY18 PRARP CSRA Focus Areas:** In addition to addressing one or more of the specified FY18 PRARP CSRA Overarching Challenges, applications should address at least one of the following FY18 PRARP CSRA Focus Areas in support of the FY18 PRARP CSRA Overarching Challenges. An application that proposes research outside of the FY18 PRARP CSRA Focus Areas is acceptable, as long as the applicant provides a strong rationale:

- Mechanisms of Pathogenesis: Identification of contributing mechanisms (e.g., diffuse/ traumatic axonal injury, roles of non-neuronal cells, neuroinflammation, immune regulation, biology/pathology of tau, vascular contributions, and omics techniques for examining mechanisms) associated with TBI and subsequent AD/ADRD pathogenesis.
- Biomarkers: Development of strategies to diagnose, prognose, or characterize neurological changes or risk factors associated with TBI and subsequent AD/ADRD (e.g., fluid-based, imaging-based, physiological, and omics techniques for biomarkers).
- Epidemiological Research: Research focusing on the incidence, distribution, and other factors relating to the health of individuals affected by TBI and subsequent AD/ADRD.
- Novel Target Identification: Basic research (non-human) directly leading to the identification of new targets for the development of existing or new investigational medicines, drugs, or agents.

Some Focus Areas include detailed specifications (from FY18 PRORP)

Some PAs include both *mandatory* and *optional/ encouraged* research areas (from FY18 PRARP)

#### NOTE: Research focus can change from year to year and from PA to PA



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# **Topic/Focus Areas (cont.)**

Research relevant to one or more FY17 PRMR Applicants should select the FY17 PRMRP Pr stage of the proposed research. Areas of Enco Areas have been identified by the Department Affairs (VA), and other relevant of the proposed research of the prop

Affairs (VA), and other rel consider these Areas provided is not exist address an Are

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### APPENDIX 2: AREAS OF ENCOURAGEMENT

Applications addressing any of the FY18 PRMRP Topic Areas are of interest to the program. Any aspect of research relevant to one or more of the FY18 PRMRP Topic Areas may be considered for funding. Areas of Encouragement related to the FY18 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 lung injury (ALI)/acute respiratory distress syndrome (ARDS) caused by the host's (e.g., immune system's) responses to trauma, transfusion, burns, infection, hemorrhagic shock, inhalation, and/or oxygen exposure.
- Novel and/or innovative detection technologies or therapeutics to reduce the incidence and/or severity of ALI/ARDS and/or other lung injury secondary to trauma, transfusion, infection, burns, hemorrhagic shock, inhalation, and/or oxygen exposure.
- Strategies to stabilize and support the safe transport of patients with ALI/ARDS in order to
  optimize therapeutic interventions, particularly in operational scenarios requiring prolonged
  field care and/or longer transport times.
- Development of metrics to associate the long-term health outcomes of ALI/ARDS with
  physiological and physical performance.

### Antimicrobial Resistance

- Development of novel and/or innovative interventions, diagnostics, and treatment for multidrug-resistant pathogens, especially those that can be used in austere settings.
- Development of novel and/or innovative therapies that prevent and/or interrupt biofilm
  production in wound infections and infected hardware models.
- Development and testing of treatment protocols and/or diagnostic tests to limit prescribing
  antibiotics for conditions that are commonly viral in nature or conditions that would resolve
  themselves without antibiotic treatment (e.g., sinusitis, bronchitis, viral upper respiratory
  infections, and acute gastroenteritis).
- Development and evaluation of therapies to treat travelers' diarrhea to improve the time to clinical cure and minimize resistance acquisition.

# **Award Information**

## What are the PA-specific requirements?

### II.B. Award Information

The PRMRP Technology/Therapeutic Development Award (TTDA) 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 FY18 PRMRP Topic Areas. Products in development should be responsive to the healthcare needs of military Service members, Veterans, and/or beneficiaries.

### Award Information section includes key details such as:

- Intent: How the announcement aligns with program goals
- Type of research supported: Basic, Applied, Clinical, Team
- Definitions: "Knowledge Product," "Clinical Trial," "Proof of Concept"

### Requirements:

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- Inclusion of preliminary data
- Blinded documents
- Clinical trials prohibited, allowed, or required?
- Military relevance and alignment
- Use of active-duty military or Veteran populations; human subjects, tissues, or cadavers; animals
- Investigational New Drug/Investigational Device Exemption

# Award Information (cont.)

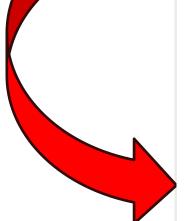
## Working with the DoD and VA

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with the DoD or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration within the FY17 PRMRP

Topic Areas can be

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n <u>Appendix 3</u>.



### APPENDIX 3 DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration within the FY17 PRMRP Topic Areas.

Air Force Office of Scientific Research http://www.wpafb.af.mil/afrl/afosr/

Air Force Research Laboratory <u>http://www.wpafb.af.mil/afrl</u>

Armed Forces Radiobiology Research Institute http://www.usuhs.edu/afrri/

Clinical and Rehabilitative Medicine Research Program https://crmrp.amedd.army.mil

Combat Casualty Care Research Program https://ccc.amedd.army.mil

Congressionally Directed Medical Research

Office of Naval Research http://www.med.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics <u>http://www.acq.osd.mil/</u>

Telemedicine and Advanced Technology Research Center http://www.tatrc.org/

Uniformed Services University of the Health Sciences http://www.usuhs.edu/research

http://www.usuns.edu/research

U.S. Army Institute of Surgical Research <u>http://www.usaisr.amedd.army.mil/</u>



# **Funding Restrictions**

## What are the funding and timeline requirements?

PAs have limits on the period of performance

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

### **II.D.5. Funding Restrictions**

The maximum period of performance is 3 years.

*Mistakes here* can put your budget over the limit

The anticipated direct costs budgeted for the entire period of performance v. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No badget will be approved by the Government exceeding **\$3M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract 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 may have a period of performance less than the maximum 3 years.



# **Submission Information**

### **CDMRP** utilizes a standard submission process

### II.D.2. Content and Form of the Application Submission

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Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

**Pre-Application Submission:** All pre-applications for both extramural and intramural organizations must be submitted through <u>eBRAP.org</u>.

**Full Application Submission:** Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through a Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in <u>Section II.C.1</u>, Eligible Applicants.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

All PAs use a twostep submission process:

(<u>1) Pre-apps</u> (Preproposal or Letter of Intent) via eBRAP

(2) Full apps via eBRAP (intramural) or Grants.gov (extramural)

# Submission Information (cont.)

# Familiarize yourself (and your BO) with eBRAP and grants.gov requirements in advance

For Both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate 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 submission deadline.

### Use the Verification Period!



# Application Submission Guidelines

#### Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions			
Application Package Location				
Download application package components for W81XWH18PRMRPFPA from Grants.gov ( <u>http://www.grants.gov</u> ) and create a Grants.gov Workspace. The Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH18PRMRPFPA from eBRAP ( <u>https://ebrap.org</u> ).			
Full Application Package Components				
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	Tab 1 – Summary: Provide a summary of the application information.         Tab 2 – Application Contacts: [This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.			
Descriptions of each required file can be found under Full Application Submission Components: <u>Attachments</u> <u>Research &amp; Related Personal Data</u> <u>Research &amp; Related Senior/Key Person Profile (Expanded)</u> <u>Research &amp; Related Budget</u> <u>Project/Performance Site Location(s) Form</u> <u>R&amp;R Subaward Budget Attachment(s) Form</u> (if applicable)	Tab 3 - Full Application Files: Upload files under each Application Component in eBRAP.         Descriptions of each required file can be found under Full Application Submission         Components:         • <u>Attachments</u> • <u>Key Personnel</u> • <u>Budget</u> • Performance Sites         Tab 4 - Application and Budget Data:         Review and edit proposed project start date,         proposed end date, and budget Form.			
Application Package Submission				
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application	Submit package components to eBRAP (https://ebrap.org). Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.			

### **Review the Full Application Guidelines** with your **BO**

- Software requirements
- Where to find application package
- Outline of components
- How to submit
- Verification guidelines



# Application Submission Checklist

#### II.H.3. Application Submission Checklist

Application Components	Action	Completee
SF424 (R&R) Application for Federal Assistance (Extramural submissions only)	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact pdf."	
	Military Relevance Statement: Upload as Attachment 7 with file name "MilRel pdf."	
	Transition Plan and Regulatory Strategy: Upload as Attachment 8 with file name "Transition.pdf."	
	Representations (Extramural submissions only): Upload as Attachment 9 with file name "MandatoryReps.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf." if applicable.	
Research and Related Personal Data	Complete as instructed.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
Research & Related Senior/Key Person Profile (Expanded)	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 (Extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification pdf) to the appropriate field.	
Budget (Intramural submissions only)	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

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







# **Pre-Application Screening**

### **Pre-Application Screening**

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• 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 background and expertise of the personnel 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 FY18 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 in <u>Section I, Overview of the Funding</u> <u>Opportunity</u>. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

Pre-application screening is done according to the criteria in the PA (typically by the Programmatic Panel)

Applicants *do not* receive feedback.

Applicants *must be invited* to submit a full application



# **Peer Review Criteria**

### II.E.1.a. Peer Review

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To determine technical merit, all applications will be evaluated according to the following scored criteria, which are listed in decreasing order of importance:

Peer Review Criteria				
Scored	Unscored			
Research S	Strategy and Feasibility Environment			
Impact	• Impact			
Transition P	<ul> <li>To what extent the project impacts a central critical problem</li> </ul>	• To what extent the project impacts a central critical problem or question in at least one		
Personnel	FY18 PRMRP Topic Area.			
	<ul> <li>If applicable, how well the proposed research project addre PRMRP Areas of Encouragement.</li> </ul>			
	<ul> <li>How the proposed research project, if successful, will make in the relevant field of research.</li> </ul>			
	<ul> <li>To what degree the proposed project could, if successful, make a significant impact on the lives of relevant patient populations in the short term and/or long term.</li> </ul>			



# Programmatic Review Criteria

### 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 FY18 PRMRP, as evidenced by the following:
  - o Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Military relevance
  - Relative impact

# Programmatic Panel membership lists are available on the CDMRP website

 Consist of scientists, clinicians, consumers, and program staff from a wide variety of representative organizations





# **Administrative Actions**

### II.H.2.a. Rejection

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The following will result in administrative rejection of the pre-ap

Preproposal Narrative is missing.

The following will result in administrative rejection of the applic

- · Submission of an application for which a letter of invitation v
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding program and fiscal year. Refer to <u>Section II.D. Application a</u> exceptions.
- Partnering PI Option: Failure to submit both associated (In applications by the deadline.

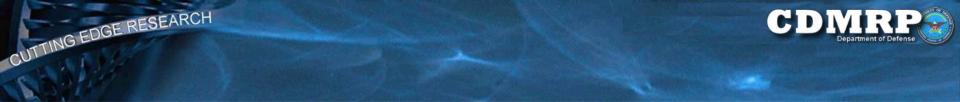
### II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to r than the Project Narrative.
- Documents not requested will be removed.

#### II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY18 PRMRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY18 PRMRP Programmatic Panel members can be found at http://cdmrp.army.mil/prmrp/panels/panels18.
- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<u>http://cdmrp.army.mil/about/2tierRevProcess</u>). 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The proposed research project does not address at least one of the Congressionally directed FY18 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.



# Panel Discussion of Experiences with CDMRP Peer Review and Grants



# The Congressionally Directed Medical Research Programs



### Angel Davey, Ph.D. Program Manager, CDMRP





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

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### CDNIRP Department of Defense

# **Strategies for Success**

# ✓ Relevance

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- Address PROGRAM-SPECIFIC GOALS
- Align the proposed work with specific guidance from the announcement

# ✓ Impact

- Propose SOLUTIONS to important problems
- Clearly articulate TRANSLATABILITY how will this work make a difference?

# Innovation

Identify gap(s) that will be filled and NOVEL APPROACHES used to accelerate progress

# 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 (cont.)

## 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



# Military Relevance and Impact

# Targeting your research to address military-relevant biomedical research and healthcare needs

## Research and communication

- Funding opportunity announcements
- Publications identifying gaps/needs
- Know your audience: stakeholders/users
- Websites
- Collaboration

# Building collaborations with DoD researchers

## Process isn't unique

- Use your professional networks
- Contact corresponding author in publications
- Attend meetings with military-relevant topics

# Resources



Below is a list of websites that may be useful in identifying additional information about DoD areas of research interest, ongoing research, or potential opportunities for collaboration.

Air Force Office of Scientific Research http://www.wpafb.af.mil/afrl/afosr/ **Air Force Research Laboratory** http://www.wpafb.af.mil/afrl **Armed Forces Radiobiology Research** Institute http://www.usuhs.edu/afrri/ **Clinical and Rehabilitative Medicine Research Program** https://crmrp.amedd.army.mil **Combat Casualty Care Research** Program https://ccc.amedd.armv.mil **Congressionally Directed Medical Research Programs** http://cdmrp.armv.mil **Defense Advanced Research Projects** Agency http://www.darpa.mil/ **Defense Technical Information Center** http://www.dtic.mil **Defense Threat Reduction Agency** http://www.dtra.mil/ Military Infectious Diseases Research Program https://midrp.amedd.armv.mil

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**Military Operational Medicine Research Program** https://momrp.amedd.armv.mil Naval Health Research Center http://www.med.navv.mil/sites/nhrc Navy and Marine Corps Public Health Center http://www.nmcphc.med.navy.mil/ Office of Naval Research http://www.med.navv.mil/ Office of the Under Secretary of Defense for Acquisition, Technology and Logistics http://www.acg.osd.mil/ **Telemedicine and Advanced Technology Research Center** http://www.tatrc.org/ **Uniformed Services University of the Health Sciences** http://www.usuhs.edu/research U.S. Army Institute of Surgical Research http://www.usaisr.amedd.army.mil/ **U.S. Army Research Institute of Environmental Medicine** 

http://www.usariem.army.mil/

# U.S. Army Medical Research Institute of Infectious Diseases

### http://www.usamriid.army.mil/

U.S. Army Medical Research and Materiel Command

http://mrmc.amedd.army.mil

**U.S. Army Research Laboratory** 

http://www.arl.army.mil

U.S. Department of Defense Blast Injury Research Program

https://blastinjuryresearch.amedd.army.mil/

**U.S. Naval Research Laboratory** 

http://www.nrl.navy.mil Walter Reed Army Institute of Research http://www.wrair.army.mil/

# Military Health System Research Symposium

https://mhsrs.amedd.army.mil/SitePages/H ome.aspx



# **Planning for Translation**

### Focus on the end product

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Think about both the civilian and military markets
 Have realistic expectations for where the product fits within the civilian and military health systems

Include stakeholders and end users early in the process
 Should facilitate community integration

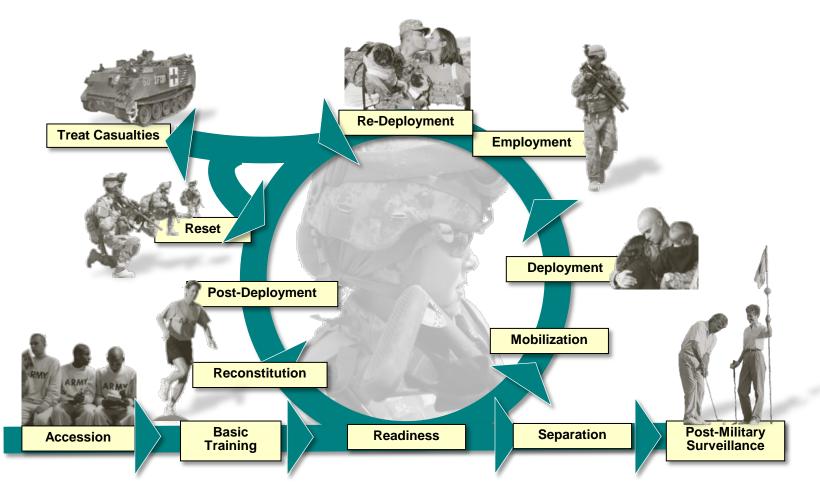
Work with your local tech transfer team. Make sure your development plan is feasible and has realistic timelines

Know the intellectual property ownership status (past, present, future)

It is never too early to talk with the FDA

Make progress by ensuring your research is rigorous and reproducible
 Sample size calculations, link models to human condition, use statisticians

CDM Military Medical Research Impacts the Service Member, Their Family, and Their Community



**DEVELOPING AND MAINTAINING A FIT AND READY FORCE** 



# Panel Discussion of Developing and Submitting Proposals

