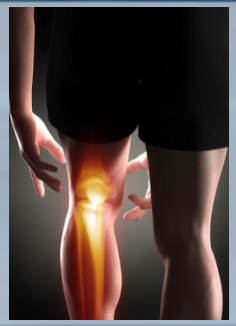
Congressionally Directed Medical Research Programs (CDMRP)

CDMRP Lunch and Learn Session

Military Health System Research Symposium

August 18, 2015



CDMRP
Department of Defense

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.

Outline

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

Overview of the CDMRP

Who is the CDMRP?

CDMRP
Department of Defense

Department of Defense

Department of the Army

ARMY MEDICINE
Serving To Heal...Honored To Serve

Army Medical Command

Medical Research and Materiel Command

CDMRP

Congressionally Directed Medical Research Programs

USAMRMC Strategic Process

CDMRP Department of Defense

Core RDA Outcomes

Fielded Medical Knowledge

Fielded Medical Materiel

Research to produce medical knowledge

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

Armed Forces Medical Examiner System

National Museum of Health and Medicine

Programs directed by Congress

Special Outcomes

Targeted Outcomes

Identification and/or Cause of Death

DoD Knowledge Resource

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 1996–2015, additional research programs and topics were added by Congress and USAMRMC for administrative management by CDMRP

The CDMRP Today

CDMRP
Department of Defense

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

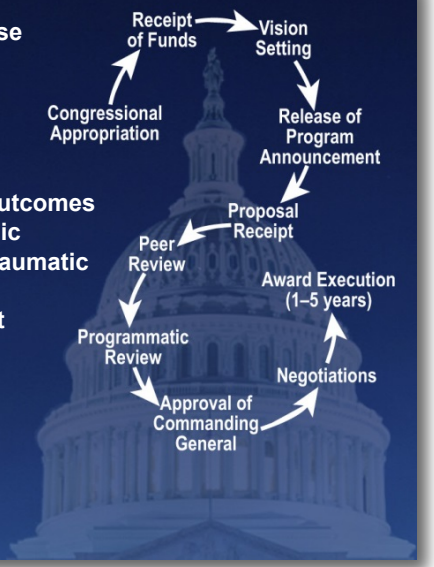
DoD PROGRAMS:

- 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 Parkinson's
- Ovarian Cancer
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Prostate Cancer
- Tuberous Sclerosis Complex
- Alcohol & Substance Abuse Disorders
- Defense Medical R & D
- Epilepsy
- Joint Warfighter Medical
- Military Burn
- Orthotics & Prosthetics Outcomes
- Peer Reviewed Orthopaedic
- Psychological Health & Traumatic Brain Injury
- Reconstructive Transplant
- Spinal Cord Injury
- Vision Research



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

CDMRP Department of Defense

Advocates

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

Congress

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

IMPROVE HEALTH (CURE)

Researchers

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

DoD

- Program management
- Contracting actions
- Regulatory requirements

A Major Funder

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

CDMRP
Department of Defense

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
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) Intramural and Extramural

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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

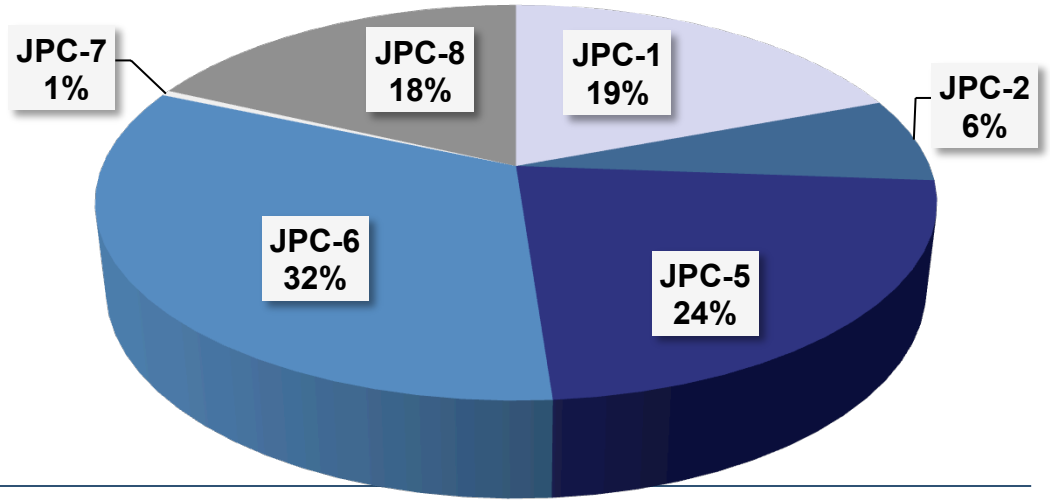
Radiation Health Effects (JPC-7)

- Biomedical Technology for Radiation Countermeasures

Clinical & Rehabilitative Medicine (JPC-8)

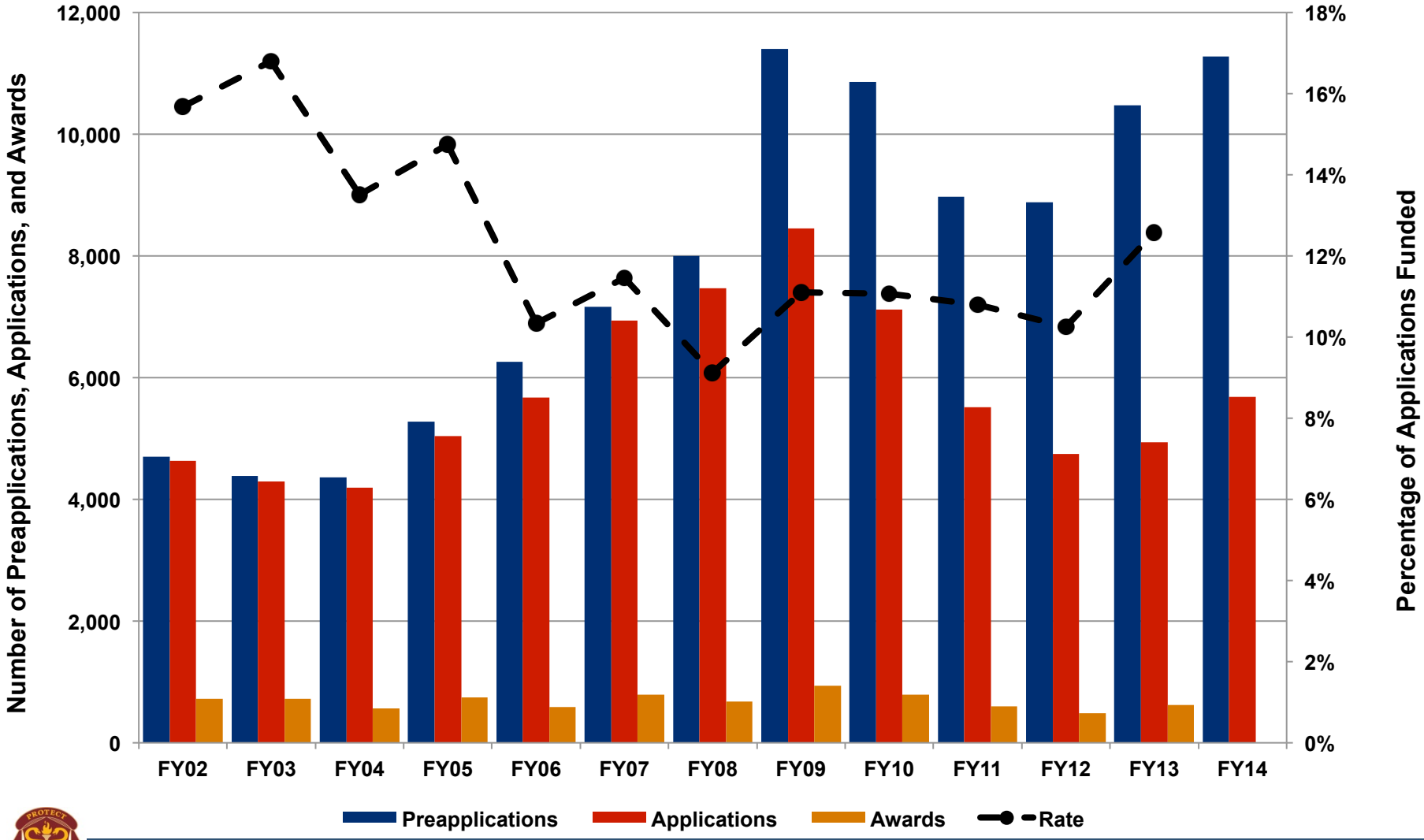
- Sensory Systems
- Regenerative Medicine
- Neuromusculoskeletal Injuries
- Pain Management

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

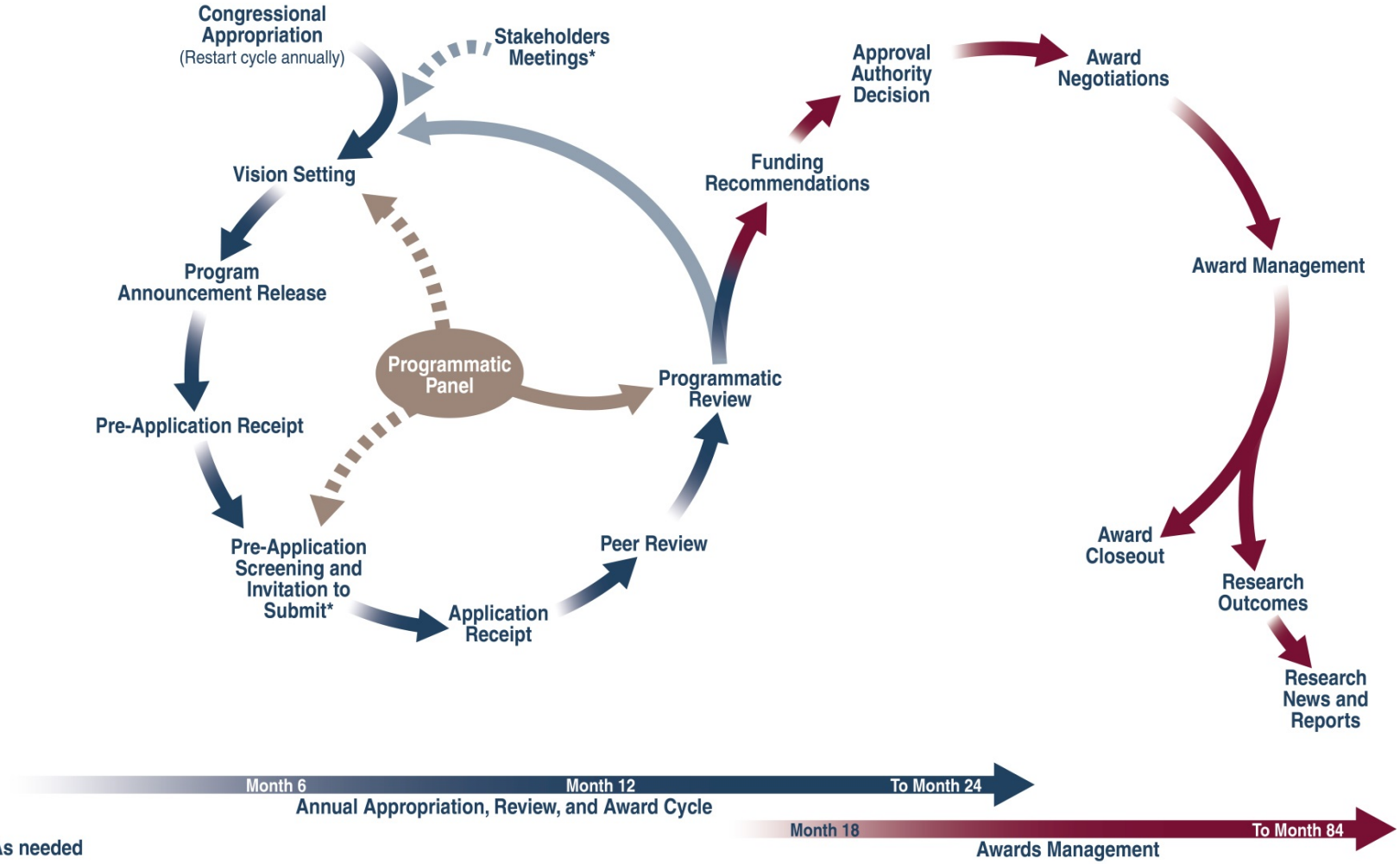


CDMRP Funding Opportunities

CDMRP Funded Awards Rate



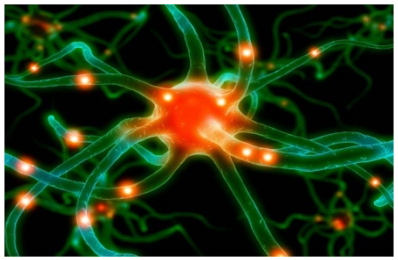
Program Cycle

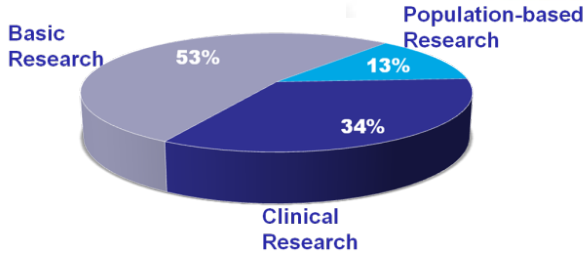


Vision Setting

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**





Award Mechanisms Pipeline

CDMRP Department of Defense

Career Development

funding for all career stages

Predoctoral | Postdoctoral | Physician Scientist | New Investigator | Established Investigator

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

Research Awards

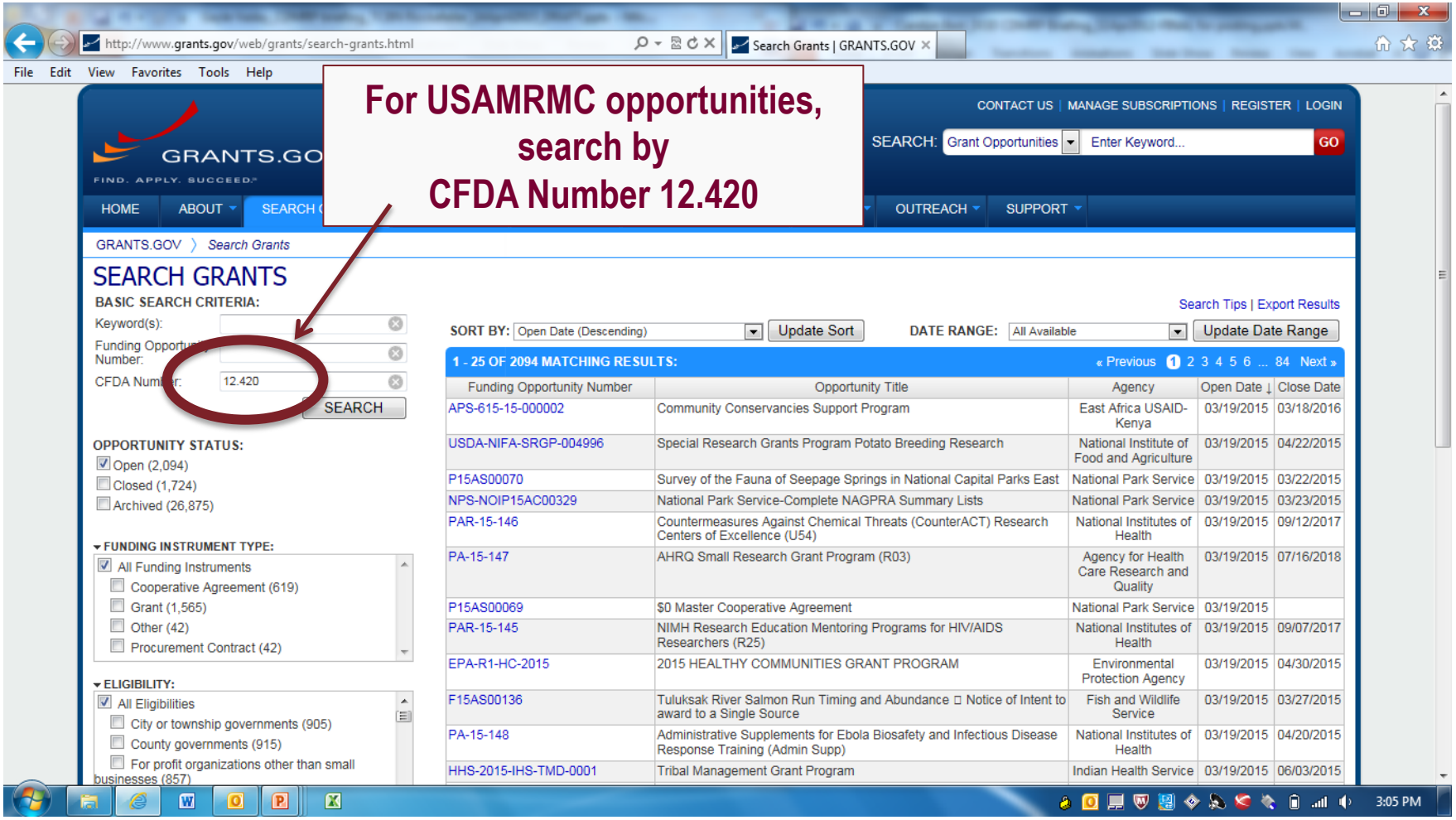
Closing gaps in research through innovative and impactful research

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)

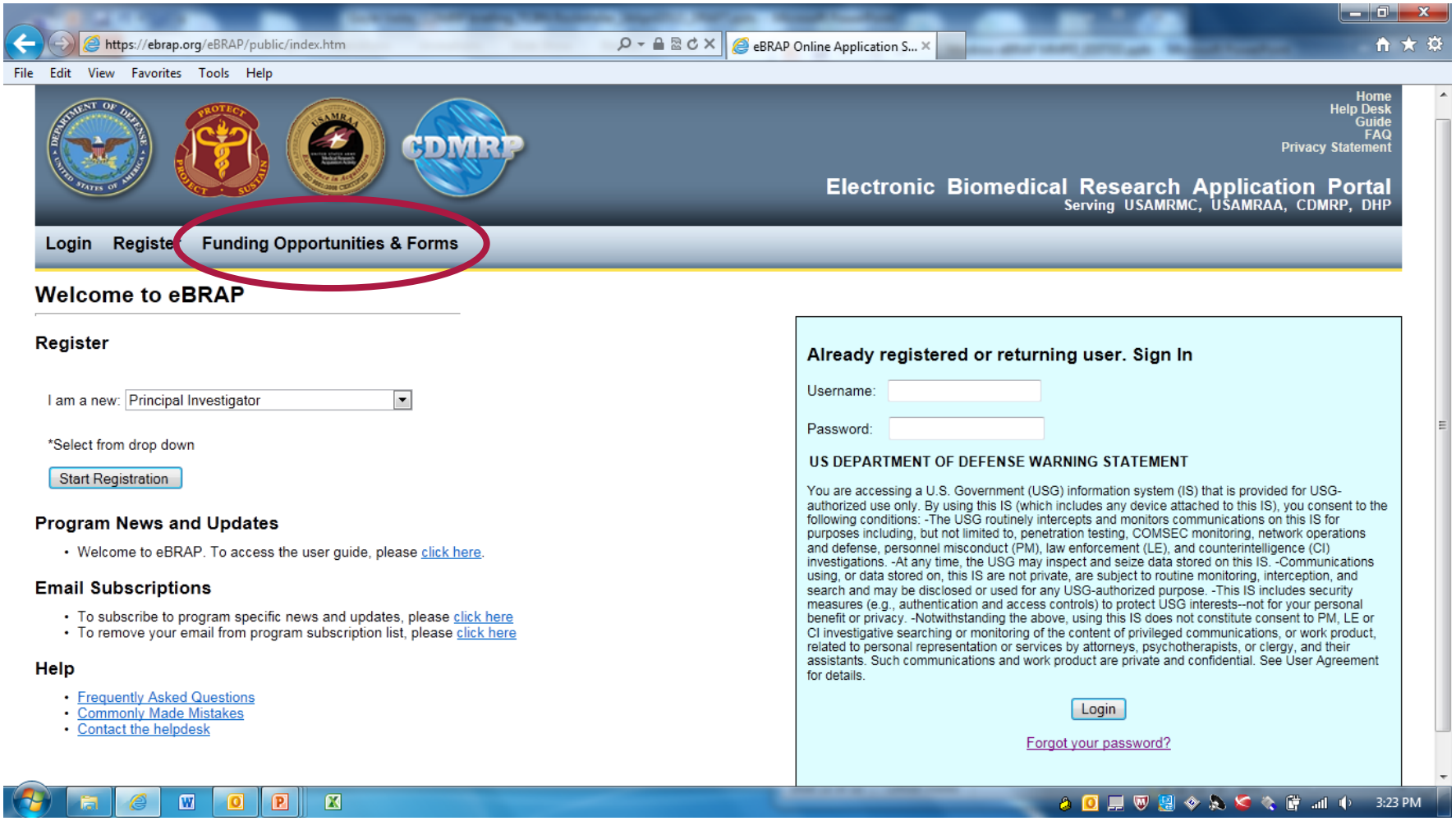
Announcements on Grants.gov

Announcements on Grants.gov

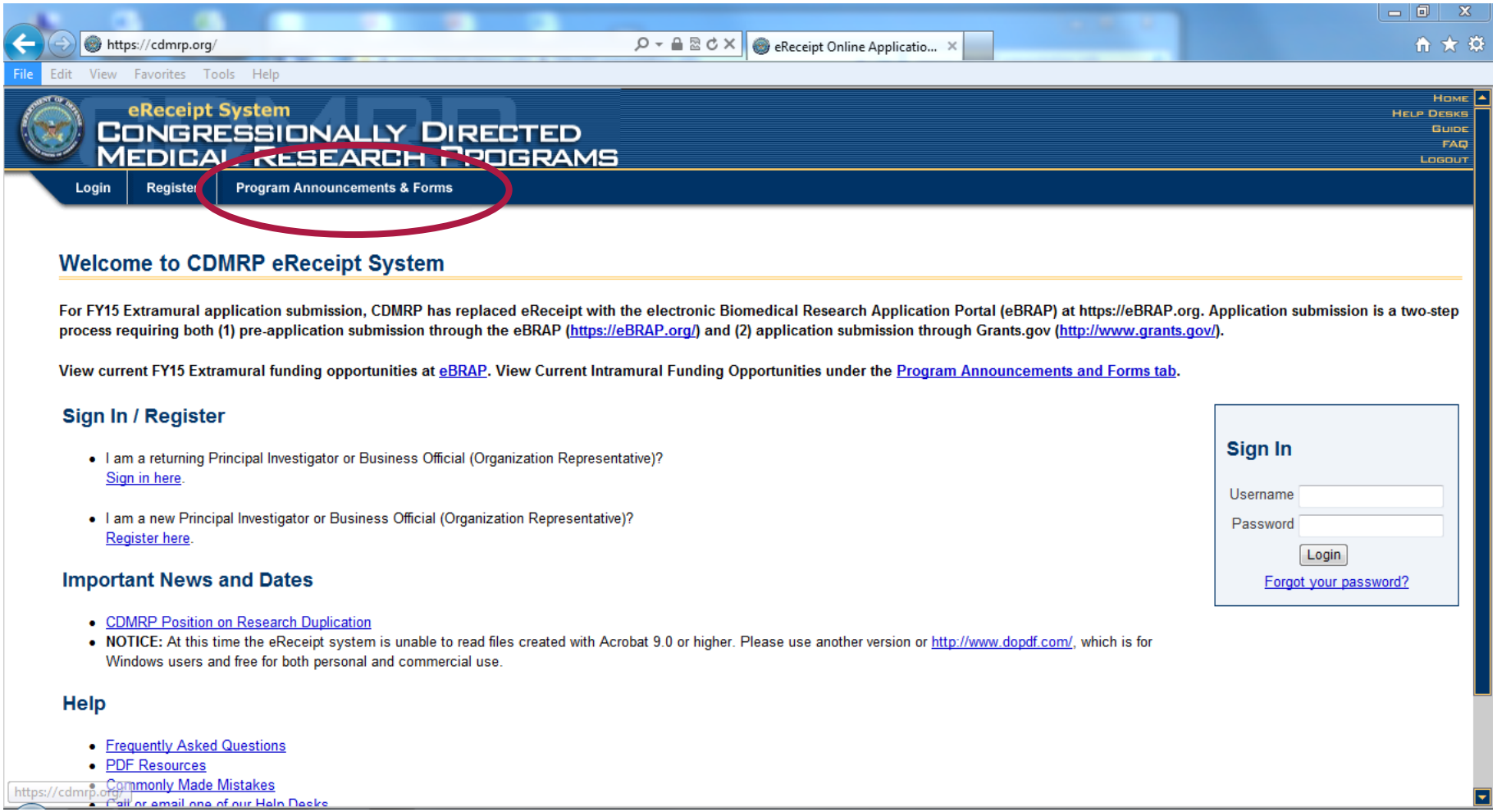


Announcements on the CDMRP Website – http://cdmrp.army.mil

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



Intramural Announcements on the CDMRP eReceipt System – https://cdmrp.org



Current Funding Opportunities

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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

eBRAP (https://eBRAP.org)

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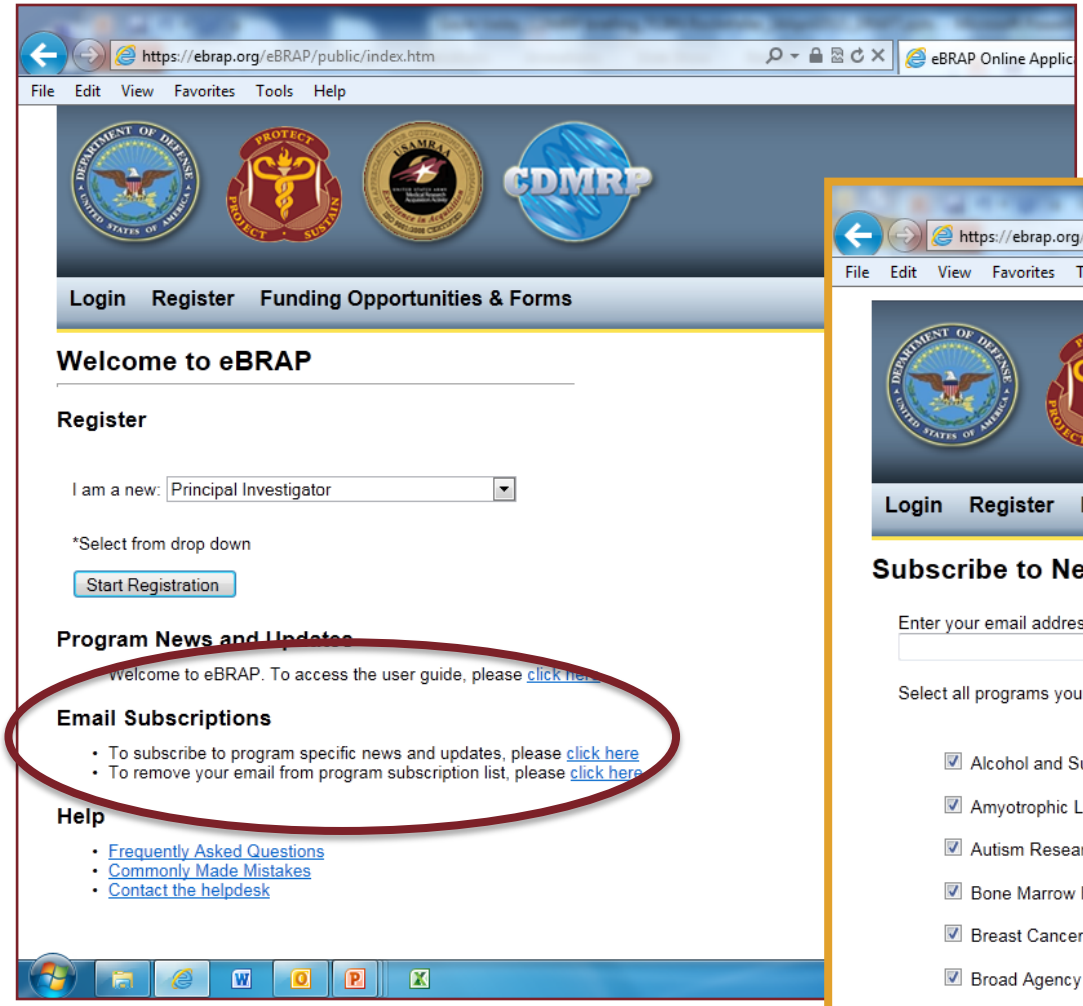
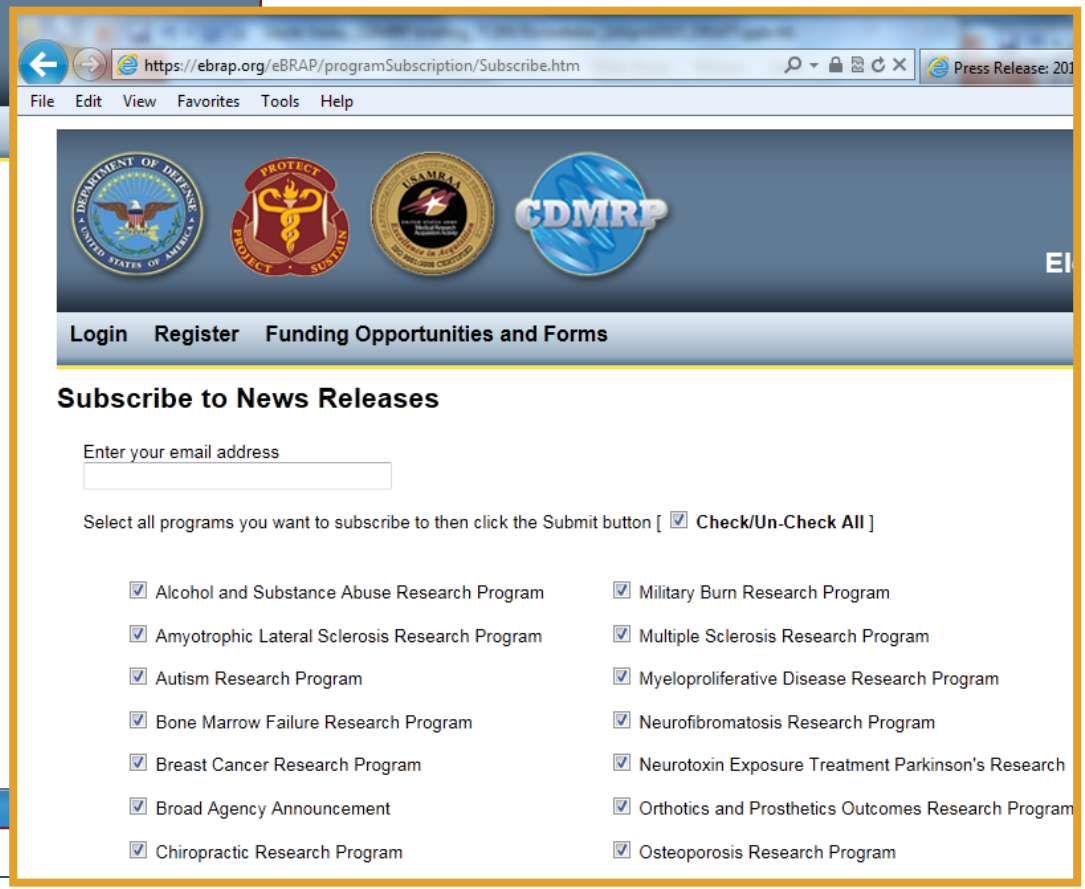
CDMRP's electronic application submission and processing tool is called eBRAP.

- **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





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, then the PI must invite the AOR to register the organization**

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

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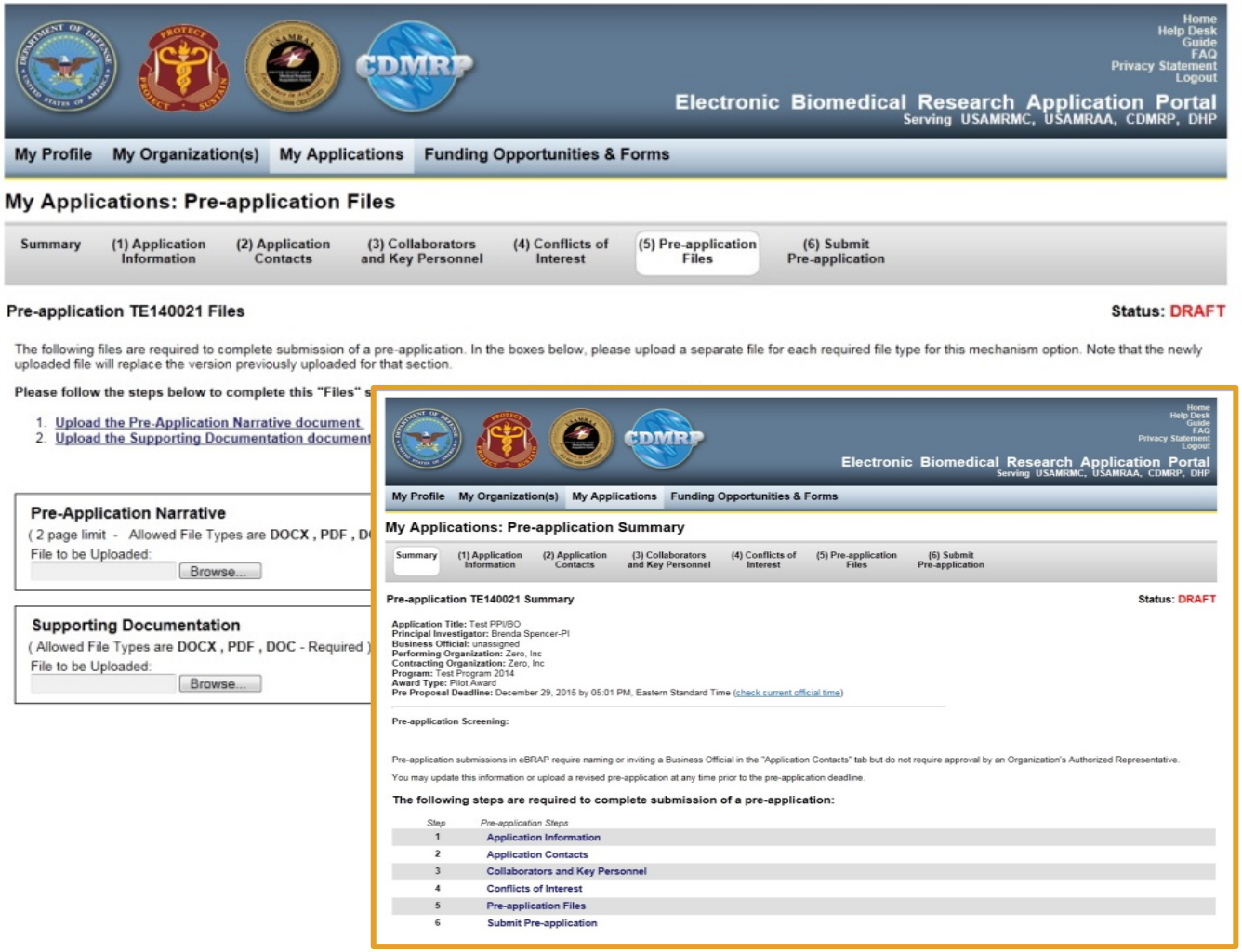
STEP 1: Pre-Application Submission in eBRAP *(required!)*

- **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 auto-compliance**
- **Auto-email notification**



How to Apply – Step 2: Submit Your Application

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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

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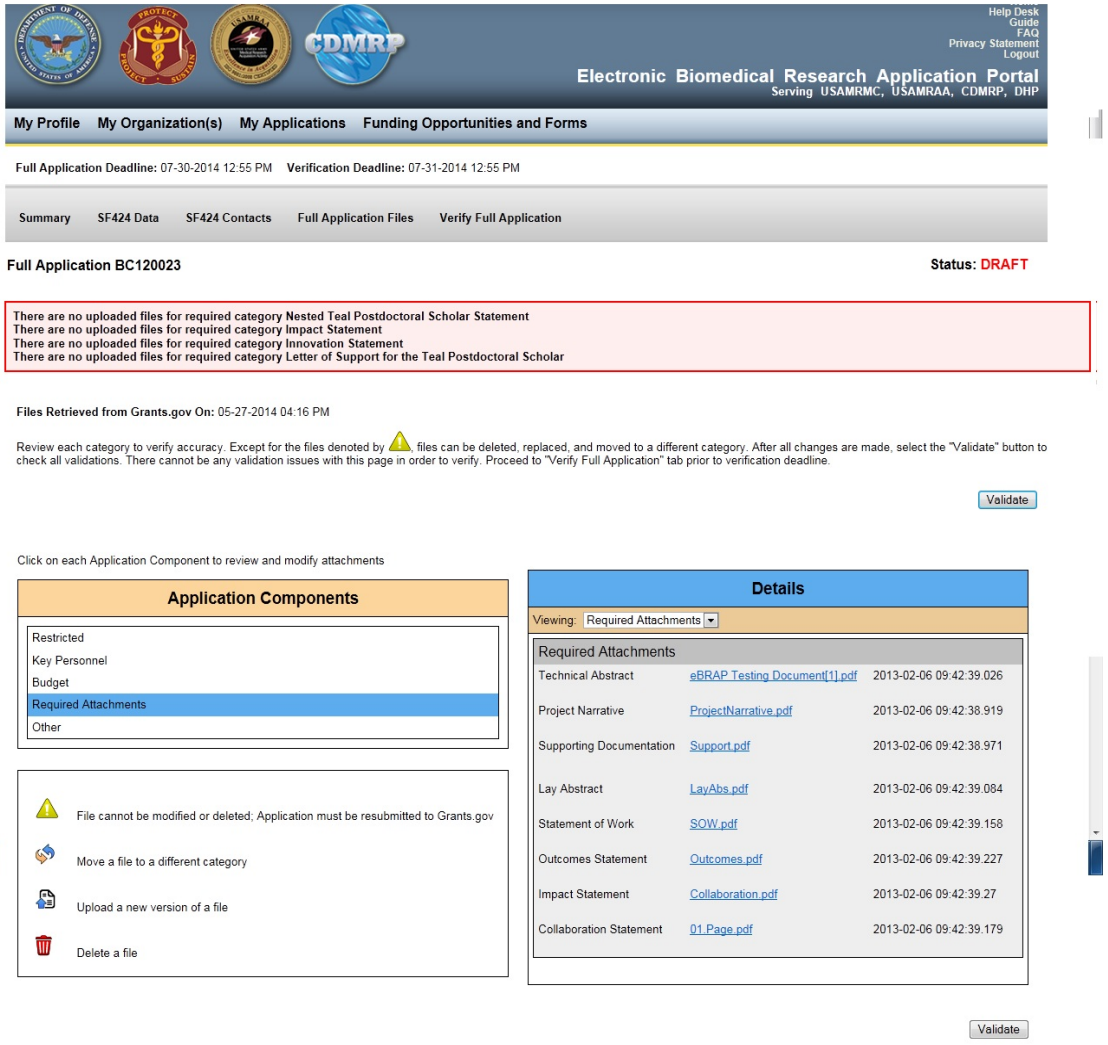
Review & Modify Full Application

- **Verification Period**
  - Auto-email notification after eBRAP has processed the Grants.gov application
  - Review and modify allowable 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; must match those in pre-application
  - Include eBRAP log number



Pitfalls to Avoid in Application Submission

- 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

Goal of the Two-Tier Review Process

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

Peer Review

- Criterion-based evaluation of full proposal
- Determination of "absolute" scientific merit
- Outcome: Written critique and scores for individual criteria and overall merit

- *No standing peer review panels*
- *No contact between reviewers and applicants*

Partnership

Programmatic Review

- Comparison among proposals of high scientific merit
- Determination of adherence to intent and program relevance
- Outcome: Funding recommendations

- *No "pay line" (portfolio balance)*
- *Funds obligated up front; no out-year budget commitments (but milestones imposed)*
- *No continuation funding*

First Tier: Peer Review

- **How the evaluation process works**
  - Technical merit assessment based on an ideal application
  - Criteria-based evaluation of entire application
- **Peer Reviewers**
  - Panels 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

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 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

Strategies for Success

- 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**

http://cdmrp.army.mil

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

Questions

CDMRP?

Funding Opportunities?

Application Submission?

Review Process?

Award Issues?

Other DoD Funding Opportunities

Medical Research and Development at USAMRMC

CDMRP Department of Defense

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

Vision:
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

New Products and Ideas (NPI)

- **NPI User Registration**
- **Submission Form**
- **FAQs**

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