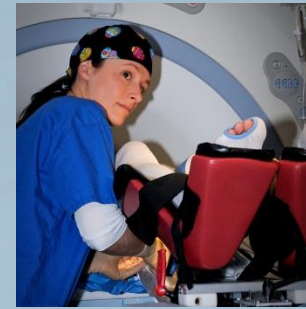


The Congressionally Directed Medical Research Programs

CUTTING EDGE RESEARCH

Peer Reviewed Medical Research Program

Patricia C. Modrow, 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

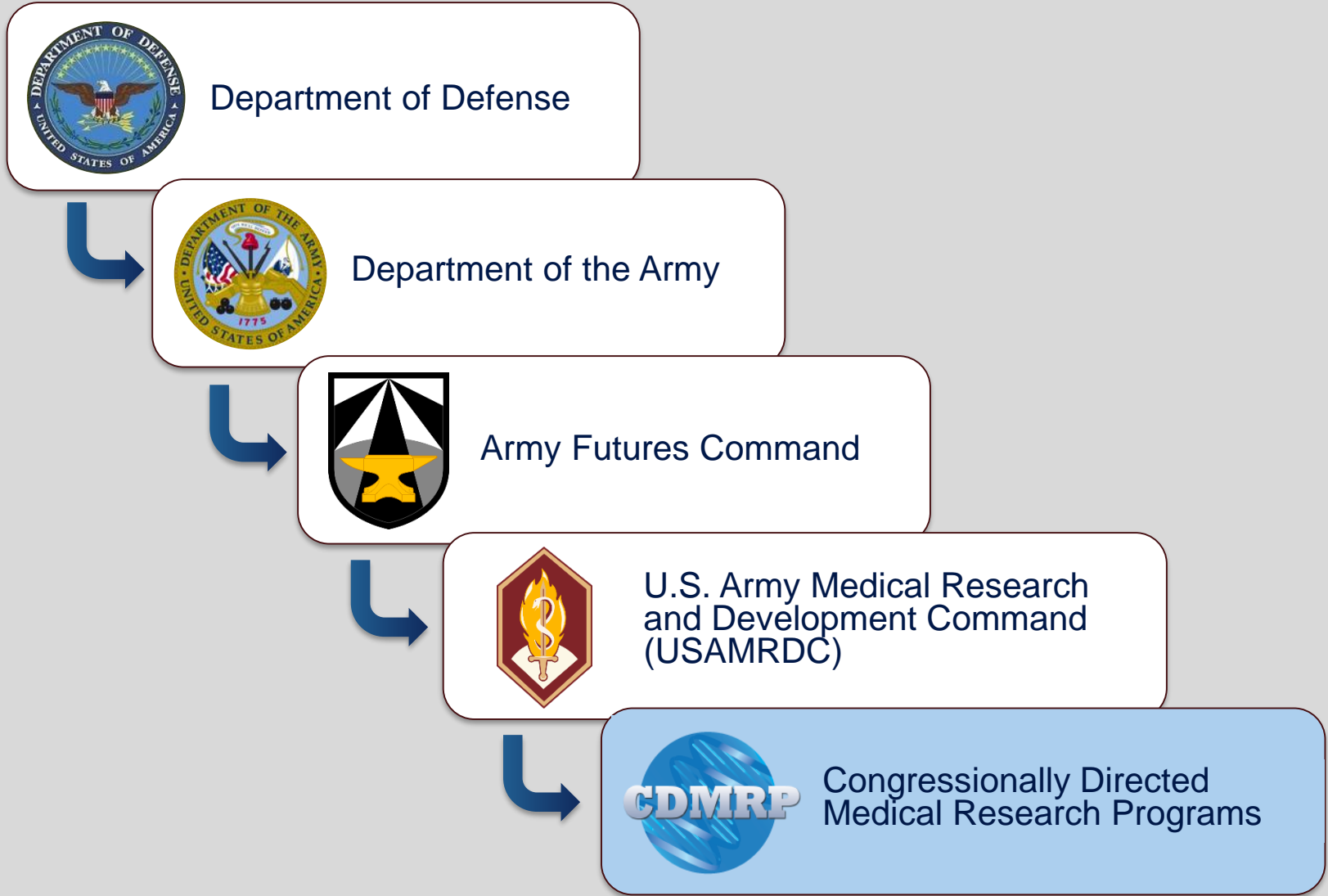
CDMRP

Department of Defense



20 March 2020

WHO is the CDMRP?



CDMRP FY20 Programs

Program	\$M
Amyotrophic Lateral Sclerosis	\$20.0
Alzheimer's	\$15.0
Autism	\$15.0
Bone Marrow Failure Disease	\$3.0
Breast Cancer	\$150.0
Breast Cancer Research Semipostal	TBD
Combat Readiness Medical	\$10.0
Chronic Pain Management	\$15.0
Duchenne Muscular Dystrophy	\$10.0
Epilepsy	\$12.0
Gulf War Illness	\$22.0
Hearing Restoration	\$10.0
Joint Warfighter Medical	\$40.0
Kidney Cancer	\$40.0
Lung Cancer	\$14.0
Lupus	\$10.0
Melanoma	\$20.0
Military Burn	\$10.0
Multiple Sclerosis	\$16.0
Neurofibromatosis	\$15.0
Orthotics and Prosthetics Outcomes	\$15.0

Program	\$M
Orthopaedic	\$30.0
Ovarian Cancer	\$35.0
Pancreatic Cancer*	\$6.0
Neurotoxin Exposure Treatment Parkinson's	\$16.0
Peer Reviewed Medical (44 Topics)	\$360.0
Peer Reviewed Cancer (14 Topics)	\$110.0
Prostate Cancer	\$110.0
Rare Cancers*	\$7.5
Reconstructive Transplant	\$12.0
Scleroderma*	\$5.0
Spinal Cord	\$40.0
Tick-Borne Disease	\$7.0
Tuberous Sclerosis Complex	\$6.0
Vision	\$20.0
TOTAL CSI = ~\$1.2B	
Additional Supported DoD Programs/Projects ⁽¹⁾	
Armed Forces Institute of Regenerative Medicine II	TBD
Defense Medical R&D	\$232.1
Psychological Health and Traumatic Brain Injury	\$165.0
Small Business Innovation Research/Small Business Technology Transfer	TBD
Trauma Clinical	\$10.0

^(*) New for FY20 ⁽¹⁾ Approximate funding of Additional Supported DoD Programs/Projects

TOTAL OVERALL = ~\$1.6B

Hallmarks



- ◆ **Research programs are targeted by Congress, and funds are added to the DoD budget**
- ◆ **Fund high-impact innovative research and coordinate with DoD, NIH, VA, CDC, and other federal and non-federal organizations to target unfunded/unmet gaps**
- ◆ **Follow the National Academy of Medicine guidance, including two-tier model for application review**
 - ❖ Conduct peer and programmatic review for all applications and oversee the processes
- ◆ **Include consumers in all aspects of the program cycle**
 - ❖ Include impact review criterion for every funding opportunity
 - ❖ Funding recommendations consider critical needs
- ◆ **Annually adapt each program's vision and investment strategy allowing rapid response to changing needs**
 - ❖ Fund bench to bedside research

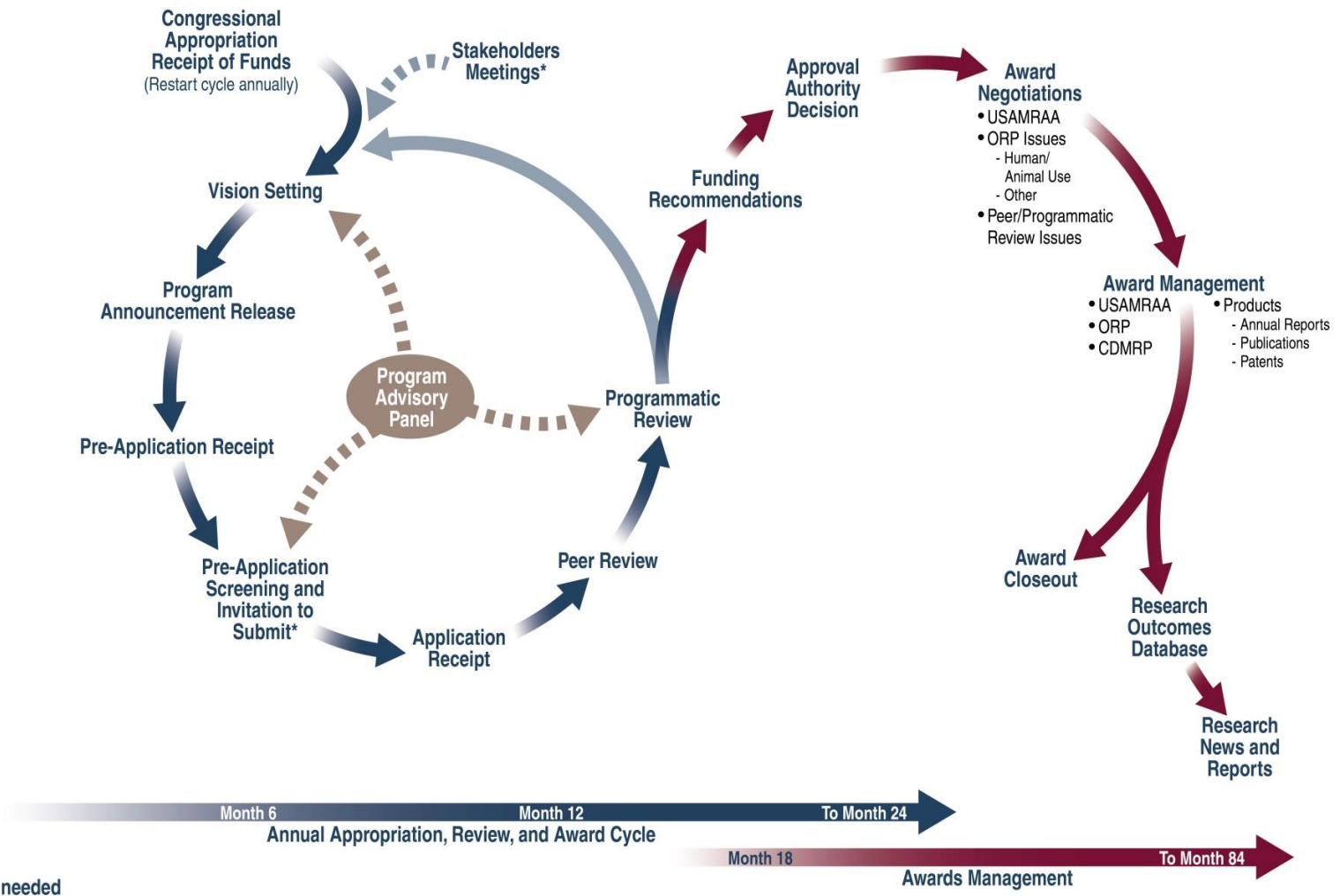
Consumers

Grassroots consumers heightened political awareness of breast cancer that led to increased funding for cancer research and the 1992 creation of the CDMRP. The voices and experiences of consumers continue to play a pivotal role in the establishment and growth of research programs.

Over 2,700 consumers representing over 1,300 organizations have served on Peer Review and Programmatic Review panels



Program Cycle



*As needed

Goal of the Two-Tier Review Process

To develop funding recommendations that balance the most meritorious science across many disciplines and offer the highest promise to fulfill the programmatic goals set forth in the relevant Program Announcement

Peer Review

- ◆ Criterion-based evaluation of full proposal
- ◆ Determination of “absolute” scientific merit
- ◆ **Outcome: Summary Statements**
 - ❖ No standing Peer Review panels
 - ❖ No contact between reviewers and applicants
 - ❖ No contact between program staff 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; limited out-year budget commitments (but milestones imposed)
 - ❖ No continuation funding

Accountability to Stakeholders

◆ **Transparency**

- ❖ Defense Technical Information Center (DTIC)
- ❖ CDMRP website
- ❖ Federal RePORTER
- ❖ International Cancer Research Partners

◆ **Adaptable Funding Strategy**

- ❖ Open and full competition
- ❖ Fund the best high-impact research from any organization or location
- ❖ Funding based on scientific merit and relevance to program mission; no “pay line”
- ❖ Obligate funds up front; no risk to the project
- ❖ Maintain low management costs

◆ **Active Award Management**

- ❖ Scientific staff support pre-award negotiations and lifecycle of award
- ❖ Closely monitor research progress through open communication, written and in-person reports, milestone meetings, and site visits
- ❖ Require PIs to present their research at investigator conferences, share data, and register trials

◆ **Keep the consumer as our true north**

PRMRP Overview



Vision

Improve the health, care, and well-being of all Military Service members, Veterans, and beneficiaries

Mission

Encourage, identify, select, and manage medical research projects of clear scientific merit and direct relevance to military health

Appropriations

- ❖ Direction from Congress to support research of “clear scientific merit” and “direct relevance to military health” in at least one topic area
- ❖ Program funds and topic areas designated by Congress annually
 - Appropriations total \$2.71B since inception
 - FY20 appropriations is \$360M; 44 topics
 - No funds allotted per topic area
- ❖ Investment strategy established by Programmatic Panel annually, with representation of Military Services, VA, HHS, NIH, and academia

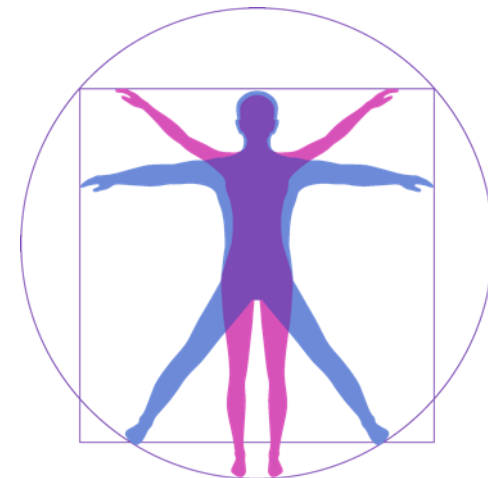
PRMRP Congressionally-Directed Topic Areas

- **Topic areas span a broad range of research fields, diseases, and conditions**
 - ❖ Support research of high scientific merit
 - ❖ Support research with direct relevance to military health
 - Research must be directly relevant to the healthcare needs of and benefit military Service members, Veterans, and/or beneficiaries
 - ❖ Support research that meets the first two objectives across as many topic areas as possible
 - Funded research is restricted to the Congressionally-specified topic areas
- **Over 200 Congressionally-specified unique topic areas offered FY99–FY06, FY08-FY20**
 - ❖ Topic areas have become their own CSI programs; 17 CSI programs through FY20
 - ❖ Funded research in 170 unique topic areas in FY99-FY19
- **No preselected allocation of funds per topic area; no payline**
 - ❖ Funding decisions are made by the Programmatic Panel using programmatic review criteria published in the Program Announcements; scientific merit, impact, relevance to military health

FY20 Topic Areas for PRMRP (44 total)

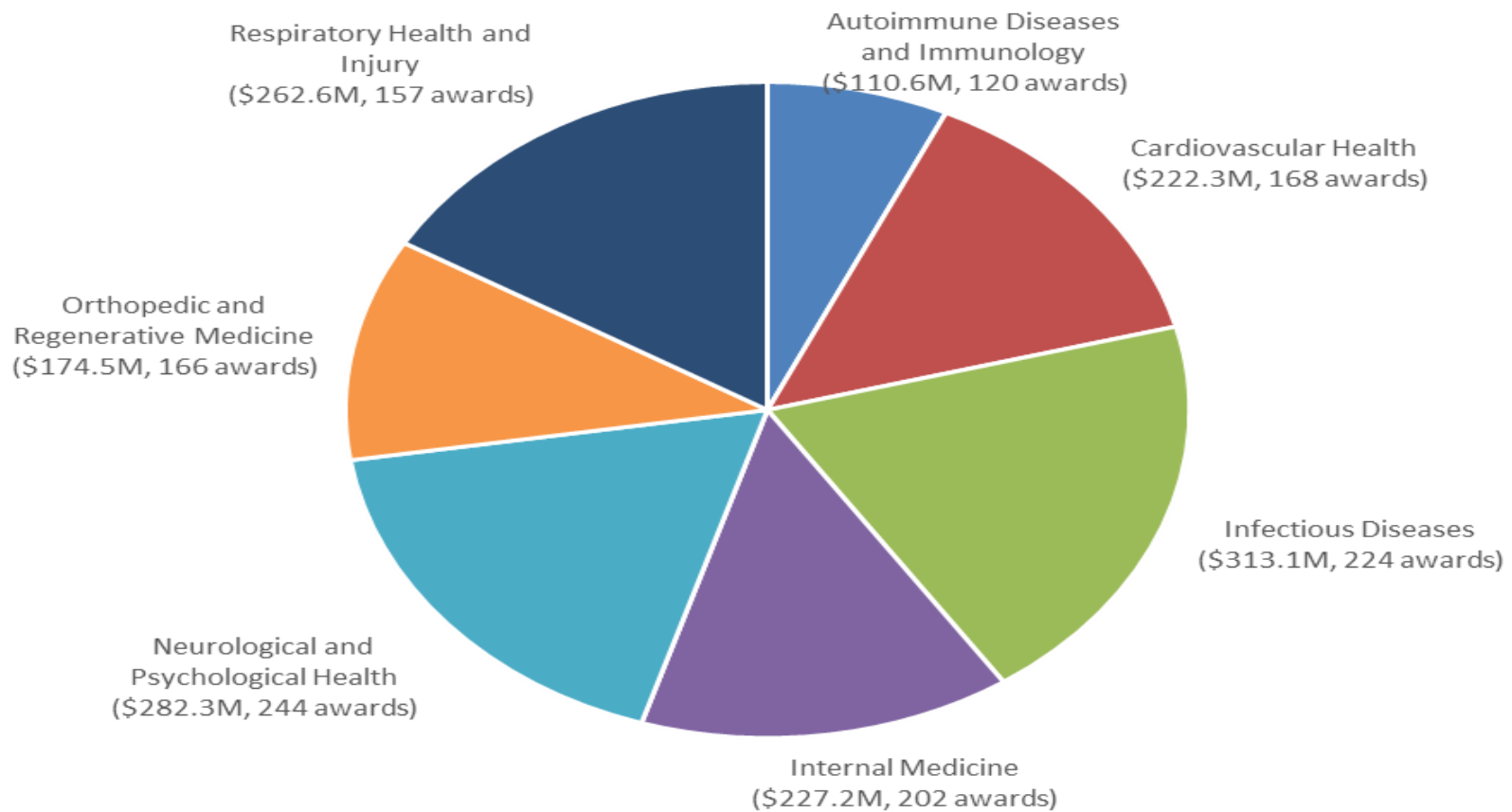
- ◆ Arthritis
- ◆ Burn Pit Exposure
- ◆ Chronic Migraine and Post-Traumatic Headache
- ◆ Congenital Heart Disease
- ◆ Constrictive Bronchiolitis
- ◆ Diabetes
- ◆ Dystonia
- ◆ Eating Disorders
- ◆ Emerging Viral Diseases
- ◆ Endometriosis
- ◆ Epidermolysis Bullosa
- ◆ Familial Hypercholesterolemia
- ◆ Fibrous Dysplasia
- ◆ Focal Segmental Glomerulosclerosis
- ◆ Food Allergies
- ◆ Fragile X
- ◆ Frontotemporal Degeneration
- ◆ Guillain-Barre Syndrome
- ◆ Hemorrhage Control
- ◆ Hepatitis B
- ◆ Hydrocephalus
- ◆ Immunomonitoring of Intestinal Transplants
- ◆ Inflammatory Bowel Disease
- ◆ Interstitial Cystitis
- ◆ Metals Toxicology
- ◆ Mitochondrial Disease
- ◆ Musculoskeletal Health
- ◆ Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- ◆ Myotonic Dystrophy
- ◆ Nutrition Optimization
- ◆ Pancreatitis
- ◆ Pathogen-Inactivated Blood Products
- ◆ Plant-Based Vaccines
- ◆ Polycystic Kidney Disease
- ◆ Pressure Ulcers
- ◆ Pulmonary Fibrosis
- ◆ Resilience Training
- ◆ Respiratory Health
- ◆ Rheumatoid Arthritis
- ◆ Sleep Disorders and Restriction
- ◆ Spinal Muscular Atrophy
- ◆ Sustained Release Drug Delivery
- ◆ Vascular Malformations
- ◆ Women's Heart Disease

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



PRMRP Award Portfolio Overview

Portfolio by Research Area and Percent Total Funding FY99 – FY18



1281 awards totaling \$1.59B (includes pending awards)

PRMRP FY20 Award Mechanisms

- ◆ **Clinical Trial Award (CTA)**
- ◆ **Discovery Award (DA)**
- ◆ **Expansion Award (ExpA)**
- ◆ **Focused Program Award (FPA)**
- ◆ **Investigator-Initiated Research Award (IIRA)**
- ◆ **Technology/Therapeutic Development Award (TTDA)**

FY20 PRMRP Award Mechanisms & Investment Strategy

Award Mechanism	Intent	Investment Strategy	Est. # Awards
Clinical Trial (CTA)	Supports rapid implementation of clinical trials of novel interventions	<ul style="list-style-type: none"> ❖ No cost limit ❖ 4-year POP 	9
Discovery (DA)	<p>Supports innovative, non-incremental, high-risk/potentially high-reward research that will provide new insights, paradigms, technologies, or applications that will lay the groundwork for future avenues of scientific investigation</p>	<ul style="list-style-type: none"> ❖ Up to \$200K direct costs ❖ 2-year POP 	75
Expansion (EA)	Supports the continued investigation and further development of highly impactful research projects that were funded through the previous PRMRP funding opportunities	<p>Varying by Funding Level:</p> <ul style="list-style-type: none"> ❖ \$0.5M - \$5.0M direct costs ❖ 3-4-year POP 	8

FY19 Investment Strategy (cont.)

Award Mechanism	Intent	Investment Strategy	Est. # Awards
Focused Program (FPA)	Supports a synergistic, multidisciplinary research program of multiple distinct, but complementary, projects addressing a unifying, overarching goal	<ul style="list-style-type: none"> ❖ Up to \$7.2M direct costs ❖ 4-year POP 	4
Investigator-Initiated Research (IIRA)	Supports studies that make an important contributions to the field of research or patient care; research with the potential to yield highly impactful data that could lead to critical discoveries or major advancements.	<ul style="list-style-type: none"> ❖ Up to \$1.6M direct costs ❖ Up to \$2.0M direct costs (Partnering PI Option) ❖ 4-year POP 	37
Technology/Therapeutic Development (TTDA)	Supports product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical applications; product may be diagnostics or therapies such as pharmacologic agents (drugs or biologics), devices, and/or clinical guidance	<ul style="list-style-type: none"> ❖ Up to \$4M direct costs ❖ 4-year POP 	14

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2016/2017 Program Announcements

Breast Cancer	Peer Reviewed Cancer
Duchenne Muscular Dystrophy	Peer Reviewed Medical
Epilepsy	NEW Peer Reviewed
Lung Cancer	Orthopaedic
Orthotics and Prosthetics	NEW Prostate Cancer
Outcomes	Psychological Health/Traumatic
Parkinson's	Brain Injury
Peer Reviewed Alzheimer's	Spinal Cord Injury

Latest News

- PCR** PET/MRI: A one-stop imaging test to detect prostate cancer? University of Michigan, July 11, 2016
- PCR** Presence of AR-V7 in circulating Tumor Cells Validated as Predictive Biomarker for Advanced Prostate Cancer Treatment Epic Sciences, June 4, 2016
- ARP** Mini-brain Model of Idiopathic Autism Reveals Underlying Pathology of Neuronal Overgrowth University California San Diego, July 13, 2016

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Funded Research

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Sign up for listserve through CDMRP website or in eBRAP

Where Do I Find CDMRP Funding Opportunities?

GRANTS.GOV SEARCH GRANTS

SEARCH Grant Opportunities Enter Keyword GO

BASIC SEARCH CRITERIA: Keywords: Funding Opportunity Number: CFDA Number: 12.420

OF 2094 MATCHING RESULTS:

Funding Opportunity Number	Opportunity Title	Agency	Open Date	Clos
NSF-15-000002	Community Consensuses Support Program	East Africa USAID-Kenya	03/19/2015	03/31
USDA-NIFA-SRGP-04496	Special Research Grants Program Potato Breeding Research	National Institute of Food and Agriculture	03/19/2015	04/2
P15AS00070	Survey of the Fauna of Seepage Springs in National Capital Parks East	National Park Service	03/19/2015	03/2
NPS-NOIP15A000039	National Park Service-Complete NAGPRA Summary Lists	National Park Service	03/19/2015	03/2
PAR-15-146	Countermeasures Against Chemical Threats (CounterACT) Research	National Institutes of Health	03/19/2015	03/1

ELIGIBILITY: All Eligibilities city or township governments (905) County governments (915) For profit organizations other than small businesses (957)

For CDMRP opportunities, search by CFDA Number 12.420

Congressional Directed Medical Research Programs

CDMRP Department of Defense

Funding and Financials

RESEARCH PROGRAMS FUNDING OPPORTUNITIES CONSUMER INVOLVEMENT SEARCH AWARDS

2014/2015 Program Announcements

- Alcohol and Substance Abuse
- Amyotrophic Lateral Sclerosis
- Bone Marrow Failure
- Breast Cancer
- Clinical and Rehabilitative Medicine
- Defense Medical Research and Development Program
- Psychological Health and Traumatic Brain Injury

https://cdmrp.army.mil

Electronic Biomedical Research Application Portal

Serving USAMRIID, USAMRIIA, CDMRP, DHP

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Welcome to eBRAP

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Already registered or returning user. Sign In

Username: Password: <https://ebrap.org>

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Help

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Forgot your password?

Applying for a Grant

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



◆ **The announcement (PA) 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

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 in any order
- ◆ Pre-application is submitted in Tab 6
- ◆ Pre-application submission is mandatory and must be on time – no grace period
- ◆ *Tips for success!*
 - ❖ *Read the Program Announcement carefully*
 - ❖ *Start pre-application in eBRAP early*
 - ❖ *Choose the correct funding opportunity and “option”*
 - ❖ *Don’t forget LOI or Preproposal Narrative*
 - ❖ *Use correct spelling of names and emails*

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**
- ◆ **If pre-application was an LOI, NO 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**
- ◆ **If using organization or commercial System-to-System (S2S), beware of Attachment 1, Project Narrative**

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 allowable 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 pre-application
- ❖ Enter eBRAP log number in Block 4.a. Federal Identifier of SF424

Help Desk
Guide
FAQ
Privacy Statement
Logout

Electronic Biomedical Research Application Portal
Serving USAMRMC, USAMRAA, CDMRP, DHP

My Profile My Organization(s) My Applications Funding Opportunities and Forms

Full Application Deadline: 07-30-2014 12:55 PM Verification Deadline: 07-31-2014 12:55 PM

Summary SF424 Data SF424 Contacts Full Application Files Verify Full Application

Full Application BC120023 Status: **DRAFT**

There are no uploaded files for required category Nested Teal Postdoctoral Scholar Statement
 There are no uploaded files for required category Impact Statement
 There are no uploaded files for required category Innovation Statement
 There are no uploaded files for required category Letter of Support for the Teal Postdoctoral Scholar

Files Retrieved from Grants.gov On: 05-27-2014 04:16 PM

Review each category to verify accuracy. Except for the files denoted by files can be deleted, replaced, and moved to a different category. After all changes are made, select the "Validate" button to check all validations. There cannot be any validation issues with this page in order to verify. Proceed to "Verify Full Application" tab prior to verification deadline.

Click on each Application Component to review and modify attachments

Application Components	
Restricted	
Key Personnel	
Budget	
Required Attachments	
Other	

File cannot be modified or deleted; Application must be resubmitted to Grants.gov

Move a file to a different category

Upload a new version of a file

Delete a file

Details		
Viewing: Required Attachments ▾		
Required Attachments		
Technical Abstract	eBRAP_Testing_Document[1].pdf	2013-02-06 09:42:39.026
Project Narrative	ProjectNarrative.pdf	2013-02-06 09:42:38.919
Supporting Documentation	Support.pdf	2013-02-06 09:42:38.971
Lay Abstract	LayAbs.pdf	2013-02-06 09:42:39.084
Statement of Work	SOW.pdf	2013-02-06 09:42:39.158
Outcomes Statement	Outcomes.pdf	2013-02-06 09:42:39.227
Impact Statement	Collaboration.pdf	2013-02-06 09:42:39.27
Collaboration Statement	01_Page.pdf	2013-02-06 09:42:39.179

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

✓ 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

✓ Planning/Timelines

- ❖ Start early – do not wait to submit until the last day or the last hour
- ❖ 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 (scientists and consumers) of the peer and programmatic reviews and **COMMUNICATE** effectively
- ❖ **REVIEW** application documents carefully before submission – Enlist experienced colleagues to help
- ❖ Review your submission in eBRAP during the Verification period
- ❖ Don't break the rules for deadlines or requirements – **BE COMPLIANT**

Pitfalls to Avoid in Application Submission



- ◆ **DO not forget to submit pre-application**
- ◆ **Do not include Programmatic Panel members for the program and fiscal year to which you are applying**
- ◆ **Do not exceed the page limits, especially project narrative; check files after creating PDF version**
- ◆ **Do not miss the submission deadline; no grace periods**
 - ❖ Grants.gov validation may take up to 72 hours
 - ❖ Organization and commercial System-to-system (S2S) submissions are sometimes problematic
 - ❖ Application verification in eBRAP is possible before the deadline
- ◆ **Submit the correct Project Narrative and Budget**
 - ❖ These components cannot be modified during the verification period in eBRAP; Grants.gov package must be resubmitted prior to deadline

Pitfalls For The Organization to Avoid

- ◆ **Register with all systems EARLY**
 - ❖ Active SAM Registration Required – keep it active for both submission and award
 - ❖ Determine Organization Points of Contact (AOR, E-Biz POC)
 - ❖ Principal Investigators (PI's) do not register
 - ❖ Resolve all S2S errors
 - ❖ Resolve all Grants.gov errors
- ◆ **Sign up for email change notifications when possible**
- ◆ **Become familiar with Federal and DoD regulations and processes**
 - ◆ Subaward budget (direct and indirect costs)
- ◆ **Make sure the following items on the SF424 match what was in the pre-application in eBRAP**
 - ❖ PI's last name
 - ❖ Organization name & DUNS
 - ❖ eBRAP log number
- ◆ **Monitor your email at least one week after submission**
 - ❖ eBRAP.org will notify you when Grants.gov application is received and processed **allowing for application verification**

CDMRP Funding Opportunities Webinar Series



Webinar Title
Funding Opportunities and Strategies for Success
High Risk/High Gain Funding Opportunities
Team Science Funding Opportunities
Clinical Research and Clinical Trial Funding Opportunities
Funding Opportunities for the Development of Technology and/or Resources
Funding Opportunities for Early Career Investigators
Consortium-Type Funding Opportunities

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