# Congressionally Directed Medical Research Programs (CDMRP)

CDMRP Lunch and Learn Session Military Health System Research Symposium August 18, 2015







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.

GEDGE



- Overview of the CDMRP
- CDMRP Funding Opportunities
- Application Submission Process
- Application Review Process
- Other DoD Funding Opportunities





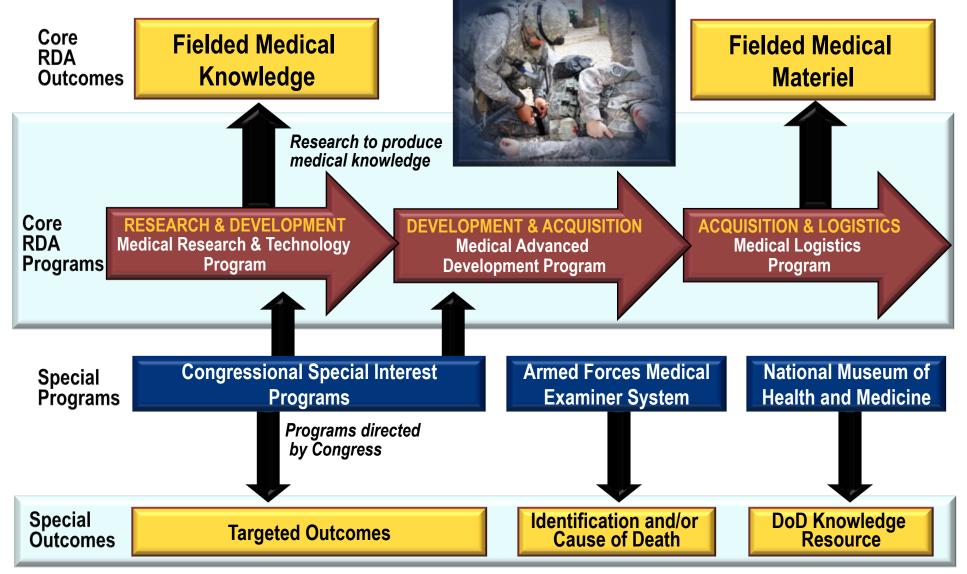
# **Overview of the CDMRP**













- In the early 1990s, grassroots advocacy efforts heightened political awareness of breast cancer
- Congress appropriated \$210M to the FY93 DoD budget for a new Breast Cancer Research Program (BCRP)
- USAMRMC was directed to manage the BCRP
- The Army sought the advice of the National Academy of Sciences Institute of Medicine (IOM), which resulted in:
  - **A two-tier review process**
  - A new model for research incorporating patient advocates into program policy, investment strategy, and research focus
- From 1996–2015, additional research programs and topics were added by Congress and USAMRMC for administrative management by CDMRP





Setting

Release of

Program

Announcement

Award Execution

(1-5 years)

Negotiations

# **The CDMRP Today**

#### CONGRESSIONAL **PROGRAMS:**

- Manages extramural research programs directed by Congress
- Started in 1992 with Breast Cancer. now 27 programs
- Congress specifies disease area, **CDMRP** determines research strategy and competitively selects the best projects
- Unique public/private partnership encompassing the military, scientists, disease survivors, consumers, and policy makers
- Fund high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

#### **DoD PROGRAMS:**

 Manage extramural and intramural portfolios for Program Area Directorates (PADs) / Joint Program Committees (JPCs) advancing their missions

#### **DIRECTOR:**



**Col Wanda Salzer** 

- Alzheimer's
- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Duchenne Muscular Dystrophy
- Gulf War Illness
- Lung Cancer
- Multiple Sclerosis
- Neurofibromatosis
- Neurotoxin Exposure Treatment 
   Reconstructive Transplant Parkinson's
- Ovarian Cancer
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Prostate Cancer
- Tuberous Sclerosis Complex

- Alcohol & Substance Abuse Disorders
- Defense Medical R & D
- Epilepsv
- · Joint Warfighter Medical
- Military Burn
- Orthotics & Prosthetics Outcomes
- Peer Reviewed Orthopaedic
- Psychological Health & Traumatic **Brain Injury**
- Spinal Cord Injury
- Vision Research



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Receipt

of Funds

Review

Programmatic

Review

Congressional

Appropriation





# **Hallmarks of the CDMRP**

- Targeted research funds added to DoD budget by Congress
- Consumer advocates participate throughout process
- IOM-recommended model for application review
- Fund highly innovative, high-impact research
- Each program's vision and investment strategy are adapted annually, allowing rapid response to changing needs
- Avoid Duplication with other funding agencies
  - \* Fills Unfunded/Unmet Gaps and Niches
- Funding flexibility
  - Funds obligated up-front; limited out-year budget commitments
  - \* Limited continuation funding
  - No "pay line;" funding recommendations based on portfolio composition, adherence to intent of mechanism, relative impact in addition to technical merit







# **CDMRP Vision and Mission**

# Vision

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

## Mission

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





# **Unique Partnerships**

#### **Advocates**

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



gaps

\* Risk/Benefit



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







# FY15 Funding Executed by CDMRP

| Program   | \$M     |  | Program  | \$M     |  |
|---|---------|--|--|---------|--|
| Alcohol and Substance Abuse   | \$4.0   |  | Neurofibromatosis                                | \$15.0  |  |
| Alzheimer's   | \$12.0  |  | Neurotoxin Exposure Treatment Parkinson's        | \$16.0  |  |
| Amyotrophic Lateral Sclerosis   | \$7.5   |  | Orthopaedic                                      | \$30.0  |  |
| Autism  | \$6.0   |  | Orthotics and Prosthetics Outcomes               | \$10.0  |  |
| Bone Marrow Failure   | \$3.2   |  | Ovarian Cancer                                   | \$20.0  |  |
| Breast Cancer   | \$120.0 |  | Peer Reviewed Cancer                             | \$50.0  |  |
| Defense Medical Research and Development*   | \$283.9 |  | Peer Reviewed Medical                            | \$247.5 |  |
| Duchenne Muscular Dystrophy   | \$3.2   |  | Prostate Cancer                                  | \$80.0  |  |
| Epilepsy  | \$7.5   |  | Psychological Health and Traumatic Brain Injury* | \$125.0 |  |
| Gulf War Illness  | \$20.0  |  | Reconstructive Transplant*                       | \$15.0  |  |
| Joint Warfighter Medical*   | \$50.0  |  | Restore Core Research Funding Reduction*         | \$179.8 |  |
| Lung Cancer   | \$10.5  |  | Spinal Cord Injury                               | \$30.0  |  |
| Military Burn   | \$8.0   |  | Tuberous Sclerosis                               | \$6.0   |  |
| Multiple Sclerosis  | \$5.0   |  | Vision   | \$10.0  |  |
| *CDMRP is assisting with the execution of a specified portion of a larger appropriation(s) TOTAL = \$1.375B |         |  |  |         |  |

## Peer Reviewed Medical Research Program<sup>tment of Defense</sup> FY15 Topic Areas

- Acupuncture
- Acute Lung Injury
- Advanced Prosthetics
- Arthritis
- Burn Pit Exposure
- Cardiovascular Health
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Dengue
- Diabetes
- DNA Vaccine Technology for Postexposure Prophylaxis
- Dystonia
- Focal Segmental Glomerulosclerosis
- Food Allergies
- Fragile X Syndrome
- Healthcare-Acquired Infection Reduction
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Inflammatory Bowel Disease

- Integrative Medicine
- Interstitial Cystitis
- Lupus
- Malaria
- Metals Toxicology
- Mitochondrial Disease
- Nanomaterials for Bone Regeneration
- Osteoarthritis
- Pancreatitis
- Pathogen-Inactivated Dried Plasma
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Psychotropic Medications
- Pulmonary Fibrosis
- Respiratory Health
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Tinnitus
- Vascular Malformation
- Women's Heart Disease

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



# Joint Program Committees (JPCs) Department of Defense Intramural and Extramural

# Medical Simulation and Information Sciences (JPC-1)

- Medical Simulation and Training
- Health Informatics and Information Technology

#### Military Infectious Diseases (JPC-2)

Polytrauma and Blast Injury

#### Military Operational Medicine (JPC-5)

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

#### Combat Casualty Care (JPC-6)

- Hemorrhage and Resuscitation
- Joint En Route Care
- Neurotrauma
- Traumatic Tissue Injury
- Forward Surgical/Intensive Critical Care
- Military Medical Photonics

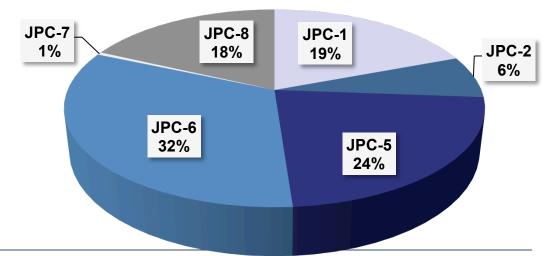
#### Radiation Health Effects (JPC-7)

 Biomedical Technology for Radiation Countermeasures

#### Clinical & Rehabilitative Medicine (JPC-8)

- Sensory Systems
- Regenerative Medicine
- Neuromusculoskeletal Injuries
- Pain Management

#### FY15 GDF – JPC Core and Restoral (\$284M)



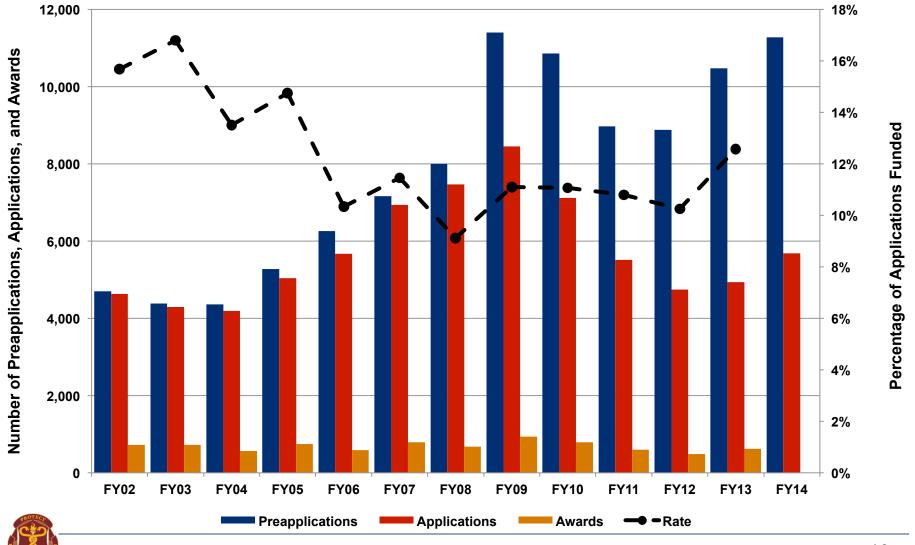




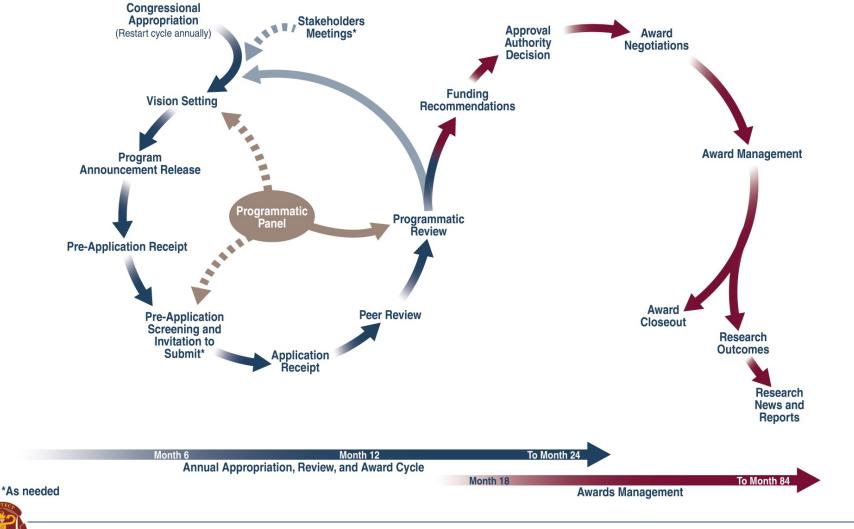
# **CDMRP Funding Opportunities**









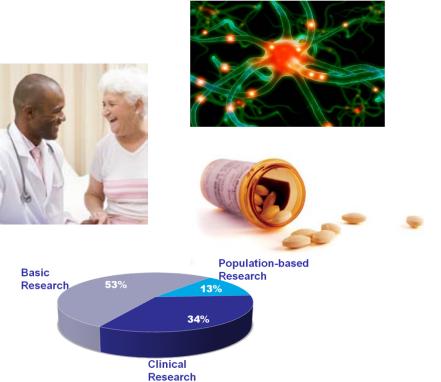






## At Vision Setting each year, the Programmatic Panel recommends an investment strategy, considering factors such as:

- Current landscape
- Emerging technologies
- Research gaps
- Impact
- Portfolio composition







#### **Career Development** funding for all career stages



#### **Research Awards** Closing gaps in research through innovative and impactful research





# **CDMRP 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)
- Program Announcement release posted on
  - & Grants.gov
  - \* CDMRP eBRAP System
  - \* CDMRP eReceipt System (intramural)
  - CDMRP website
  - FedBizOps (BAAs)





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| About Grants.go<br>Grants.gov is your place to FIND<br>grants. The United States Depan<br>Services is proud to be the many<br>-an initiative that is having an un<br>grant community.<br>Learn more about Grants.go<br>Find Open Grant O<br>NEWEST OPPORTUNITIES | D and APPLY for federal<br>rtment of Health and Human<br>aging partner for Grants.gov-<br>nparalleled impact on the |   | Grants.gov Updates<br>Grants.gov Calendar<br>Check out our calendar to get the latest updates about our<br>upcoming releases, maintenance, and outages. |
| Funding Opportunity Number   | Opportunity Title   | View More »  Agency                           | Grants.gov Releases<br>For more information about recent changes and<br>enhancements, please see the latest release notes.                              |
| APS-615-15-000002  | Community Conservancies Support Program   | East Africa USAID-<br>Kenya                   | Grants.gov Blog<br>Visit the Grants.gov Blog to get up-to-date status of<br>upcoming maintenance and outages.   |
| USDA-NIFA-SRGP-004996 Special Research Grants Program Potato Breeding Research   |   | National Institute of<br>Food and Agriculture | Financial Assistance  |
| P15AS00070   | P15AS00070 Survey of the Fauna of Seepage Springs in National Capital Parks East                                    |   | Grants.gov does not provide personal financial assistance.<br>Please visit USA.gov, to learn where you may find   |
| NPS-NOIP15AC00329 National Park Service-Complete NAGPRA Summary Lists  |   | National Park Service                         | personal financial assistance.  |
| PAR-15-146   | Countermeasures Against Chemical Threats (CounterACT) Research Centers of   | National Institutes of                        | Suspect Fraudulent Activity?  |





# **Announcements on Grants.gov**

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| CFDA Number: 12.420   | S Funding Opportunity Number    | Opportunity Title   | Agency  | Open Date ⊥ Close Date                         |
| SEARCH  | APS-615-15-000002               | Community Conservancies Support Program   | East Africa USAID-<br>Kenya                                 | 03/19/2015 03/18/2016                          |
| OPPORTUNITY STATUS:   | USDA-NIFA-SRGP-004996           | Special Research Grants Program Potato Breeding Research  | National Institute of                                       | 03/19/2015 04/22/2015                          |
| Øpen (2,094)  | P154000070                      | Our weather France of Oceanies Oceanies in National Oceanies Reads  | Food and Agriculture  | 00/00/00/00 00/00/00/00                        |
| Closed (1,724)  | P15AS00070<br>NPS-NOIP15AC00329 | Survey of the Fauna of Seepage Springs in National Capital Parks East   |   | 03/19/2015 03/22/2015                          |
| Archived (26,875)   | PAR-15-146                      | National Park Service-Complete NAGPRA Summary Lists<br>Countermeasures Against Chemical Threats (CounterACT) Research | National Institutes of                                      | 03/19/2015 03/23/2015<br>03/19/2015 09/12/2017 |
| FUNDING INSTRUMENT TYPE:      All Funding Instruments     Cooperative Agreement (619) | A PA-15-147                     | Centers of Excellence (U54)<br>AHRQ Small Research Grant Program (R03)  | Health<br>Agency for Health<br>Care Research and<br>Quality | 03/19/2015 07/16/2018                          |
| Grant (1,565)   | P15AS00069                      | \$0 Master Cooperative Agreement  | National Park Service                                       | 03/19/2015                                     |
| Other (42) Procurement Contract (42)  | PAR-15-145                      | NIMH Research Education Mentoring Programs for HIV/AIDS<br>Researchers (R25)  | National Institutes of<br>Health                            | 03/19/2015 09/07/2017                          |
| ▼ELIGIBILITY:   | EPA-R1-HC-2015                  | 2015 HEALTHY COMMUNITIES GRANT PROGRAM  | Environmental<br>Protection Agency                          | 03/19/2015 04/30/2015                          |
| All Eligibilities     City or township governments (905)                              | ► F15AS00136                    | Tuluksak River Salmon Run Timing and Abundance   Notice of Intent to award to a Single Source                         | Fish and Wildlife<br>Service                                | 03/19/2015 03/27/2015                          |
| County governments (915)  | PA-15-148                       | Administrative Supplements for Ebola Biosafety and Infectious Disease Response Training (Admin Supp)                  | National Institutes of<br>Health                            | 03/19/2015 04/20/2015                          |
| For profit organizations other than small<br>businesses (857)                         | HHS-2015-IHS-TMD-0001           | Tribal Management Grant Program   | Indian Health Service                                       | 03/19/2015 06/03/2015                          |











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| I am a new:       Principal Investigator         *Select from drop down         Start Registration <b>Program News and Updates</b> • Welcome to eBRAP. To access the user guide, please click here. <b>Email Subscriptions</b> • To subscribe to program specific news and updates, please click here         • To remove your email from program subscription list, please click here         • To remove your email from program subscription list, please click here         • Commonly Made Mistakes         • Contact the helpdesk | Username:  |
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# Intramural Announcements on the Department of Defense COMRP eReceipt System – https://cdmrp.org

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| <u>CDMRP Position on Research Duplication</u>  |  |                              |
| <ul> <li>NOTICE: At this time the eReceipt system is unable to<br/>Windows users and free for both personal and comment</li> </ul> | to read files created with Acrobat 9.0 or higher. Please use another version or <u>http://www.dopd</u><br>ercial use.  | dt.com/, which is for        |
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| Help   |  |                              |
| Frequently Asked Questions   |  |                              |
| PDF Resources     Commonly Made Mistakes   |  |                              |
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# **Current Funding Opportunities**

#### **Announcements (pre-application stage open):**

- Restorative Transplant Research
- Orthotics and Prosthetics Outcomes
- Defense Medical Research and Development
  - \* Medical Simulation and Information Systems
- Breast Cancer
- Gulf War Illness
- Epilepsy
- Alzheimer's
- Military Burn

### **Pre-announcements (pending approval and release):**

- Peer Reviewed Orthopaedic
- Psychological Health/Traumatic Brain Injury



**Applied Innovation in Military Medicine** 



# **CDMRP Application Submission Process**





**CDMRP's electronic application submission and processing** tool is called eBRAP.

- Enables communication with the worldwide research community
- Provides web-based accessibility for research community
  - **\* eBRAP requires log-in username and password**
- Computer-automated processes streamline workflow for pre-application and full application retrieval and processing
- Enables researchers to review and modify Grants.gov application components during the verification period
   specified in the PA or BAA



# Before You Apply – Sign up for email notifications in eBRAP

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| Program News and Updates<br>Welcome to eBRAP. To access the user guide, please <u>click new</u><br>Email Subscriptions  | Enter your email address Select all programs you want to subscribe to then click the Subr                                | nit button [ 🗷 Check/Un-Check All ]   |
| <ul> <li>To subscribe to program specific news and updates, please <u>click here</u></li> <li>To remove your email from program subscription list, please <u>click here</u></li> </ul> Help | <ul> <li>Alcohol and Substance Abuse Research Program</li> <li>Amyotrophic Lateral Sclerosis Research Program</li> </ul> | <ul> <li>Military Burn Research Program</li> <li>Multiple Sclerosis Research Program</li> </ul> |
| Frequently Asked Questions     Commonly Made Mistakes   | Autism Research Program  | Myeloproliferative Disease Research Program   |
| Contact the helpdesk  | Bone Marrow Failure Research Program   | Neurofibromatosis Research Program  |
|   | Breast Cancer Research Program   | Neurotoxin Exposure Treatment Parkinson's Research  |
|   | Broad Agency Announcement  | Orthotics and Prosthetics Outcomes Research Program   |
|   | ☑ Chiropractic Research Program  | ☑ Osteoporosis Research Program   |



# Before You Apply – Register in eBRAF

## User registration

- Principal Investigator (PI)
- Business Official (BO)
- \* Account Administrator
- Authorized Organizational Representative (AOR)
- During registration, the PI must request to be affiliated with his/her organization
  - If the organization listed is not registered, then the PI must invite the AOR to register the organization



# How to Apply – Step 1: Submit Your Pre-Application

#### **STEP 1: Pre-Application Submission in eBRAP** (required!)

- Type of pre-application depends on the award mechanism
  - *Letter of Intent:* will not be reviewed; no invitation will be required for application submission
  - *Preproposal:* will be reviewed; invitation is required for application submission
- Follow Tabs 2-5 in any order
- Pre-application is submitted by the PI in Tab 6
- Pre-application submission is MANDATORY and must be ON TIME
- Tips for success!
  - \* Read the announcement carefully
  - \* Choose the correct funding opportunity and "option"
  - \* Check spelling of names and emails

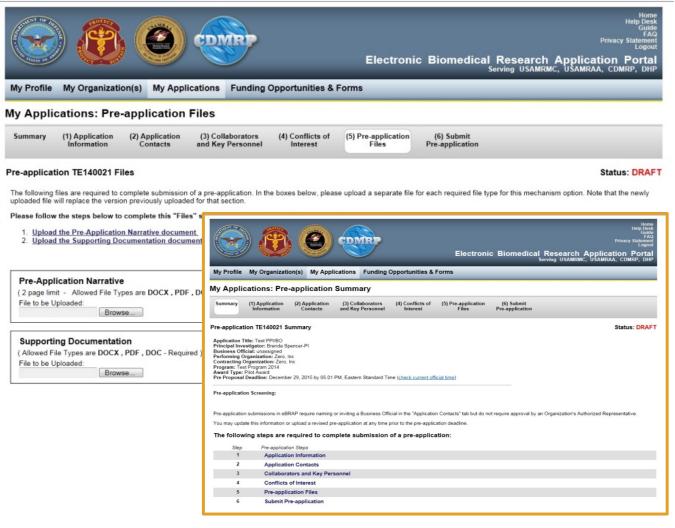


\* Start the process early to allow time to resolve issues



## **Pre-Application Files in eBRAP**

- Specified in announcement
- Page and/or text field limits
- Real-time autocompliance
- Auto-email notification







## **STEP 2: Application Submission in Grants.gov**

- If the pre-application was a preproposal, an invitation is required
- Sponsored Program Office (or equivalent) submits through Grants.gov
- Submission must be on time; no grace period
- Adhere strictly to the Program Announcement requirements





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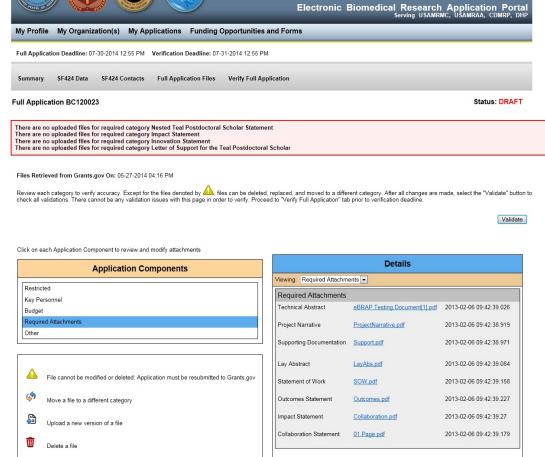
#### **Review & Modify Full Application**

#### Verification Period

- Auto-email notification after eBRAP has processed the Grants.gov application
- Review and modify <u>allowable</u> components – not Project Narrative or Budget
- Affiliation with organization is required

#### Tips for success!

- Choose correct Grants.gov application package
- Check spelling of names and emails; <u>must match those in pre-application</u>
- Include eBRAP log number



Validate



- Do not involve or include Programmatic Panel members for the announcement to which you are applying
- Do not exceed the page limits; check files after creating PDF version
- Do not miss the submission deadline
  - **\* Grants.gov validation may take up to 72 hours**
  - System-to-system submissions are sometimes problematic
  - \* Application verification in eBRAP is possible before the deadline
- Submit the correct Project Narrative and Budget these elements cannot be modified during the verification period in eBRAP





# **CDMRP Application Review Processes**

## CDMRP Goal: Provide a fair and thorough review for every application





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

| Peer<br>Review   | Partnership | Programmatic<br>Review  |
|--|-------------|---|
| <ul> <li>Criterion-based evaluation of ful<br/>proposal</li> <li>Determination of "absolute"<br/>scientific merit</li> <li>Outcome: Written critique and<br/>scores for individual criteria and<br/>overall merit</li> </ul> |             | <ul> <li>Comparison among proposals<br/>of high scientific merit</li> <li>Determination of adherence to<br/>intent and program relevance</li> <li>Outcome: Funding<br/>recommendations</li> </ul> |
| <ul> <li>No standing peer review panels</li> <li>No contact between reviewers and<br/>applicants</li> </ul>  | 1           | <ul> <li>No "pay line" (portfolio balance)</li> <li>Funds obligated up front; no<br/>out-year budget commitments (but<br/>milestones imposed)</li> <li>No continuation funding</li> </ul>         |





# **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 recruited based on expertise needed
- Identities are not made known to applicants; contact between applicants and reviewers not permitted

### Outcome: Summary Statement





# Second Tier: Programmatic Review

#### How the evaluation process works

- \* Comparison-based
- \* Strong scientific merit
- \* Adherence to award mechanism's intent
- Potential for impact
- Program relevance
- **\* Consideration of portfolio composition**
- Programmatic reviewers
  - Programmatic Panel (or equivalent)
  - \* Ad hoc reviewers



### Outcome: Funding recommendations



# **Strategies for Success**

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





- Propose solutions to important problems: IMPACT
- Identify gap(s) that will be filled: INNOVATION
- Align the proposed work with guidance from the announcement: RELEVANCE
- Justify a technically sound plan with clear approaches for contingencies: FEASIBILITY
  - \* Include evidence of appropriate EXPERTISE (collaboration, consultants, etc.)
  - \* Ensure the study is APPROPRIATELY POWERED for the proposed research outcome





- \* Explain the proposed work with CLARITY and UNBURDENED by jargon
- \* Demonstrate AVAILABILITY and ACCESS to critical resources, reagents, and/or subject populations
- \* Respect the different backgrounds of the reviewers and COMMUNICATE effectively
- \* Don't break the rules for deadlines or content Be COMPLIANT









### **CDMRP Staff at MHSRS**

**Dr. Linda Bambrick CDR Mark Clayton Mr. Brett Chaney Dr. Angel Davey Dr. Rebecca Fisher** Mr. Jason Ghannadian **Dr. Melissa Green-Parker Dr. Patricia Henry** Dr. Eva Lai **Mr. Wilbur Malloy Dr. Charles Peterson Mr. Robert Read Col Ray Santullo Ms. Sandy Snyder Dr. Dwayne Taliaferro Dr. Christie Vu Dr. Prem Yadav** 





## CDMRP? Funding Opportunities? Application Submission? Review Process? Award Issues?





# **Other DoD Funding Opportunities**



# Medical Research and Development at USAMRMC

#### <u>Mission</u>:

Responsively and responsibly create, develop, deliver, and sustain medical capabilities for the Warfighter.

<u>Vision</u>: Lead the advancement of military medicine.













Infectious

Comb





# USAMRMC Funding Opportunities

#### Broad Agency Announcement (BAA)

- \* BAA 15-1, October 2014
- **Continuously Open through 30 September 2015**
- Announcement lists topic areas of current interest

#### Postings

- SAMRAA: <u>http://www.usamraa.army.mil/</u>
- FedBizOps: <u>http://fbo.gov</u> (keyword search: USAMRMC)
- Grants.gov: <u>http://www.grants.gov (</u>F.O. Number W81XWH-BAA-15-1)

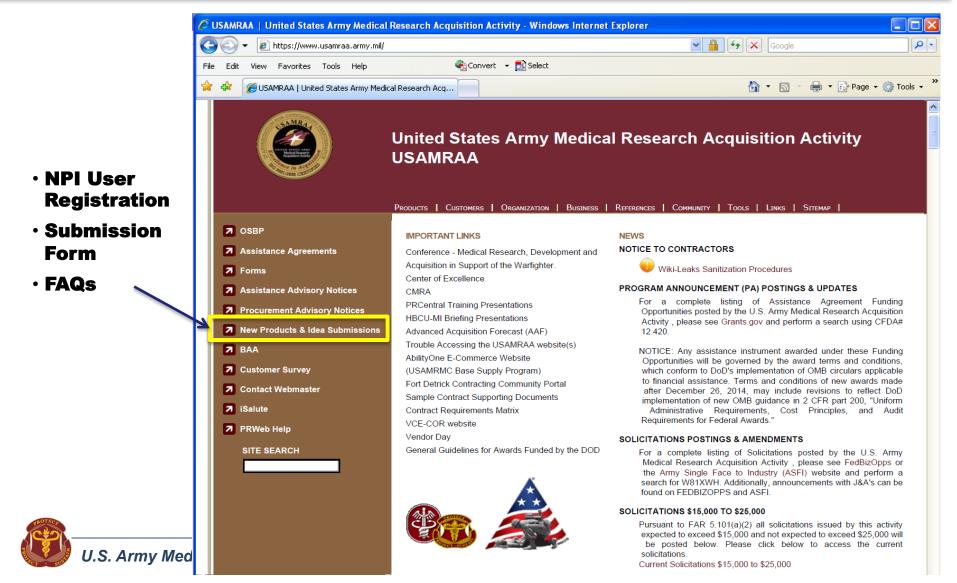
#### Process

- Pre-applications submitted to eBRAP.org
- Full Applications are invited only; submitted through Grants.gov
- \* Full Applications undergo external peer review











- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs
  - Goal to utilize unique features of small businesses to provide innovation for U.S. Army's mission and needs
  - https://www.armysbir.army.mil
  - https://www.dodsbir.net
  - **SBIR must involve small business**



- STTR requires partnership of small business with universities, federally funded R&D centers, and other non-profit research institutions
- Multiple SBIR solicitations throughout the year
  - USAMRMC releases about 20 topics each year and in FY14 awarded 56 phase I and 27 phase II SBIR contracts
  - Topics change with every solicitation

