WHO is the CDMRP?

Department of Defense

Department of the Army

Army Materiel Command

U.S. Army Medical Research and Materiel Command (USAMRMC)

Congressionally Directed Medical Research Programs
USAMRMC Strategic Process

Core Outcomes

- Fielded Medical Knowledge
- Fielded Medical Materiel

Core Programs

- Research to produce medical knowledge
- RESEARCH & DEVELOPMENT Medical Research & Technology Program
- DEVELOPMENT & ACQUISITION Medical Advanced Development Program
- ACQUISITION & LOGISTICS Medical Logistics Program

CSI Programs

- Congressional Special Interest (CSI) Programs

Outcomes

- Targeted Outcomes

Programs directed by Congress
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 health care solutions for Service Members, Veterans and the American public
History

- In 1992, grassroots efforts heightened political awareness of breast cancer
- 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
CDMRP Funding History

Millions ($)

- Alcohol and Substance Abuse Disorders
- Breast Cancer
- Combat Readiness
- Duchenne Muscular Dystrophy
- Hearing Restoration
- Lung Cancer
- Multiple Sclerosis
- Orthotics and Prosthetics Outcomes
- Peer Reviewed Alzheimer’s
- Prostate Cancer
- Trauma Clinical Research Repository
- Centers of Excellence*
- Rapid Innovation Fund*
- Amyotrophic Lateral Sclerosis
- Breast Cancer/Research Semintrial
- Defense Women's Health
- Epilepsy
- Institutionally Based Programs
- Lupus
- Myeloproliferative Disorders
- Osteoporosis
- Peer Reviewed Cancer
- Reconstructive Transplant
- Tuberous Sclerosis Complex
- Defense Medical R&D*
- Small Business Innovation Research/Small Business Technology Transfer*
- Autism
- Chronic Myelogenous Leukemia
- Deployment Related Medical
- Genetic Studies of Food Allergies
- Joint Warrior Medical
- Melanoma
- National Prion
- Ovarian Cancer
- Peer Reviewed Medical
- Spinal Cord Injury
- Vision
- Defense Medical R&D C/S Restoral*
- Trauma Clinical*
- Bone Marrow Failure
- Chronic Pain
- DOD/VA Medical
- Gulf War Illness
- Kidney Cancer
- Military Burn
- Neurofibromatosis
- Parkinson’s
- Peer Reviewed Orthopaedic
- Tick-Borne Disease
- Armed Forces Institute of Regenerative Medicine II*
- Psychological Healthy Traumatic Brain Injury*
- Vision Prosthesis*

*FY18 / FY19 Approximate funding of Additional Supported DoD Programs/Projects
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
  - Prostate cancer
  - Ovarian cancer
  - Lung cancer
  - Gulf War Illness
  - Tuberous Sclerosis Complex
FY06 – FY17 Funding Rate

Percentage Rates of Applications Funded

Number of Pre-Applications, Applications, and Awards

Pre-Applications*, Applications*, Awards*, Rate
Hallmarks

- 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 Medicine-recommended 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

**Consumers**
- Demonstrate need
- Participate at all levels
- Bring passion and perspective

**Congress**
- Adds funds to budget
- Provides targeted guidance

**Researchers**
- Focuses on innovation and research gaps
- Risk/benefit
- Product-oriented

**DoD**
- Oversees program management
- Contracting actions
- Regulatory requirements
Grassroots consumer efforts led to targeted research funding and the creation of the CDMRP. The voices and experiences of consumers play 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

<table>
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<tr>
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<td>Amyotrophic Lateral Sclerosis</td>
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<td>Autism</td>
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<td>Bone Marrow Failure</td>
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<td>Breast Cancer</td>
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<td>Combat Readiness*</td>
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<tr>
<td>Chronic Pain*</td>
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<tr>
<td>Duchenne Muscular Dystrophy</td>
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<td>Epilepsy</td>
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<td>Gulf War Illness</td>
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<tr>
<td>Hearing Restoration</td>
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<tr>
<td>Joint Warfighter Medical</td>
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<td>Kidney Cancer</td>
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<td>Lupus</td>
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<td>Melanoma*</td>
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<tr>
<td>Military Burn</td>
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<tr>
<td>Multiple Sclerosis</td>
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<tr>
<td>Neurofibromatosis</td>
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<table>
<thead>
<tr>
<th>Program</th>
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<tr>
<td>Orthotics and Prosthetics Outcomes</td>
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<td>Ovarian Cancer</td>
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<td>Parkinson's</td>
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<td>Peer Reviewed Cancer (15 Topics)</td>
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<td>Peer Reviewed Medical (49 Topics)</td>
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<td>Tuberous Sclerosis Complex</td>
<td>$6.0</td>
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<tr>
<td>Vision</td>
<td>$20.0</td>
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</table>

Additional Supported DoD Programs/Projects (1)

- 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

TOTAL = $1.4B

(1) New for FY19  (1) Approximate funding of Additional Support DoD Programs/Projects
FY19 Topic Areas for 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.

(*) New for FY19
FY19 Topic Areas for 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

(*) New for FY19

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

Radiation Health Effects
- Biomedical Technology for Radiation Medical Countermeasures

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

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

1. Congressionl Appropriation
2. Vision Setting
3. Funding Opportunities Released
4. Stakeholders Meetings*
5. Program Panel
6. Pre-Application Receipt
7. Pre-Application Screening and Invitation to Submit*
8. Application Receipt
9. Programmatic Review
10. Peer Review
11. Funding Recommendations
12. Commanding General Approval
13. Award Negotiations
14. Award Management
15. Research Outcomes
16. Research News and Reports
17. Award Closeout
18. Annual Appropriation, Review, and Award Cycle
19. Month 6
20. Month 12
21. To Month 24
22. Month 18
23. To Month 84

*As needed
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
- Portfolio composition
Award Mechanisms Pipeline

Research Awards
Closing gaps through innovative and impactful research

- Initial Concepts
- Early Ideas
- Clinical/Translational
- Team Science
- Clinical Trials
- Predoctoral
- Postdoctoral
- Physician Scientist
- New Investigator
- Established Investigator

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
  ❖ 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

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.
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 (CFDA 12.420)
  - electronic Biomedical Research Application Portal (eBRAP) system
  - CDMRP website
  - FedBizOps.gov (BAAs)
Funding Opportunities on the CDMRP Website

Visit us at:
http://cdmrp.army.mil
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 | Synopsis of ALSRP Award Mechanisms

### Fiscal Year 2018 Department of Defense Amyotrophic Lateral Sclerosis Program

**Reference Table of Award Mechanisms and Submission Requirements**

<table>
<thead>
<tr>
<th>Award Mechanism</th>
<th>Eligibility</th>
<th>Key Mechanism Elements</th>
<th>Funding</th>
<th>Submission Deadlines</th>
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<tr>
<td>Therapeutic Development Award</td>
<td>Independent investigators at all levels</td>
<td>- Pre-application is required; full application submission is by invitation only.</td>
<td>- Maximum period of performance is 2 years.</td>
<td>Pre-Application</td>
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<tr>
<td>Go to:</td>
<td></td>
<td>- Supports post-discovery, preclinical development of therapeutics for ALS</td>
<td>- Maximum funding of $1,000,000 for direct costs for the standard award.</td>
<td>(Preproposal):</td>
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<tr>
<td></td>
<td></td>
<td>- Preliminary data, including identity and purity of an identified bioactive compound(s), are required</td>
<td>- Maximum funding of $1,250,000 for direct costs for submissions under the</td>
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<td></td>
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<td>Types of efforts that will be supported include:</td>
<td>Therapeutically Relevant Marker Option</td>
<td>5:00 p.m. Eastern</td>
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<td></td>
<td></td>
<td>o Confirmation of candidate therapeutics obtained from screening or by other means</td>
<td>Indirect costs may be proposed in accordance with the institution’s</td>
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<td></td>
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<td>o Validation of lead pharmacological agents up to IND submission</td>
<td>requirements</td>
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<td></td>
<td></td>
<td>o Optimization of potency and pharmacology, studies of formulation, stability, and production methods based on Good Manufacturing Practices</td>
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<td></td>
<td></td>
<td>o Investigational New Drug (IND)-enabling studies</td>
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<tr>
<td>Grants.gov Funding Opportunity Number:</td>
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<td>W81XWH-18-ALSRT-TDA</td>
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Visit the Electronic Biomedical Research Application Portal at: https://ebrap.org
Funding Opportunities on Grants.gov

Search for funding opportunities through “Search Grants”
**SEARCH GRANTS**

**BASIC SEARCH CRITERIA:**
- **CFDA**
  - CFDA Number: 12.420

**OPPORTUNITY STATUS:**
- Forecasted (0)
- Posted (23)
- Closed (1)
- Archived (757)

**FUNDING INSTRUMENT TYPE:**
- All Funding Instruments
  - Cooperative Agreement (23)
  - Grant (23)
  - Procurement Contract (2)

**ELIGIBILITY:**
- All Eligibilities
  - Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled 'Additional Information on Eligibility' (23)

**SORT BY:**
- Posted Date (Descending)

**DATE RANGE:**
- All Available

**MATCHING RESULTS:**
<table>
<thead>
<tr>
<th>Opportunity Number</th>
<th>Opportunity Title</th>
<th>Agency</th>
<th>Opportunity Status</th>
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**Search Grants by CFDA# 12.420 for USAMRMC opportunities**
Subscribe to Email Notifications

Sign up for listserve through CDMRP website or in eBRAP
Subscribe to Email Notifications (cont.)

My Profile: News Releases Subscriptions

Subscribe to News Releases

Your current email address:

Select all programs you want to subscribe to then click the Submit button [☐ Check/Un-Check All]

- ☐ Alcohol and Substance Abuse Disorders Research Program
- ☐ Amyotrophic Lateral Sclerosis Research Program
- ☐ Army Rapid Innovation Fund
- ☐ Autism Research Program
- ☐ Neurofibromatosis Research Program
- ☐ Orthotics and Prosthetics Outcomes Research Program

Select the program(s) you want to receive email notices about
Application Process Overview

CDMRP Application Process Overview

Step 1
- Register/Update eBRAP Account
- Verify/Update SAM Registration
- Submit Pre-application in eBRAP
  - Preproposal
  - Letter of Intent
- Receive Invitation to Submit Full Proposal Application

Step 2
- Submit Full Application to Grants.gov (extramural) or eBRAP (intramural)

Step 3
- Verify Application in eBRAP

BO: Business Official from applicant organization
PI: Principal Investigator from applicant organization
eBRAP: electronic Biomedical Research Application Portal
SAM: System of Award Management
Applying for Funding

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

◆ 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: Read the announcement carefully
Overview

What is the timeline for submission?

- 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
II.A. Program Description

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 (OASC[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.
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

“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
**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.

**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.

**NOTE:** Research focus can change from year to year and from PA to PA
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:**
  - 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 PRMARP Topic Areas can be found in Appendix 3.

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 PRMARP Topic Areas.

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

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

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

Clinical and Rehabilitative Medicine Research Program
https://cramr.amedda.army.mil

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

Congressionally Directed Medical Research Programs
http://www.cdmrp.osd.mil

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

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
http://www.acq.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/
II.D.5. Funding Restrictions

The maximum period of performance is 3 years.

The anticipated direct costs budgeted for the entire period of performance will be approved by the Government. If indirect cost rates have been negotiated, 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 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.

Mistakes here can put your budget over the limit
All PAs use a two-step submission process:

(1) Pre-apps (Preproposal or Letter of Intent) via eBRAP

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

*BO = Business Official
### Application Submission Guidelines

**Table 1. Full Application Submission Guidelines**

<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Package Location</strong></td>
<td></td>
</tr>
<tr>
<td>Download application package components for W81XWH18PRMRFPFA from Grants.gov (<a href="http://www.grants.gov">http://www.grants.gov</a>) 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.</td>
<td>Download application package components for W81XWH18PRMRFPFA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</td>
</tr>
</tbody>
</table>

**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.
- **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:
  - **Attachments**
  - **Research & Related Personal Data**
  - **Research & Related Senior/Key Person Profile (Expanded)**
  - **Research & Related Budget**
  - **Project Performance Site Location(s) Form**
  - **R&R Subaward Budget Attachment(s) Form** (if applicable)
- **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
- **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/Controller/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**
Detailed guidance is provided in the PA for the contents of these sections.

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

### Application Submission Checklist

<table>
<thead>
<tr>
<th>Application Component</th>
<th>Action</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-424 (R&amp;R) Application for Federal Assistance (Extramural submissions only)</td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
<tr>
<td>Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)</td>
<td>Complete these tabs as instructed.</td>
<td></td>
</tr>
<tr>
<td>Attachments</td>
<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf”</td>
<td></td>
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<tr>
<td></td>
<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf”</td>
<td></td>
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<tr>
<td></td>
<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf”</td>
<td></td>
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<tr>
<td></td>
<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf”</td>
<td></td>
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<tr>
<td></td>
<td>Impact Statement: Upload as Attachment 6 with file name “Impact.pdf”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Military Relevance Statement: Upload as Attachment 7 with file name “MiliRel.pdf”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transition Plan and Regulatory Strategy: Upload as Attachment 8 with file name “Transition.pdf”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Representations (Extramural submissions only): Upload as Attachment 9 with file name “MandatoryReps.pdf”, if applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DoD Military Budget Form(s): Upload as Attachment 10 with file name “MFBudget.pdf”, if applicable</td>
<td></td>
</tr>
<tr>
<td>Research and Related Personal Data</td>
<td>Complete as instructed.</td>
<td></td>
</tr>
<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach PI Previous/Current Pending Support (Support_LastName.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Previous/Current Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td>Budget (Extramural submissions only)</td>
<td>Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td>Budget (Intramural submissions only)</td>
<td>Complete the DoD Military Budget Form and justification.</td>
<td></td>
</tr>
<tr>
<td>Project/Performance Site Location(s) Form</td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
<tr>
<td>R&amp;R Subaward Budget Attachment(s) Form, if applicable</td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
</tbody>
</table>
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 rationales, 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 Section I, Overview of the Funding Opportunity. 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
II.E.1.a. Peer Review

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

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

- **Impact**
  - To what extent the project impacts a central critical problem or question in at least one FY18 PRMRP Topic Area.
  - If applicable, how well the proposed research project addresses one or more FY18 PRMRP Areas of Encouragement.
  - How the proposed research project, if successful, will make important scientific advances in the relevant field of research.
  - 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.
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 PRMRC, as evidenced by the following:
  - 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
II.H.2.a. Rejection

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

- Preproposal Narrative is missing.
- 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, programs, and/or fiscal years. Refer to Section II.D. Application and Submission Exceptions.
- Partnering PI Option: Failure to submit both associated (individual) applications by the deadline.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review.
- 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 PRMMP 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 PRMMP Programmatic Panel members can be found at [http://cdmrp.army.mil/prmrp/panels/panels18](http://cdmrp.army.mil/prmrp/panels/panels18)
- The application fails to conform to this Program Annoucement 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 ([http://cdmrp.army.mil/about/2tierRevProcess](http://cdmrp.army.mil/about/2tierRevProcess)). 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 PRMMP 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 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.
Strategies for Success

✓ Relevance

- 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.

<table>
<thead>
<tr>
<th>Website</th>
<th>Department / Research Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Force Office of Scientific Research</td>
<td>Air Force</td>
</tr>
<tr>
<td>Air Force Research Laboratory</td>
<td>Air Force</td>
</tr>
<tr>
<td>Armed Forces Radiobiology Research Institute</td>
<td>Military Health</td>
</tr>
<tr>
<td><a href="http://www.usuhs.edu/afrri/">http://www.usuhs.edu/afrri/</a></td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Clinical and Rehabilitative Medicine Research Program</td>
<td></td>
</tr>
<tr>
<td><a href="https://crmrp.amedd.army.mil">https://crmrp.amedd.army.mil</a></td>
<td>Military Health</td>
</tr>
<tr>
<td>Combat Casualty Care Research Program</td>
<td>Program Research Program</td>
</tr>
<tr>
<td><a href="https://ccc.amedd.army.mil">https://ccc.amedd.army.mil</a></td>
<td></td>
</tr>
<tr>
<td>Congressionally Directed Medical Research Programs</td>
<td>Military Health</td>
</tr>
<tr>
<td><a href="http://cdmrp.army.mil">http://cdmrp.army.mil</a></td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Defense Advanced Research Projects Agency</td>
<td>Military Health</td>
</tr>
<tr>
<td>Defense Technical Information Center</td>
<td>Military Health</td>
</tr>
<tr>
<td><a href="http://www.dtic.mil">http://www.dtic.mil</a></td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Defense Threat Reduction Agency</td>
<td>Military Health</td>
</tr>
<tr>
<td>Military Infectious Diseases Research Program</td>
<td>Military Health</td>
</tr>
<tr>
<td><a href="https://midrp.amedd.army.mil">https://midrp.amedd.army.mil</a></td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Military Operational Medicine Research Program</td>
<td>Military Health</td>
</tr>
<tr>
<td><a href="https://momrp.amedd.army.mil">https://momrp.amedd.army.mil</a></td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Naval Health Research Center</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Navy and Marine Corps Public Health Center</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Office of Naval Research</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Office of the Under Secretary of Defense for Acquisition, Technology</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>and Logistics</td>
<td></td>
</tr>
<tr>
<td>Telemedicine and Advanced Technology Research Center</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Uniformed Services University of the Health Sciences</td>
<td>Program Research Program</td>
</tr>
<tr>
<td><a href="http://www.usuhs.edu/research">http://www.usuhs.edu/research</a></td>
<td></td>
</tr>
<tr>
<td>U.S. Army Institute of Surgical Research</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>U.S. Army Medical Research Institute of Infectious Diseases</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>U.S. Army Research Laboratory</td>
<td>Program Research Program</td>
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<tr>
<td><a href="http://www.arl.army.mil">http://www.arl.army.mil</a></td>
<td></td>
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<tr>
<td>U.S. Department of Defense Blast Injury Research Program</td>
<td>Program Research Program</td>
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<tr>
<td><a href="https://blastinjuryresearch.amedd.army.mil/">https://blastinjuryresearch.amedd.army.mil/</a></td>
<td></td>
</tr>
<tr>
<td>U.S. Naval Research Laboratory</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Walter Reed Army Institute of Research</td>
<td>Program Research Program</td>
</tr>
<tr>
<td>Military Health System Research Symposium</td>
<td>Program Research Program</td>
</tr>
<tr>
<td><a href="https://mhsrs.amedd.army.mil/SitePages/Home.aspx">https://mhsrs.amedd.army.mil/SitePages/Home.aspx</a></td>
<td></td>
</tr>
</tbody>
</table>

Military Health System Research Symposium
Planning for Translation

◆ Focus on the end product

◆ 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
DEVELOPING AND MAINTAINING A FIT AND READY FORCE

Military Medical Research Impacts the Service Member, Their Family, and Their Community
Panel Discussion of Developing and Submitting Proposals