



Department of Defense (DoD) Biomedical Research Funding: Congressionally Directed Medical Research Programs (CDMRP) Overview

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Outline



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



Who is the CDMRP?





OF THE ARMY

ARMY MEDICINE Serving To Heal...Honored To Serve

> ARMY MEDICAL COMMAND

MEDICAL RESEARCH AND MATERIEL COMMAND



CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS



USAMRMC Strategic Process

Research to produce medical knowledge



Core RDA Outcomes Fielded Medical Knowledge

Fielded Medical Materiel

Core RDA Programs

RESEARCH & DEVELOPMENT

Medical Research & Technology Program **DEVELOPMENT & ACQUISITION**

Medical Advanced
Development Program

ACQUISITION & LOGISTICS

Medical Logistics Program

Special Programs

Congressional Special Interest Programs

Programs directed by Congress

Armed Forces Medical Examiner System

National Museum of Health and Medicine

Special Outcomes

Targeted Outcomes

Identification and/or Cause of Death

DoD Knowledge Resource



CDMRP Vision and Mission



Vision

Find and fund the best research to eradicate diseases and support the Warfighter for the benefit of the American public.

Mission

We provide hope by promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust.



History 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 1996–2014, additional research programs were added by Congress and USAMRMC for administrative execution by CDMRP**



The CDMRP Today



♦ CONGRESSIONAL PROGRAMS:

- Manages extramural research programs directed by Congress
- Starting in 1992 with breast cancer, CDMRP now manages 27 programs
- Congress specifies disease area, CDMRP determines research investment strategy and competitively selects the best projects to meet program goals
- CDMRP funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected
- Unique public/private partnership encompassing the military, scientists, disease survivors, advocates, consumers, and policy makers
- **♦ EXECUTION MANAGEMENT AGENT** for the Research Area Directorates (RADs)/ Joint Program Committees (JPCs) to support their military mission
- ♦ DIRECTOR: Col Wanda Salzer



Unique Partnerships



Advocates

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





IMPROVE HEALTH (CURE)

Congress

- Add funds to budget
- Targeted guidance
- Opportunity to leverage

Researchers

- Innovation and gaps
- * Risk/Benefit
- Product-oriented





DoD

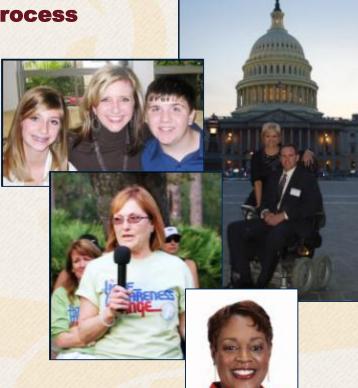
- Program management
- Contracting actions
- Regulatory requirements



Hallmarks of the CDMRP



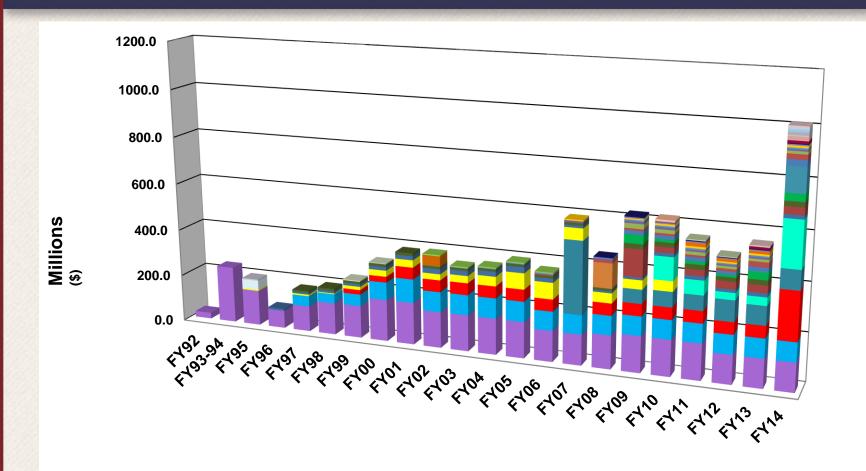
- **♦ Targeted research funds added to DoD budget by Congress**
- ♦ Consumer advocates participate throughout process
- **♦ IOM-recommended model for application review**
- **♦ Fund highly innovative, high-impact research**
- ◆ Each program's vision and investment strategy are adapted annually, allowing 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 Funding History





CDMRP has managed over 37 funded research programs between FY92 – FY14, totaling \$8.7 billion



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 Transplantation*	\$15.0
Joint Warfighter*	\$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

TOTAL = \$1.375B

^{*}CDMRP is assisting with the execution of a specified portion of a larger appropriation(s)



FY15 Military-Focused Programs



- **♦ Alcohol and Substance Abuse**
- ♦ Defense Medical Research and Development
- **♦ Epilepsy**
- ♦ Joint Warfighter
- **♦ Military Burn**
- **♦ Orthopaedic**
- **♦ Orthotics and Prosthetics Outcomes**
- ♦ Psychological Health and Traumatic Brain Injury
- **♦ Reconstructive Transplantation**
- **♦ Spinal Cord Injury**
- **♦ Vision**



FY15 National (Disease-Focused) Programs



- **♦ 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 Parkinson's
- **♦ Ovarian Cancer**
- **♦ Peer Reviewed Cancer (11 topics)**
- **♦ Peer Reviewed Medical (41 topics)**
- **♦ Prostate Cancer**
- **♦ Tuberous Sclerosis Complex**

Cancer Programs

Breast Cancer
Lung Cancer
Ovarian Cancer
Peer Reviewed Cancer
Prostate Cancer

Military-Relevant Programs

Alzheimer's

Amyotrophic Lateral Sclerosis

Gulf War Illness

Lung Cancer

Peer Reviewed Cancer

Peer Reviewed Medical



Peer Reviewed Cancer Research Program FY15 Topic Areas



- **♦ Colorectal Cancer**
- **♦** Genetic Cancer
- **♦ Kidney Cancer**
- **♦ Listeria Vaccine for Cancer**
- **♦ Liver Cancer**
- Melanoma and other skin cancers
- **♦ Mesothelioma**
- Myeloproliferative Disorders
- ♦ Neuroblastoma
- **♦ Pancreatic Cancer**
- **♦ Stomach Cancer**

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



Peer Reviewed Medical Research Program 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 Angiodema
- ♦ 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 Osteoarthritig
- 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



A Major Funder of Research



- ♦ CDMRP is the leading U.S. funder for Neurofibromatosis research
- ♦ CDMRP is the second largest funder in the U.S. for research on
 - * Breast cancer
 - Prostate cancer
 - * Ovarian cancer
 - Lung cancer
 - Gulf War Illness
 - * Tuberous Sclerosis Complex



Disease-Focused Programs





Advance the understanding of spinal cord injury and ameliorate its consequences...

Improve the lives of individuals with autism spectrum disorder now...

...research that will eliminate death and suffering from prostate cancer

To eradicate deaths from lung cancer...





... to detect, diagnose, prevent, and control ovarian cancer





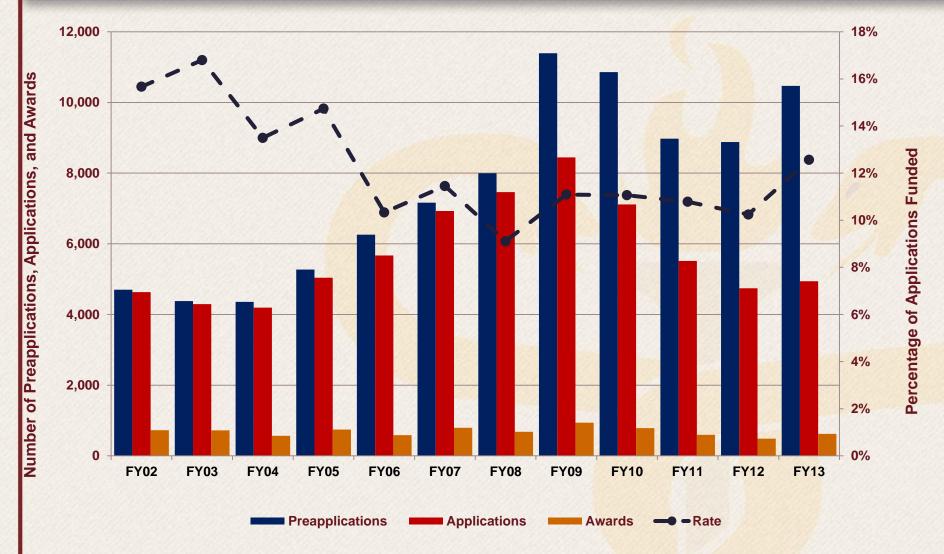


CDMRP Funding Opportunities



CDMRP Funded Awards Rate

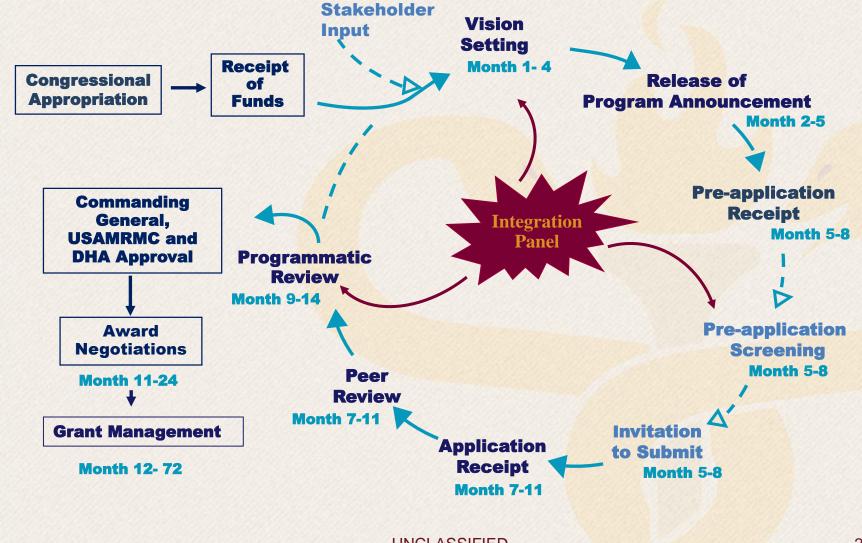






Program Cycle







Vision Setting

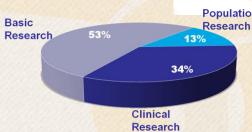


At Vision Setting each year, the Integration Panel recommends an investment strategy, considering factors such as:

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









CDMRP Funding Opportunities



- **♦** Offered as awards
- 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
- **♦** Pre-announcement release
- Program Announcement release
 - Posted on Grants.gov, CDMRP eBRAP System, CDMRP website



Program Announcements on Grants.gov

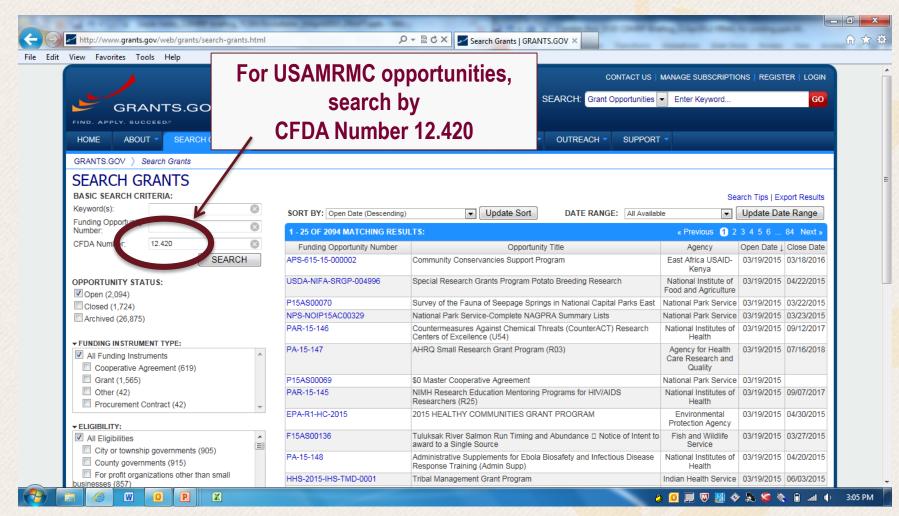






Program Announcements on Grants.gov







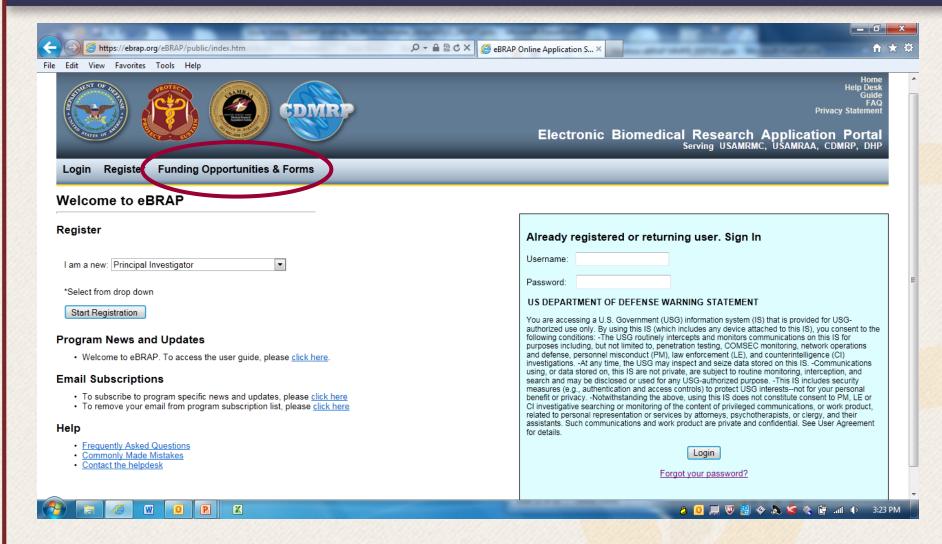
Program Announcements on the CDMRP Website – http://cdmrp.army.mil







Program Announcements on the CDMRP eBRAP System – https://eBRAP.org





Award Mechanisms Designed to Support the Research Development Pipeline



Development of Ideas Clinical Trials Initial Concepts Clinical/Translational **Clinical Trial** Concept Clinical **Team Science Pilot** Clinical **Early Ideas Translational Exploration Discovery Therapeutic** Idea **Partnering PI Exploration -**Breakthrough **Development** Idea Development Option Levels 3 and 4 **Hypothesis** Outcomes Breakthrough Consortium **Development** Research Level 1 **♦** Translational ♦ Breakthrough **Partnership** Levels 2 and 3 **♦** Translational **Team Science**



Award Mechanisms Designed to Support the Career Development Pipeline



Career Path Postdoctoral New Investigator Postdoctoral **Training** ♦ New Investigator Horizon Era of Hope Scholar **Physician Scientist** Breakthrough **Predoctoral ♦** Career Development Levels 1 and 2 **♦ Ovarian Cancer Academy** Physician Research Horizon **Training** HDRA Nested **Trainee**





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

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Questions on CDMRP or Its Funding Opportunities?





CDMRP Application Submission Process



eBRAP (https://eBRAP.org)



CDMRP's electronic application submission and processing tool

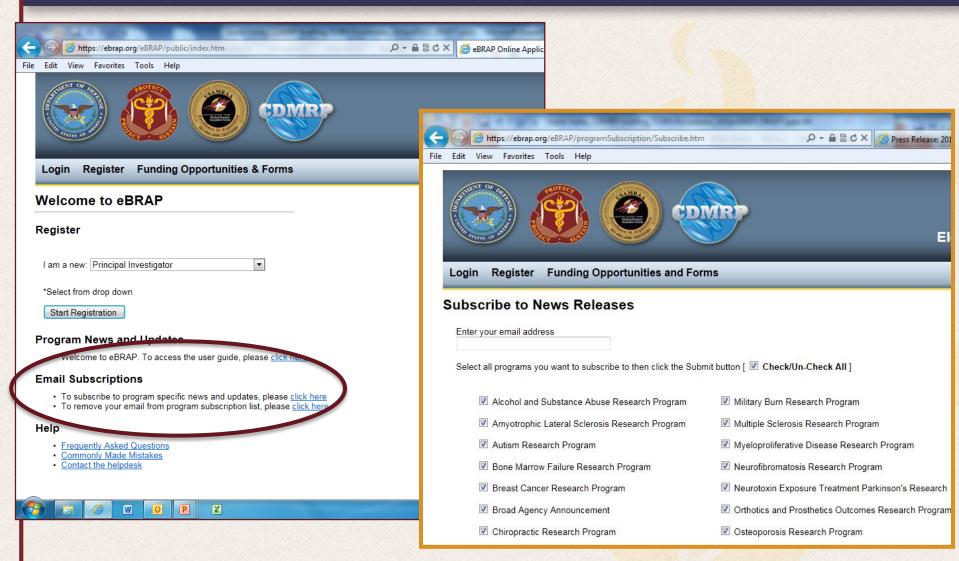
- ♦ Enables communication with the worldwide research community
- Provides web-based accessibility for research community
 - eBRAP requires log-in username and password
- ♦ Computer-automated processes streamlines workflow for pre-application and full application retrieval and processing
- ♦ Enables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

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Before You Apply – Sign up for email notifications in eBRAP







Before You Apply – Register in eBRAP



- **♦** 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, 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!)

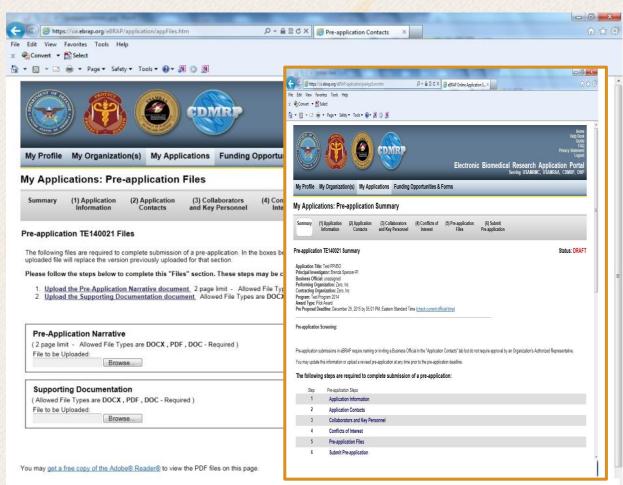
- ♦ Type of pre-application depends on the award mechanism
 - Letter of Intent: will not be reviewed; no invitation will be required for application submission
 - Preproposal: will be reviewed; invitation is required for application submission
- ♦ Follow Tabs 2-5 in any order
- Pre-application is submitted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



Pre-Application Files in eBRAP



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





How to Apply – Step 2: Submit Your Application



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**

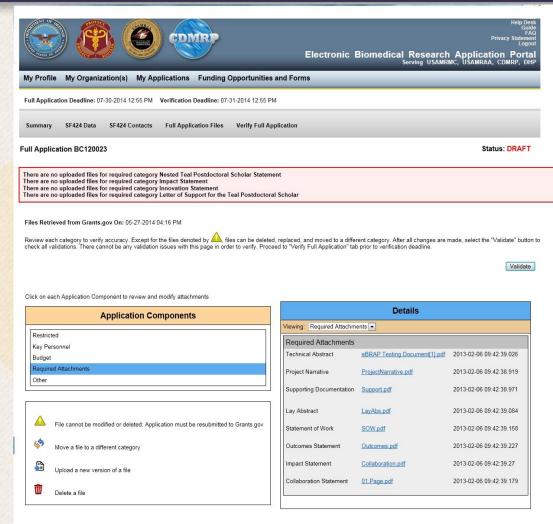


How to Apply – Step 3: Application Verification in eBRAP



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
 - Use correct spelling of names and emails; must match those in preapplication
 - Include eBRAP log number



Validate



Pitfalls to Avoid in Application Submission



- ♦ Do not include Integration Panel members for the program and fiscal year 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



Pitfalls to Avoid in Application Submission (continued)



- ♦ Make sure the following items on the SF424 match what was in the pre-application in eBRAP
 - Pl's last name
 - Pl's email
 - Organization name
 - CDMRP log number
- ♦ Monitor your email at least one week after submission
 - You will be notified if CDMRP has received and processed your application from Grants.gov; then application verification can take place
- ♦ Partnering PIs must follow the link in the email from eBRAP and complete the registration process before the submission deadline
 - Failure to do so could delay or eliminate ability to view and modify applications during the verification period





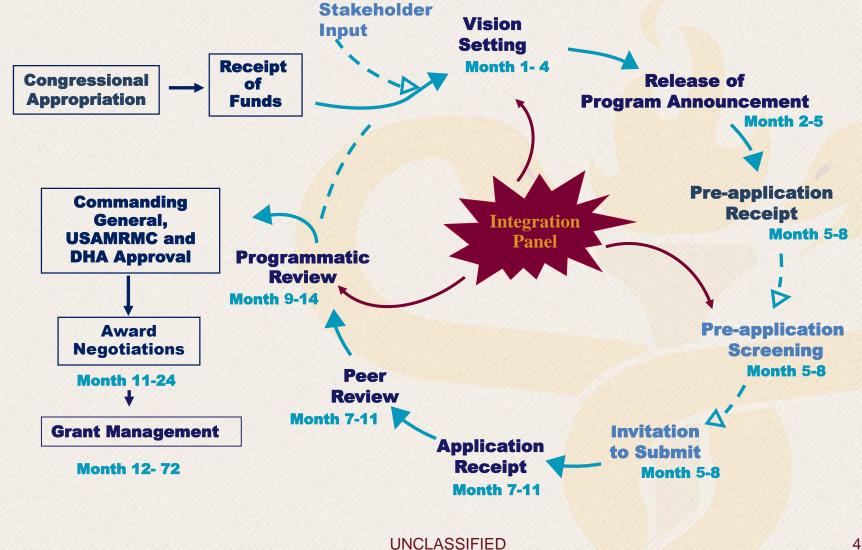
CDMRP Application Review Processes

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



Program Cycle







Goal of Two-Tier Review Process



To find scientifically meritorious proposals and fund those that best fulfill program goals





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

- Integration Panel (or equivalent)
- * Ad hoc reviewers
- **♦ Outcome: Funding recommendations**



Strategies for Success



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



Strategies for Success (continued)



- Explain the proposed work with CLARITY and UNBURDENED by jargon
- Respect the different audiences of the technical and public abstracts and COMMUNICATE effectively
- Don't break the rules Be COMPLIANT





Questions on CDMRP Application Submission or Review?





Other DoD Funding Opportunities



Medical Research and Development at USAMRMC





<u>Casual</u>

Mission:

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





Lead the advancement of military medicine.















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

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

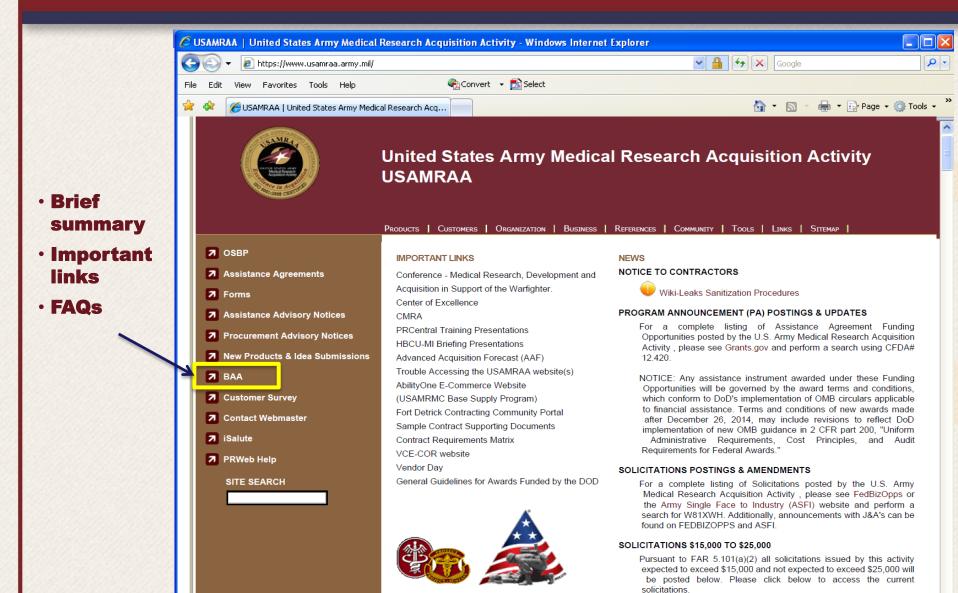
♦ Process

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



Broad Agency Announcement (BAA)





Current Solicitations \$15,000 to \$25.000



USAMRMC Funding Opportunities



New Products & Ideas (NPI)

- ♦ Unsolicited proposals for new products and ideas that support the USAMRMC mission
- https://www.usamraa.army.mil/
- **♦ Continuously open**
- ♦ Preproposals reviewed internally for USAMRMC priority
- ♦ Not a substitute where other submission vehicles are more appropriate (e.g., BAA; PAs; RFPs)
- Initial review completed and applicant notified within 30 days
- **♦ Review may include:**
 - Request for further information
 - Request full unsolicited proposal
 - Proposal may fit current solicitation or program announcement





New Products and Ideas (NPI)

SITE SEARCH





General Guidelines for Awards Funded by the DOD

SOLICITATIONS FOSTINGS & AMENDMENT

For a complete listing of Solicitations posted by the U.S. Army Medical Research Acquisition Activity, please see FedBizOpps or the Army Single Face to Industry (ASFI) website and perform a search for W81XWH. Additionally, announcements with J&A's can be found on FEDBIZOPPS and ASFI.

SOLICITATIONS \$15,000 TO \$25,000

Pursuant to FAR 5.101(a)(2) all solicitations issued by this activity expected to exceed \$15,000 and not expected to exceed \$25,000 will be posted below. Please click below to access the current solicitations.

Current Solicitations \$15,000 to \$25,000



USAMRMC Funding Opportunities



- ♦ 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



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https://cdmrp.army.mil



