

The Congressionally Directed Medical Research Programs

HIGH-IMPACT RESEARCH

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CDMRP

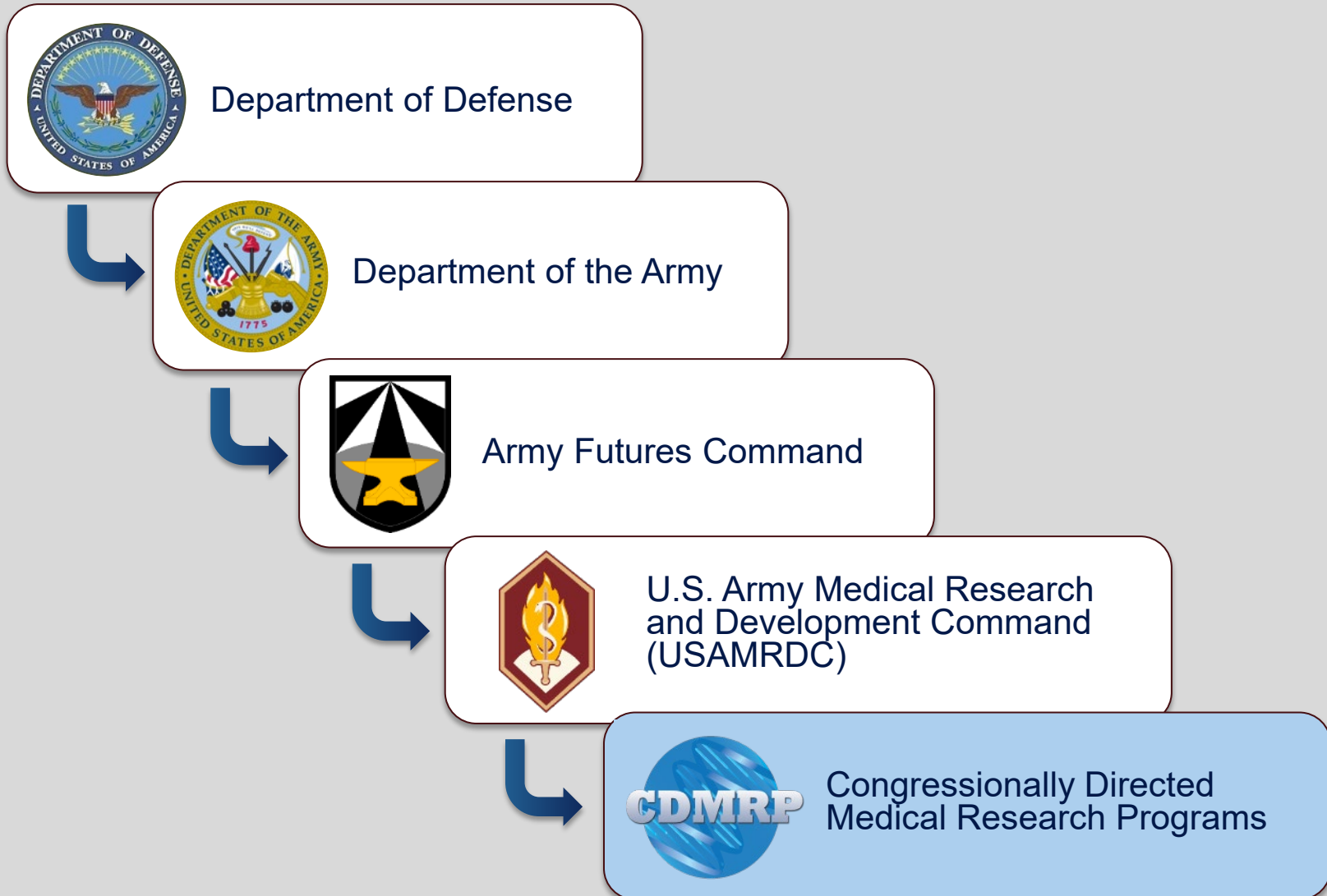
Department of Defense



Outline

- ◆ Overview of the CDMRP
- ◆ CDMRP Funding Process
 - ❖ Program Cycle
 - ❖ Application Review
- ◆ CDMRP Funding Opportunities
- ◆ Application Submission Process

WHO is the CDMRP?



Vision and Mission

Vision

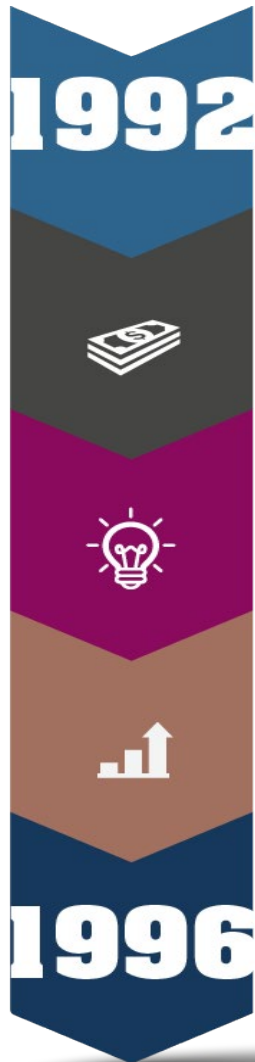
Transforming healthcare
through innovative and
impactful research



Mission

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

How It All Started



- ◆ In 1992, grassroots efforts heightened political awareness of breast cancer
- ◆ Congress appropriated \$210M to the FY93 DoD budget for a new Breast Cancer Research Program (BCRP) and directed USAMRDC to manage it
- ◆ The Army sought the advice of the National Academy of Medicine (previously the Institute of Medicine [IOM]); 1993 IOM recommendations* included:
 - ❖ A two-tier review process – peer and programmatic reviews
 - ❖ A new research model – incorporating consumers into program policy, investment strategy, and research focus
- ◆ Since 1996, additional research programs and topics have been added by Congress and administratively managed by the CDMRP

* Institute of Medicine, Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command, The National Academies Press, 1993.

Hallmarks



- ◆ Congress adds targeted research funds to the DoD budget
- ◆ Funds high-impact innovative research
- ◆ Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- ◆ Follows the National Academy of Medicine-recommended model for application review
- ◆ Consumers participate throughout the process and are the “True North” and foundation of the programs
- ◆ Annually adapts each program’s vision and investment strategy allowing rapid response to changing needs
- ◆ Funding flexibility
 - ❖ Funds obligated up-front; limited out-year budget commitments
 - ❖ No continuation funding
 - ❖ No “pay line” – funding recommendations are based on portfolio composition, adherence to mechanism intent, relative impact, and technical merit
- ◆ Transparency and accountability to stakeholders
- ◆ Low management costs maximize research dollars

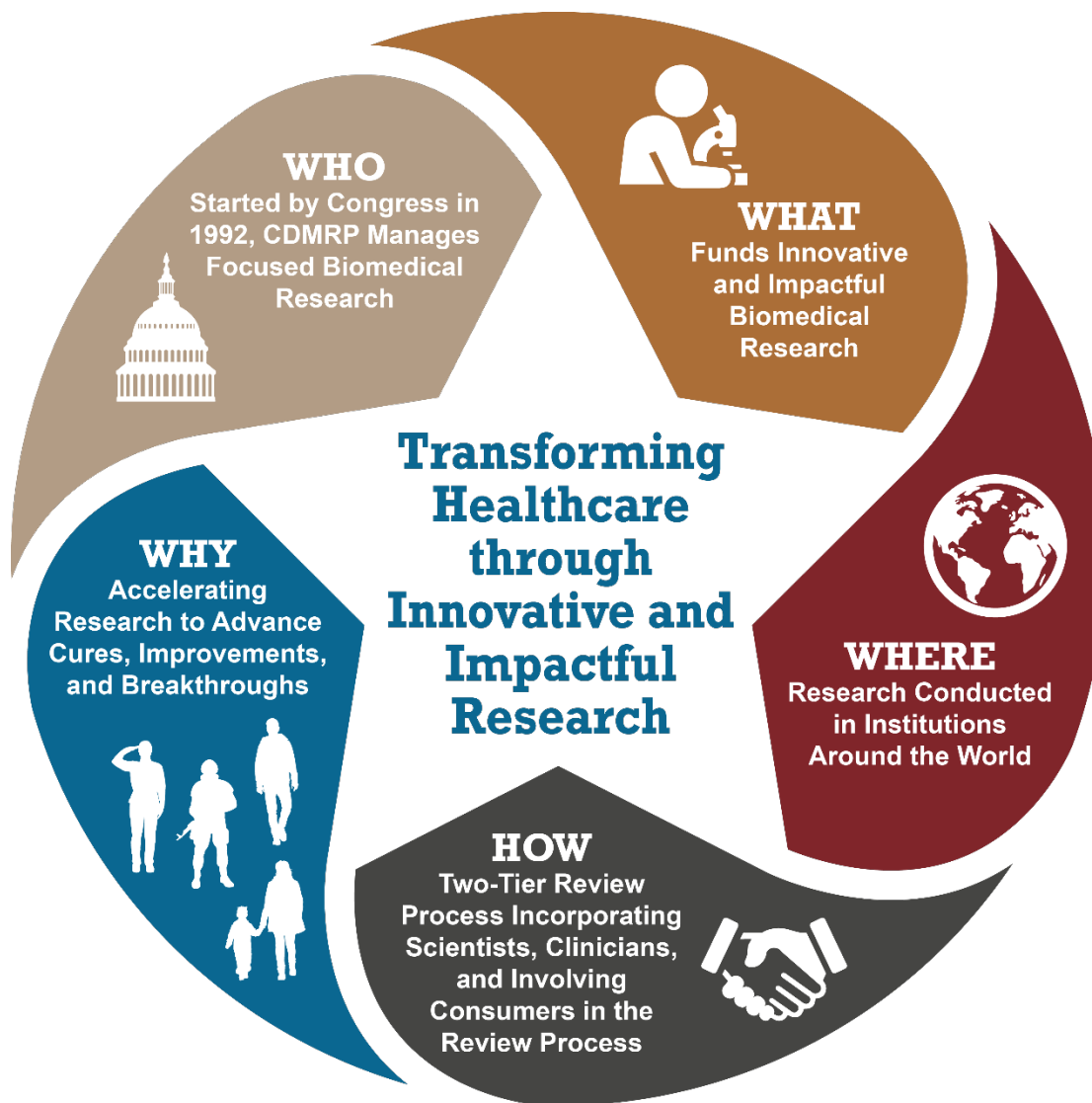
CDMRP FY22 Programs

Research Program	FY22 \$M
Alcohol and Substance Abuse Disorders	\$4.0
Amyotrophic Lateral Sclerosis	\$40.0
Autism	\$15.0
Bone Marrow Failure	\$7.5
Breast Cancer	\$150.0
Chronic Pain Management	\$15.0
Combat Readiness Medical	\$10.0
Duchenne Muscular Dystrophy	\$10.0
Epilepsy	\$12.0
Hearing Restoration	\$10.0
Joint Warfighter Medical	\$40.0
Kidney Cancer	\$50.0
Lung Cancer	\$20.0
Lupus	\$10.0
Melanoma	\$40.0
Military Burn	\$10.0
Multiple Sclerosis	\$20.0
Neurofibromatosis	\$20.0

Research Program	FY22 \$M
Orthotics and Prosthetics Outcomes	\$20.0
Ovarian Cancer	\$45.0
Pancreatic Cancer	\$15.0
Parkinson's	\$16.0
Peer Reviewed Alzheimer's	\$15.0
Peer Reviewed Cancer (20 Topics)	\$130.0
Peer Reviewed Medical (50 Topics)	\$370.0
Peer Reviewed Orthopaedic	\$30.0
Prostate Cancer	\$110.0
Rare Cancers	\$17.5
Reconstructive Transplant	\$12.0
Spinal Cord Injury	\$40.0
Tick-Borne Disease	\$7.0
Toxic Exposures	\$30.0
Traumatic Brain Injury and Psychological Health	\$175.0
Tuberous Sclerosis Complex	\$8.0
Vision	\$20.0

TOTAL = \$1.544B

Unique Partnerships

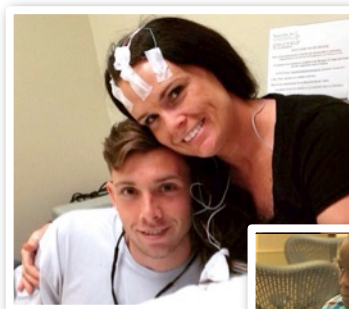


Consumers



Grassroots consumer efforts led to targeted research funding and the creation of the CDMRP. The voices and experiences of consumers play a pivotal role in the growth of CDMRP research programs.

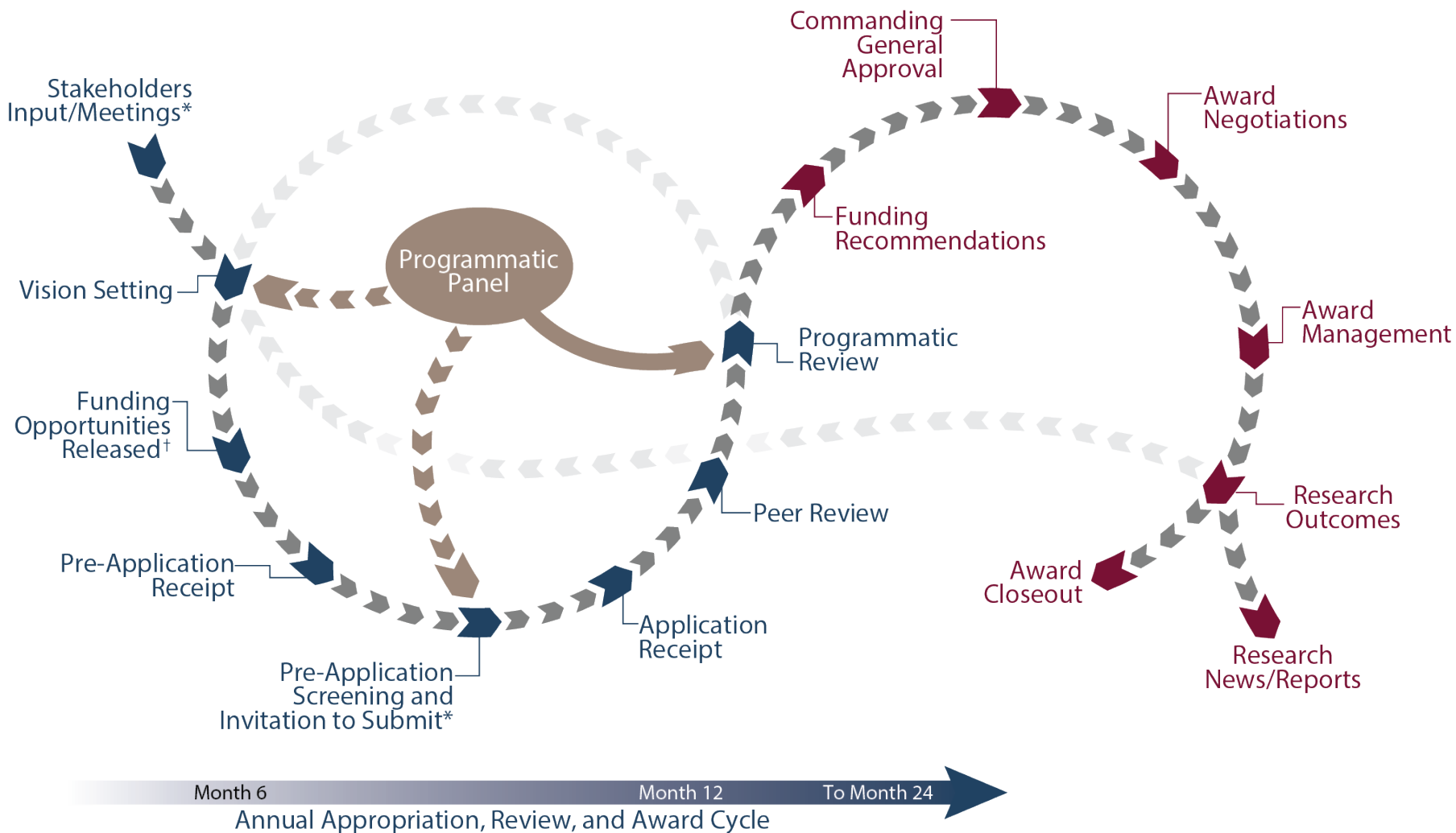
*In 2020, ~466 consumers served on CDMRP Peer Review panels and ~84 served on Programmatic Review**



Consumers are the “True North” and foundation of the CDMRP



Program Cycle



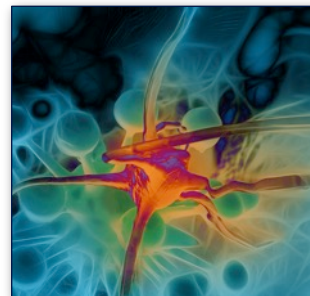
*As needed

†Pending Congressional appropriation

Vision Setting

Each year, the Programmatic Panel recommends an investment strategy, considering factors such as:

- ◆ Congressional language
- ◆ Input and guidance from senior leaders and stakeholders
- ◆ Current research landscape
- ◆ Research, capability, and clinical gaps, and unmet needs
- ◆ Emerging technologies
- ◆ Impact
- ◆ Portfolio composition



Award Mechanisms Pipeline

Research Awards

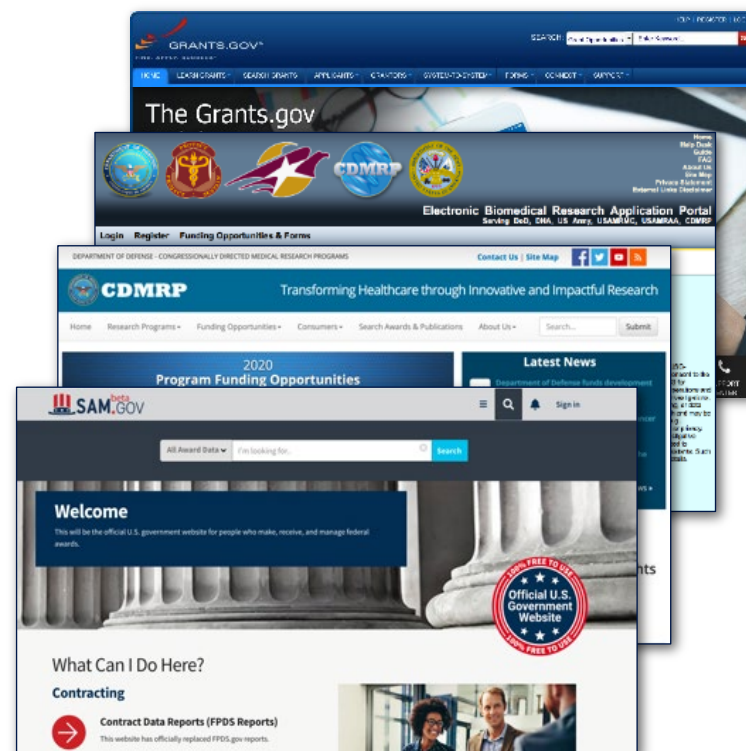
Closing gaps through innovative and impactful research



Funding for all career stages

Funding Opportunities

- ◆ Each funding opportunity is made available through a program announcement (PA) or program-specific broad agency announcement (BAA)
 - ❖ Awarded primarily as grants and cooperative agreements
- ◆ Numerous types of award mechanisms
 - ❖ Tailored to the goals of each program
 - ❖ Programs, topics, and focus areas may vary from year to year
- ◆ Pre-announcement release
 - ❖ CDMRP website and email blast
- ◆ Funding opportunity postings
 - ❖ Grants.gov (CFDA 12.420)
 - ❖ electronic Biomedical Research Application Portal (eBRAP) system
 - ❖ CDMRP website
 - ❖ beta.SAM.gov (BAAs)



Application 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 funding opportunity

Peer Review

- ◆ Criterion-based evaluation of full proposal
- ◆ Determination of “absolute” scientific merit
- ◆ **Outcome: Summary Statements**
 - ❖ No standing panels; reviewers are recruited based on expertise needed
 - ❖ No contact between applicants, reviewers, and program staff

Partnership



Programmatic Review

- ◆ Comparison among proposals of high scientific merit
- ◆ Determination of adherence to intent, program relevance, and potential for impact
- ◆ **Outcome: Funding Recommendations**
 - ❖ No “pay line” (portfolio balance)
 - ❖ Funds obligated up-front; limited out-year budget commitments (but milestones imposed)
 - ❖ No continuation funding

Finding Funding Opportunities

[illegible]

Funding Opportunity Documents

Program Announcement

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Pancreatic Cancer Research Program

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-PCARP-IDA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), July 1, 2021
- Invitation to Submit an Application: August 2021
- Application Submission Deadline: 11:59 p.m. ET, October 1, 2021
- End of Application Verification Period: 5:00 p.m. ET, October 6, 2021
- Peer Review: December 2021
- Programmatic Review: February 2022

General Application Instructions

General Application Instructions

Version 604

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

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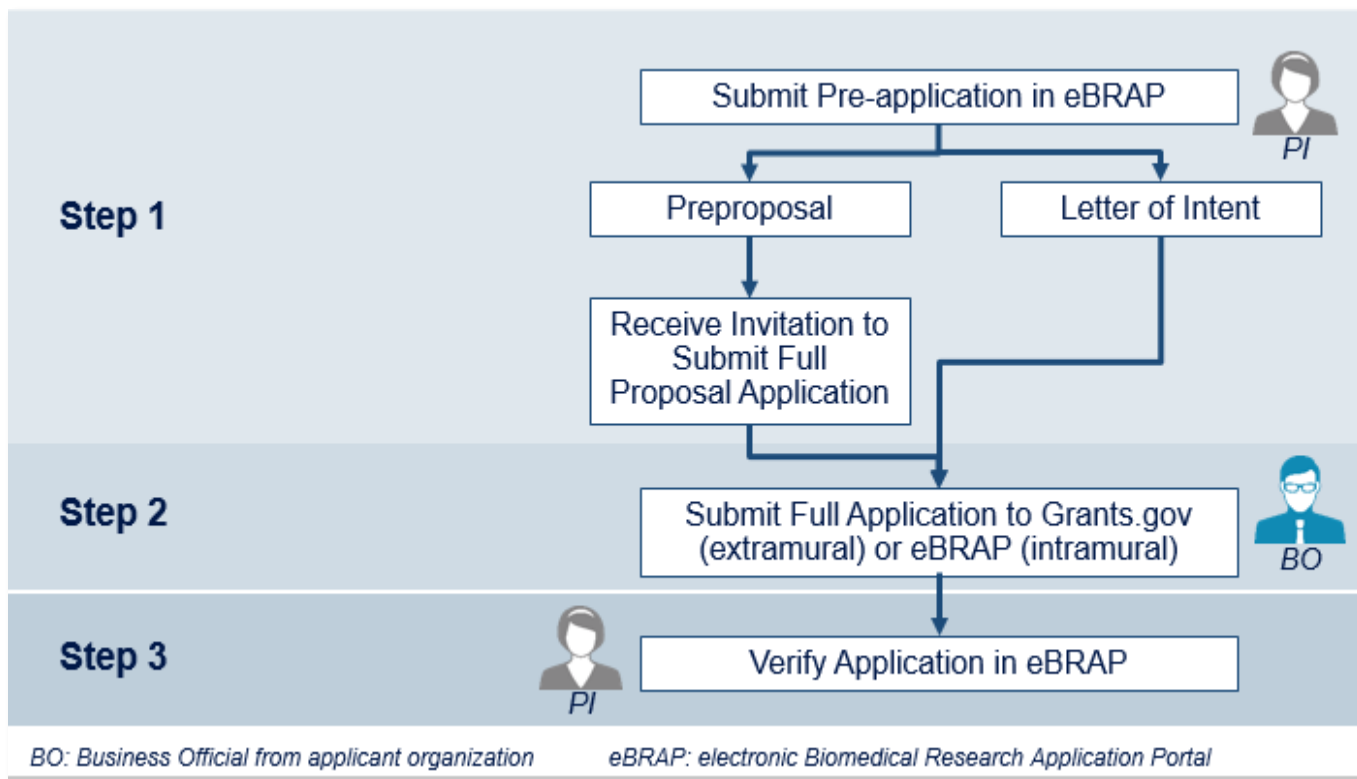
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This General Application Instructions document must be read in conjunction with the program announcement for this funding opportunity, which is available for downloading from

Single most important tip:
Read both documents carefully

Submission Information

CDMRP utilizes a standard submission process

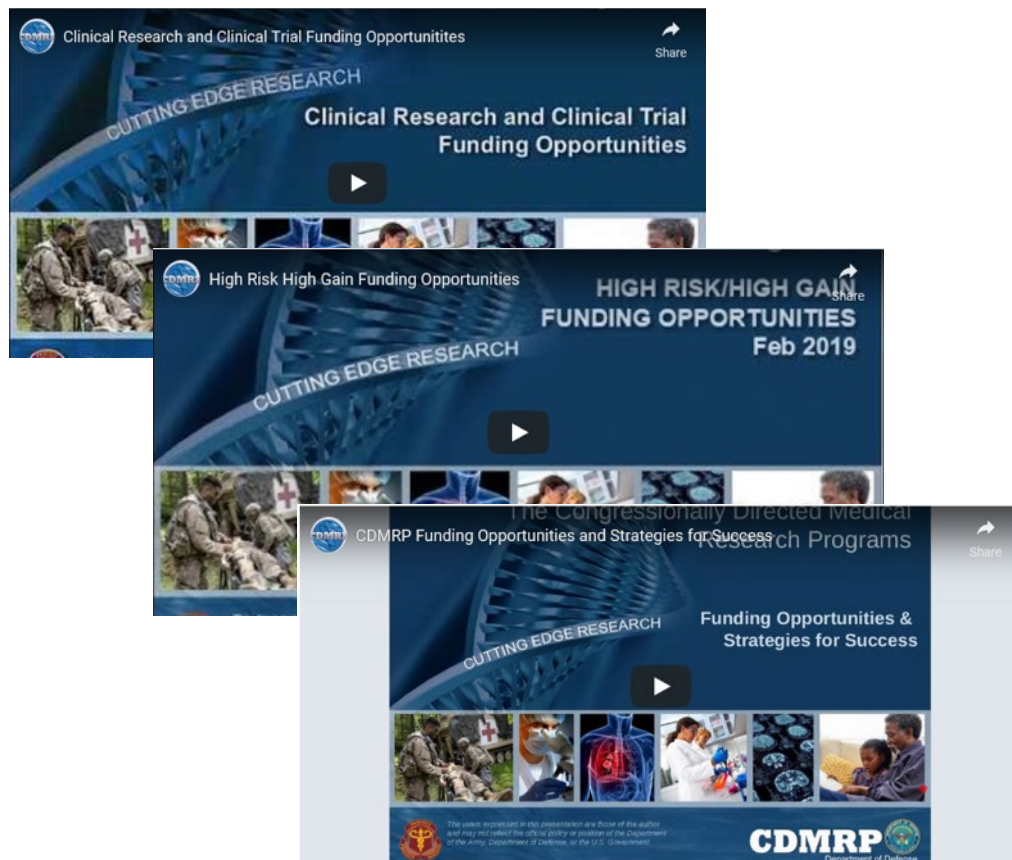


All PAs use a two-step submission process:

(1) Pre-apps
(Preproposal) via eBRAP

(2) Full apps
Grants.gov
(extramural)

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

https://cdmrp.army.mil/pubs/Webinars/webinar_series

For more information, please visit:
cdmrp.army.mil



Peer Reviewed Medical Research Program (PRMRP)

HIGH-IMPACT RESEARCH

Cecilia Dupecher, PhD
Program Manager



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Peer Reviewed Medical Research Program (PRMRP)

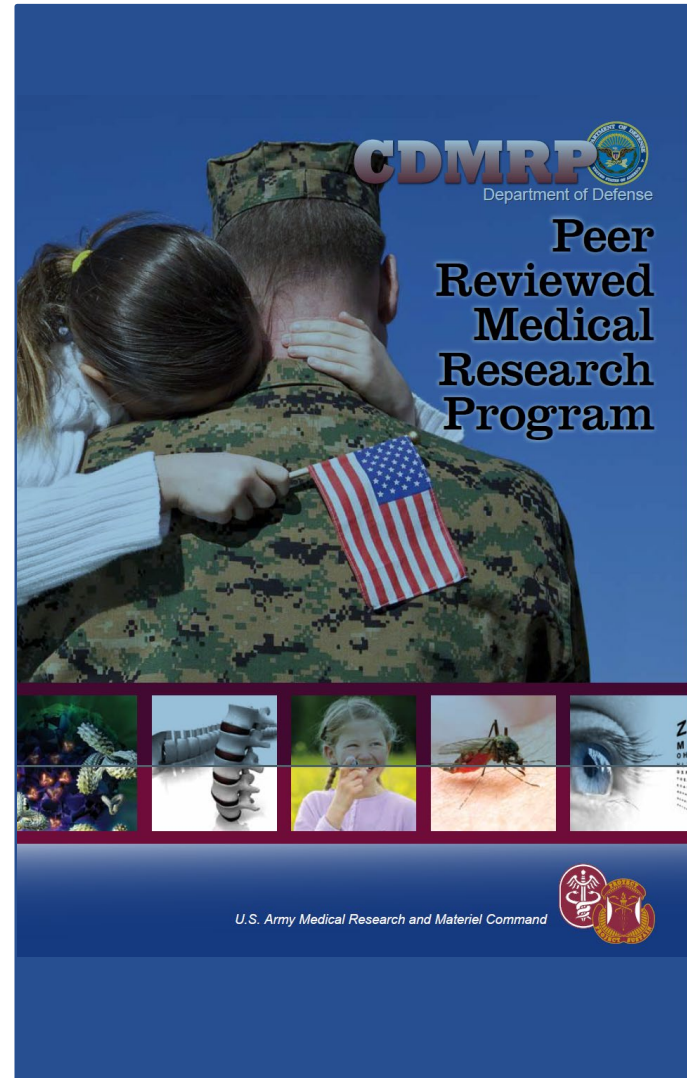
◆ **Vision:** Improve the health, well-being and care of all Military Service members, Veterans, and beneficiaries

◆ **Mission:** Encourage, identify, select and manage medical research projects of clear scientific merit that lead to impactful advances in military health care

◆ History

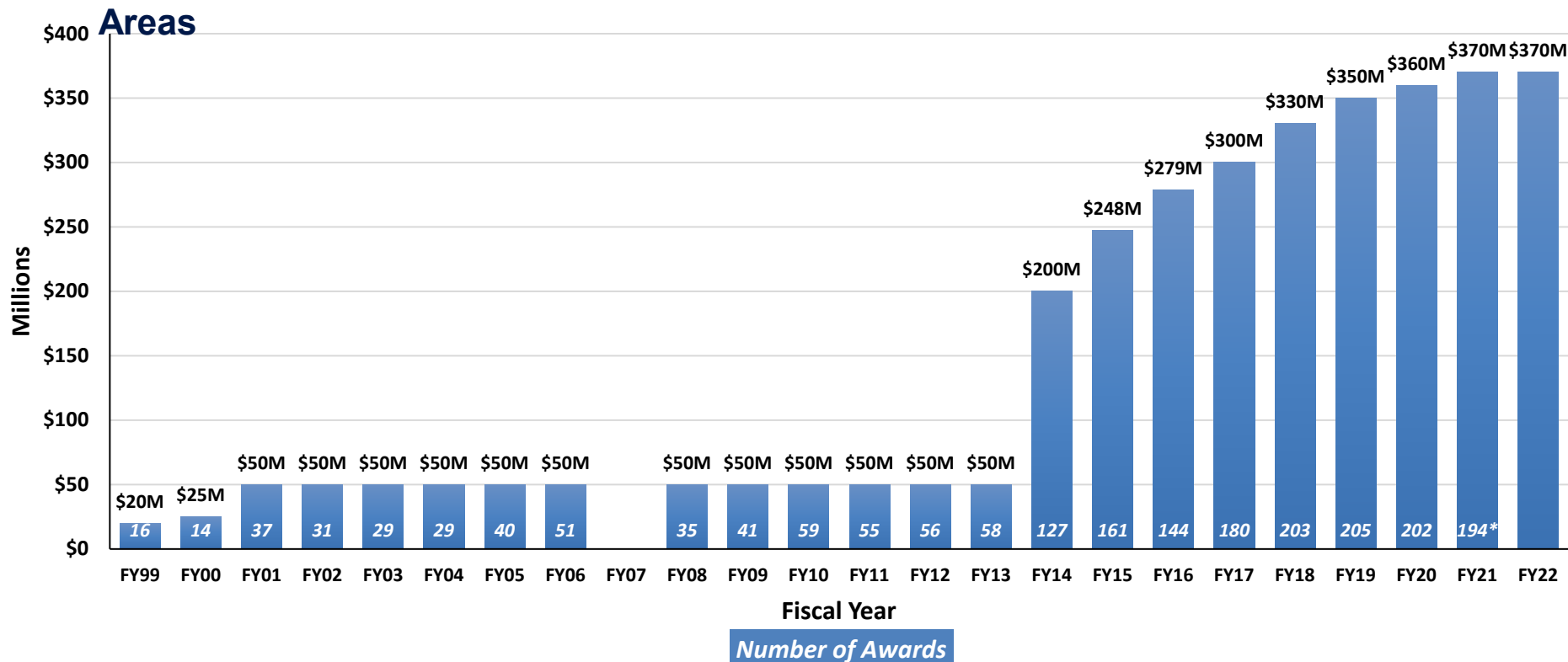
- ❖ Initiated in 1999 to address diseases and conditions with relevance to military health
- ❖ Direction from congress to support research of “clear scientific merit” and “direct relevance to military health” in specified topic areas

<https://cdmrp.army.mil/prmrp/default>



PRMRP Funding History

- Total congressional appropriations: \$3.45 billion (B)
- Total awards made (through FY21*): 1,967 totaling \$2.77B in 169 Topic Areas



- Research considered under PRMRP funding is restricted to the Congressionally specified topics (shall be devoted only to the purposes listed) → Congressional language

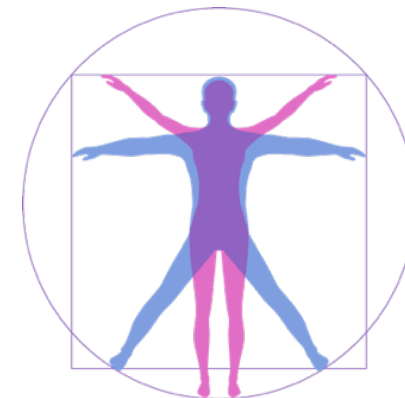
FY22 Topic Areas for Peer Reviewed Medical Research (50 total)



- ◆ Arthritis
- ◆ Cardiomyopathy
- ◆ Congenital Heart Disease
- ◆ Diabetes
- ◆ Dystonia
- ◆ Eating Disorders
- ◆ Ehlers-Danlos Syndrome*
- ◆ Endometriosis
- ◆ Epidermolysis Bullosa
- ◆ Familial Hypercholesterolemia
- ◆ Fibrous Dysplasia
- ◆ Focal Segmental Glomerulosclerosis
- ◆ Food Allergies
- ◆ Fragile X
- ◆ Friedreich's Ataxia*
- ◆ Frontotemporal Degeneration
- ◆ Guillain-Barre Syndrome**
- ◆ Hemorrhage Control
- ◆ Hepatitis B
- ◆ Hydrocephalus
- ◆ Hypercholesterolemia*
- ◆ Hypertension
- ◆ Inflammatory Bowel Diseases
- ◆ Interstitial Cystitis**
- ◆ Malaria
- ◆ Mitochondrial Disease

- ◆ Musculoskeletal Disorders Related to Acute and Chronic Bone Conditions and Injuries*
- ◆ Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- ◆ Myotonic Dystrophy
- ◆ Nephrotic Syndrome*
- ◆ Non-Opioid Therapy for Pain Management
- ◆ Nutrition Optimization
- ◆ Pancreatitis**
- ◆ Pathogen-Inactivated Blood Products
- ◆ Peripheral Neuropathy
- ◆ Plant-Based Vaccines
- ◆ Platelet-like Cell Production
- ◆ Polycystic Kidney Disease
- ◆ Pressure Ulcers
- ◆ Pulmonary Fibrosis
- ◆ Respiratory Health
- ◆ Rett Syndrome**
- ◆ Rheumatoid Arthritis
- ◆ Sleep Disorders and Restriction
- ◆ Suicide Prevention
- ◆ Sustained Release Drug Delivery
- ◆ Trauma*
- ◆ Vascular Malformations
- ◆ Viral Diseases (Previously Emerging Viral Disease)
- ◆ Women's Heart Disease

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



PRMRP's Portfolio Driven Approach

- Food Allergies
- Guillain-Barre Syndrome
- Inflammatory Bowel Diseases
- Rheumatoid Arthritis
- Cardiomyopathy**
- Congenital Heart Disease
- Familial Hypercholesterolemia
- Hypercholesterolemia
- Hypertension*
- Vascular Malformations
- Women's Heart Disease
- Hemorrhage Control
- Pathogen-Inactivated Blood Products
- Platelet-like Cell Production*
- Trauma
- Viral Diseases
- Hepatitis B
- Malaria**
- Plant-Based Vaccines*
- Ehlers-Danlos Syndrome
- Endometriosis
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Polycystic Kidney Disease
- Interstitial Cystitis
- Nephrotic Syndrome
- Pancreatitis

- Polycystic Kidney Disease
- Pressure Ulcers
- Dystonia
- Eating Disorders
- Fragile X
- Friederich's Ataxia
- Frontotemporal Degeneration
- Hydrocephalus
- Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome
- Myotonic Dystrophy
- Non-Opioid Therapy for Pain Management**
- Peripheral Neuropathy*
- Rett Syndrome
- Sleep Disorders and Restriction
- Suicide Prevention*
- Trauma
- Diabetes
- Mitochondrial Disease
- Nutrition Optimization
- Arthritis
- Fibrous Dysplasia
- Musculoskeletal Disorders (related to acute and bone conditions and injuries)
- Pulmonary Fibrosis
- Respiratory Health
- Trauma

Auto Immune Diseases
and Immunology

Cardiovascular Health

Hemorrhage Control and
Blood Products

Infectious Diseases

Internal Medicine

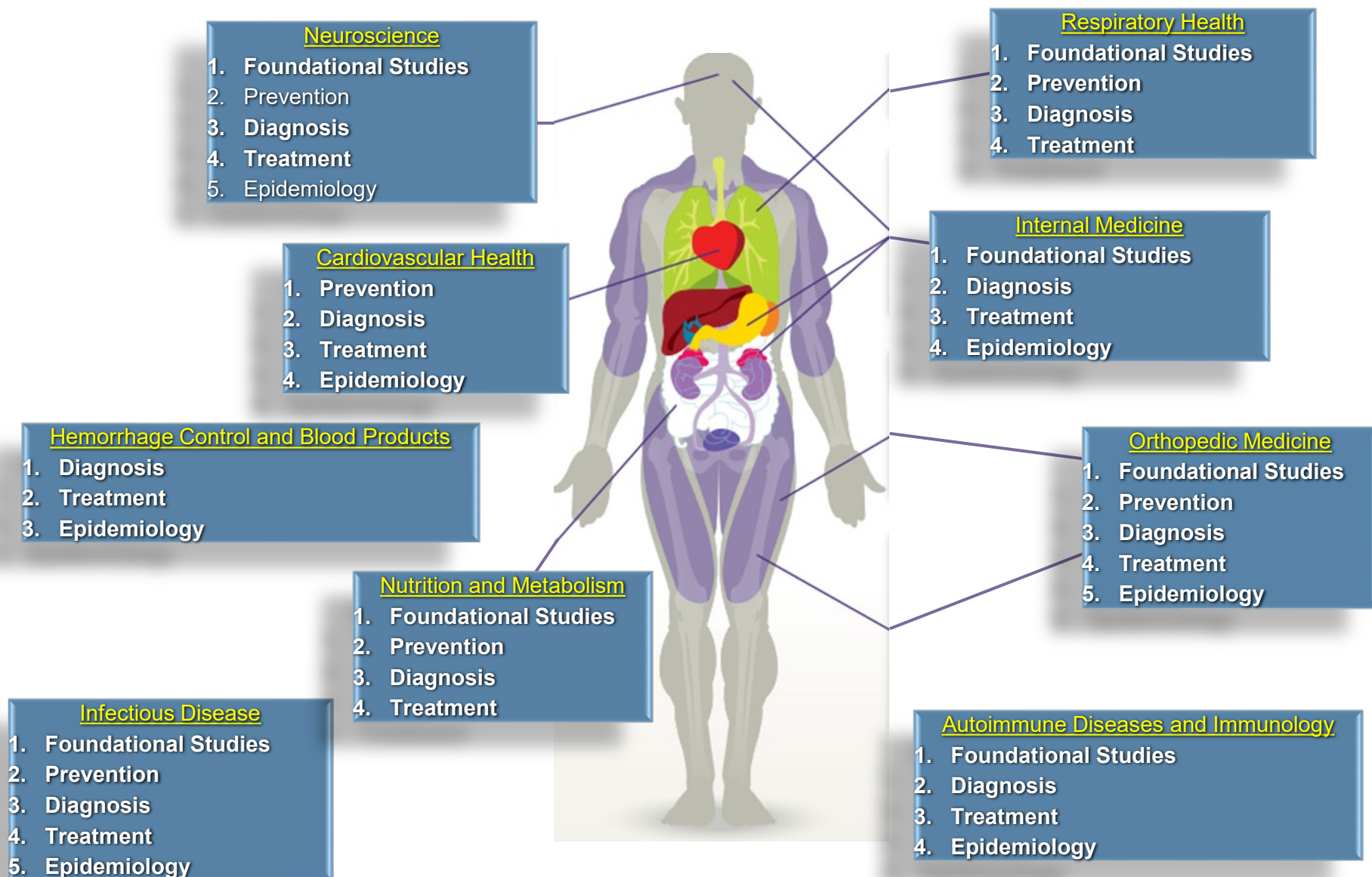
Neuroscience

Nutrition and Metabolism

Orthopaedic Medicine

Respiratory Health

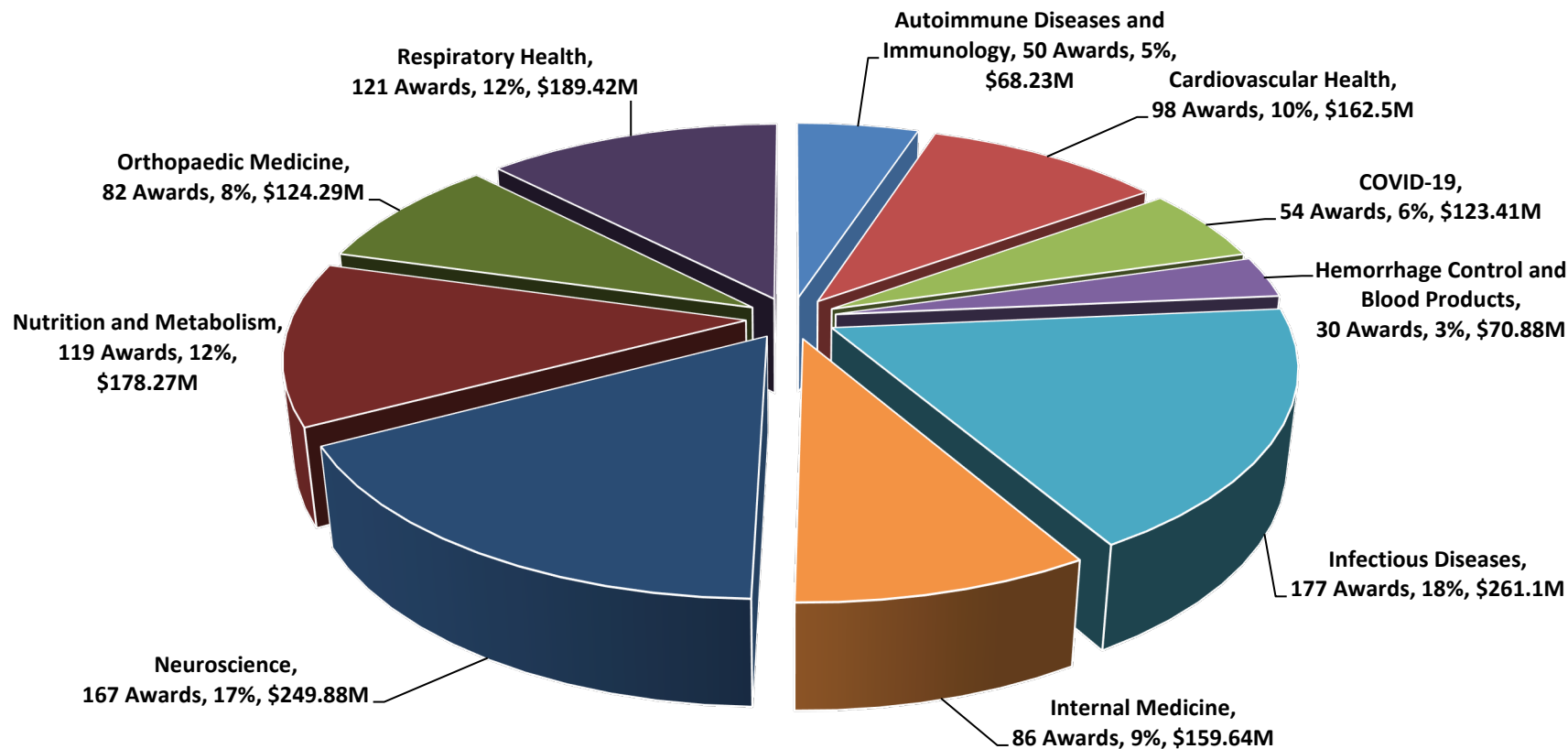
PRMRP's Portfolio Driven Approach



PRMRP Award Portfolio Overview (FY17-FY21*)

*FY21 not final – awards under negotiation

No preselected allocation of funds per Topic Area/Portfolio



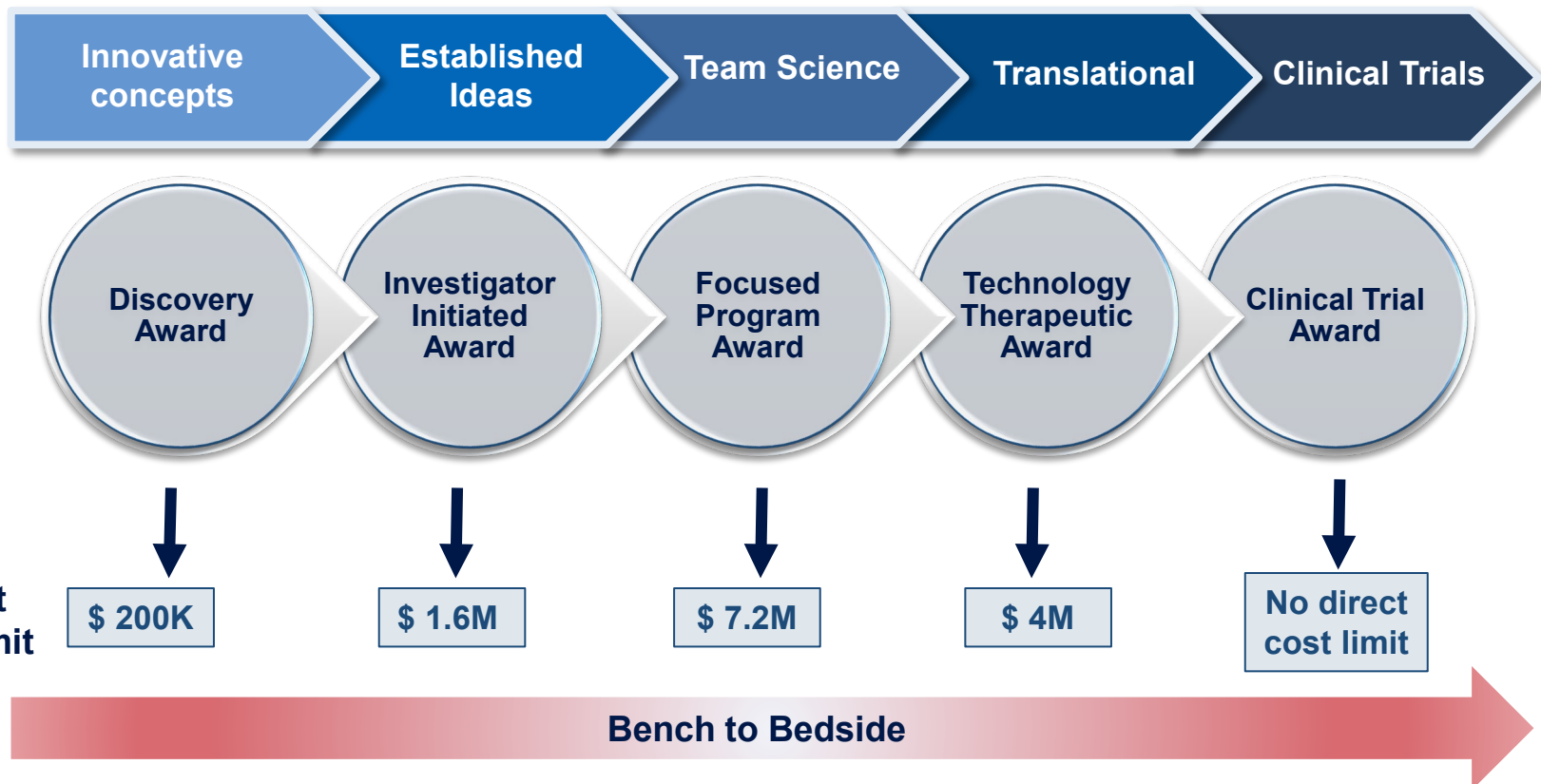
987 Awards, \$1.589B



PRMRP Award Mechanisms Pipeline

Five Funding Opportunities offered in FY22

→ Applicants must address one Topic Area and one portfolio-specific Strategic Goal



FY22 PRMRP Funding Opportunities Available

Letter of Intent – No Invitation needed

Discovery

Direct cost max: \$200K
POP: 2 years

Eligibility: Post-docs,
clinical fellows and
above

**Supports the
exploration of highly
innovative concepts or
untested theories**

Investigator Initiated

Direct cost max: \$1.6M
\$2.0M PPIO
POP: 4 years

Eligibility: PIs at or
above Assistant
professor

**Supports basic
through translational
research that will
improve and impact
the field of research or
patient care**

Technology/ Therapeutic

Direct cost max: \$2.0M
(FL1) / \$4.0M (FL2)
POP: 4 years

Eligibility: PIs at or
above Assistant
professor

**Supports translation of
preclinical findings
into impactful products
for clinical application**

Letter of intent is required for these mechanisms

Preproposal – Invitation Required

Focused
Program

Direct cost max: \$7.2M
POP: 4 years

**Eligibility: Pls at or
above Full Professor**

**Supports synergistic,
multidisciplinary
research program of at
least four distinct but
complementary
projects addressing an
overarching goal**

Clinical Trial
with planning
phase

Direct cost max: \$500K
for planning phase
POP: 18months/4 years

**Eligibility: Pls at or
above Assistant
Professor**

**Supports regulatory
costs for trial planning
to include IND/IDE
submission; must have
FDA approval before
trial may be funded**

Clinical Trial

**Direct cost max: no
limit**
POP: 4 years

**Eligibility: Pls at or
above Assistant
Professor**

**Supports rapid
implementation of
trials of novel
interventions with the
potential to have
impact on patient care**

May range from small to large

Pre-proposal submission is required; application submission is by invitation only

Required for all Funding Opportunities

Military Health Statement

Is the proposed research relevant to the healthcare needs of military Service Members, Veterans, Military Beneficiaries, and/or the American Public?

EXAMPLES INCLUDE:

- ✓ Dual-use capacity to benefit the civilian population and also a need related to military health
- ✓ Aspects of the target disease/condition with direct relevance to military health
- ✓ Contribution to family readiness of Service members (mission readiness)
- ✓ Support for the Warfighter and requirement for use in deployed setting

Proposals must address one:

**FY22 PRMRP
Topic Area**



**FY22 PRMRP
Portfolio-Specific
Strategic Goal**



Application must address one goal and one topic area

Example: Infectious Diseases Portfolio Strategic Goals

Foundational Studies

- Improve understanding of long-term complications of infections (e.g., long COVID [coronavirus disease], myalgic encephalomyelitis/chronic fatigue syndrome [ME/CFS], sequelae from combat wounds)

Prevention

- Develop or optimize vaccine strategies, platforms, or compounds, to include active or passive immunoprophylaxis, especially for Dengue, Lassa, and Crimean-Congo Hemorrhagic fever viruses, and beta-coronaviruses

Diagnosis

- Develop diagnostics for early/pre-symptomatic detection of viral diseases, such as novel host-based biomarkers or other predictors of early/pre-symptomatic infection
- Develop strategies for rapid prediction of protective antigens/epitopes
- Identify testable correlates of protection, especially for Dengue, Lassa, and Crimean-Congo Hemorrhagic Fever viruses

Treatment

- Establish new, and expand upon current, clinical networks for therapeutic drug testing to prevent transmission, resistance, or severe/chronic disease

Epidemiology

- Identify strategies for surveillance or develop modeling tools and/or biomarkers to predict outbreaks, epidemics, or treatment resistance

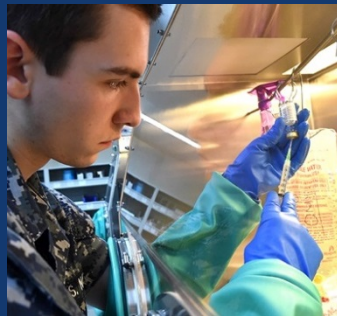
Topic Areas

- Viral Diseases
- Hepatitis B
- Malaria
- Plant-Based Vaccines

PRMRP Submission Deadlines

Award Mechanism	LOI	Pre-Proposal	Dates	Invitation to submit	Full Application Deadline
Discovery Award (DA)			22 April 22		20 May 22
Investigator-Initiated Research Award (IIRA)			29 April 22		27 May 22
Technology/Therapeutic Development (TTDA)			29 April 22		27 May 22
Focused Program Award (FPA)			6 May 22	17 June 22	12 Aug 22
Clinical Trial (CTA)			6 May 22	17 June 22	12 Aug 22

For more information, please visit:
cdmrp.army.mil



Peer Reviewed Cancer Research Program (PRCRP)

CUTTING EDGE RESEARCH

Donna M. Kimbark, Ph.D.

Peer Reviewed Cancer Research Program



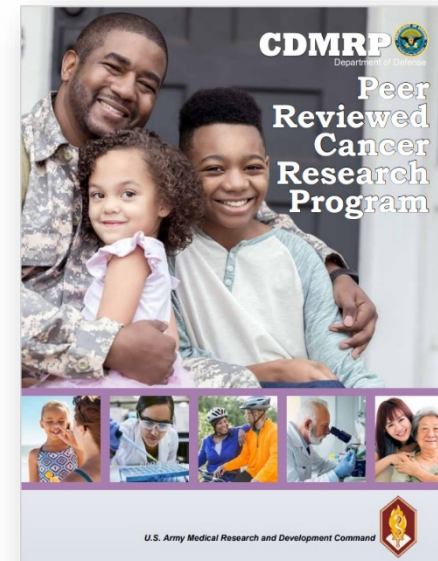
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PRCRP Introduction

- **History** – Began in Fiscal Year (FY) 2009 with an appropriation of \$16 Million (M) and Congressional language directing the topic areas (specific cancers and other research areas) to be funded. From FY09-FY22, a total of 35 topic areas have been included under the PRCRP.
 - FY09-FY21[‡]: \$654.8 M, 920 awards
 - FY22: \$130 M, TBD*
- **Vision** – To advance mission readiness of those U.S. military members affected by cancer and to improve quality of life by decreasing the burden of cancer on Service members, their families, Veterans, and the American public.
- **Mission** – To successfully promote high-impact cancer research for prevention, detection, treatment, quality of life, and survivorship.



[‡]FY21 Awards are under negotiation to be finalized 30 September 2022

*To be announced

FY22 Topic Areas

- ◆ Bladder Cancer
- ◆ Blood Cancers
- ◆ Brain Cancer
- ◆ Colorectal Cancer
- ◆ Endometrial Cancer
- ◆ Esophageal Cancer
- ◆ Germ Cell Cancers
- ◆ Head and Neck Cancer
- ◆ Liver Cancer
- ◆ Lymphoma
- ◆ Mesothelioma
- ◆ Metastatic Cancers
- ◆ Myeloma
- ◆ Neuroblastoma
- ◆ Pediatric brain tumors
- ◆ Pediatric, Adolescent, and Young Adult Cancers
- ◆ Sarcoma
- ◆ Stomach Cancer
- ◆ Thyroid Cancer
- ◆ Von Hippel-Lindau syndrome malignancies (excluding cancers of the kidney and pancreas)



FY22 Details

- ◆ FY22 Topics areas = 20 (including new or returning)
- ◆ Prohibited cancers:
 - ❖ Breast Cancer
 - ❖ Pancreatic Cancer
 - ❖ Prostate Cancer
 - ❖ Ovarian Cancer
 - ❖ Kidney Cancer
 - ❖ Lung Cancer
 - ❖ Melanoma
 - ❖ Rare Cancer
- ◆ *The inclusion of the individual rare cancer research program shall not prohibit the peer-reviewed cancer research program from funding the above-mentioned cancers or cancer subtypes that may be rare by definition*
- ◆ Relevance to Service Members and their families required

FY22 Congressional Language: Relevance to Military Health Focus Areas

Required for All Funding Opportunities

- ◆ Environmental/Exposure risk factors associated with cancer (e.g., ionizing radiation, chemicals, infectious agents, and environmental carcinogens)
- ◆ Gaps in cancer research that may affect mission readiness
 - ❖ Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment
 - ❖ Gaps in quality of life and/or survivorship

Impact of Cancer on Military Health	
 <h3>Cancer Risk Factors</h3> <p>Traumatic brain injury increases hazard ratio for development of brain cancer</p> <p>Environmental exposures such as asbestos leads to mesothelioma risk</p> <p>Exposures to ionizing radiation leads to uterine, thyroid, blood, and other cancers</p> <p>Infectious diseases such as H. pylori is associated with stomach cancer risk</p>	 <h3>Mission Readiness</h3> <p>Cancer diagnoses in Service Members and their families lead to force vulnerabilities</p> <p>Gaps in our knowledge of cancer care cause gaps in mission readiness</p> <p>Cancer affects the whole unit's readiness, not just a single Service Member</p> <p>Military Health Systems are burdened with healthcare costs due to cancer diagnoses and treatment</p>

<https://cdmrp.army.mil/prcrp/pdf/Cancer%20Risk%20Table%202022.pdf>

FY22 PRCRP Cancer Capability Gaps

Prevention



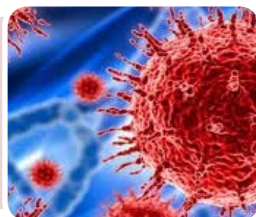
- Develop prevention strategies/early detection methods
- Identify/Elucidate mechanism to improve prevention

Diagnostics



- Identify strategies to predict treatment, recurrence, resistance
- Distinguish features driving cancer occurrence across the age spectrum
- Develop minimal invasive detection

Treatment



- Transform Cancer Treatment
- Advance Immunotherapy
- Multidimensional studies of biospecimens
- Elucidate mechanisms to improve treatment

Behavioral



- Develop strategies to address survivorship issues
- Develop strategies to reduce short/long term treatment effects

Diversity



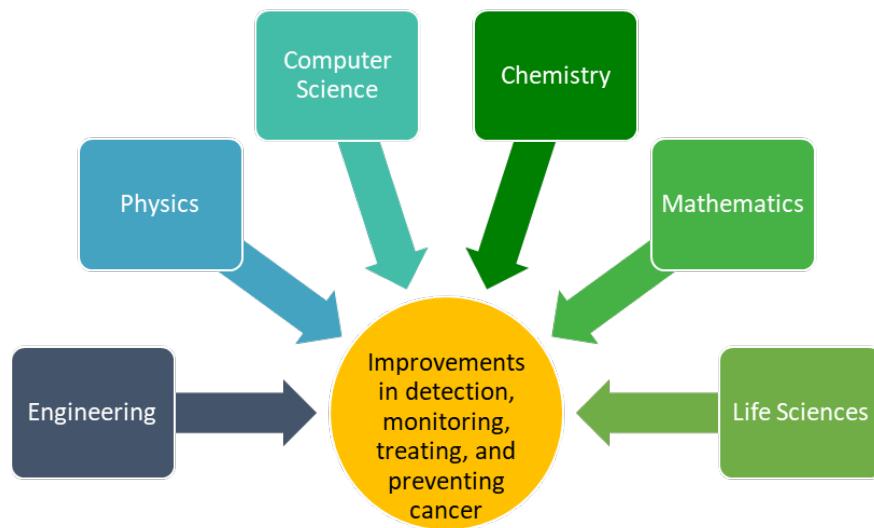
- Improve prevention, diagnosis, treatment, outcomes in underserved, under recognized populations
- Develop strategies to improve access to care

Resources



- Develop open access platform(s) or methods/tools to coordinate & integrate multiple databases and biorepositories interfaces

FY22 PRCRP Strategic Plan: Convergent Science Approach



◆ Initiative I: Convergence and Career Development

- ❖ Virtual Cancer Center
- ❖ Aims to enhance the career development stage with the inclusion of convergent science training to include military health

◆ Initiative II: Innovation and Impact

- ❖ Opportunity to support innovative, impactful ideas
- ❖ Opportunity to enhance support of clinically relevant ideas

Convergent science* *“is a means of solving vexing research problems, in particular, complex problems... It entails integrating knowledge, methods, and expertise from different disciplines and forming novel frameworks to catalyze scientific discovery and innovation.”*

<https://www.nsf.gov/od/oia/convergence/index.jsp>

PRCRP Strategic Plan Funding Opportunities

Convergence Science

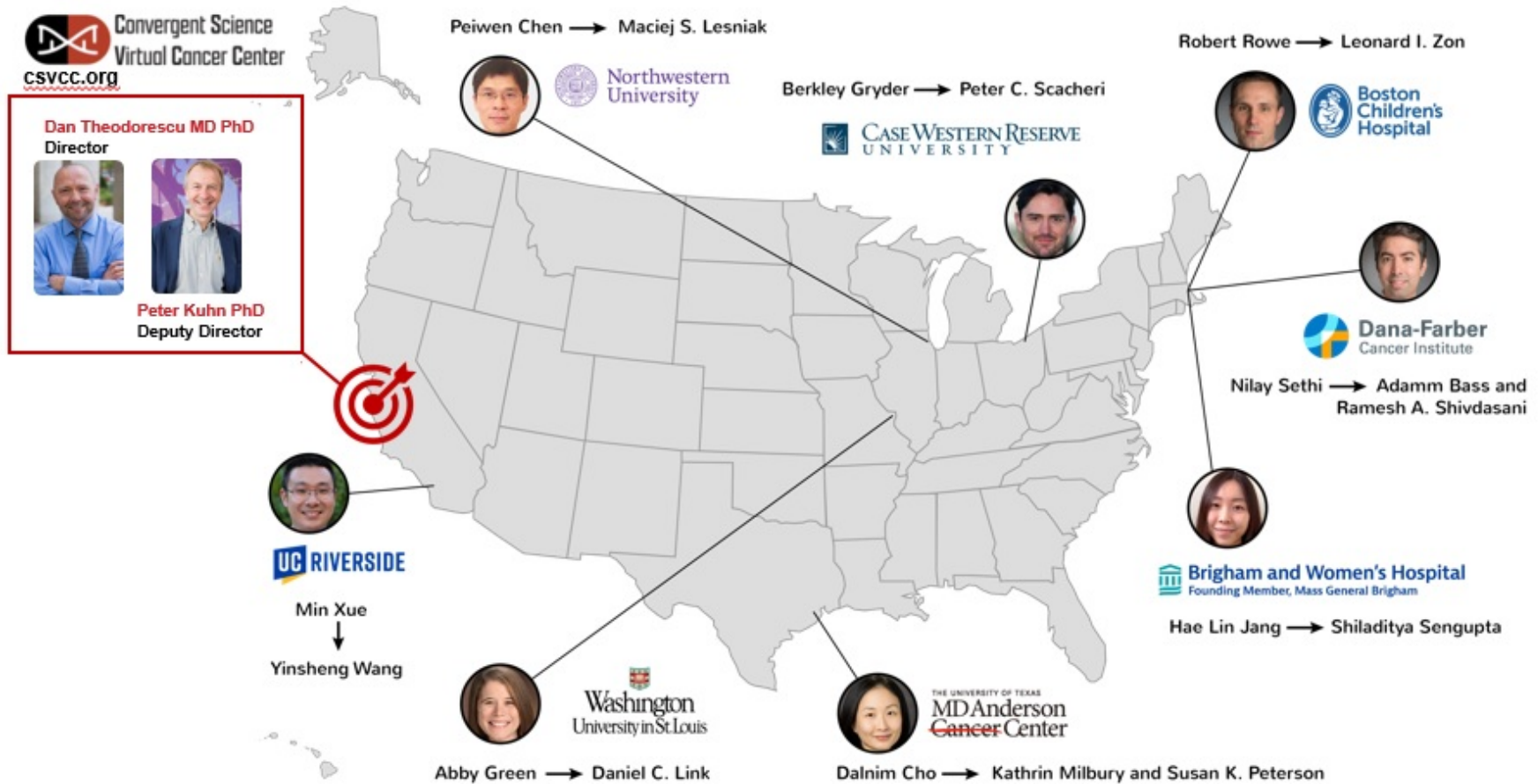
- FY20 Virtual Cancer Center*
- Career Development Award – Scholar Award
- Convergent Science Cancer Consortium Development Award

Innovation and Impact

- Career Development Award - Fellow Option
- Idea Award
- Impact Award
- Translational Team Science Award
- Behavioral Health Science Award

*FY20 Virtual Cancer Center Director Award not offered in FY22

FY20- FY24 PRCRP Virtual Cancer Center



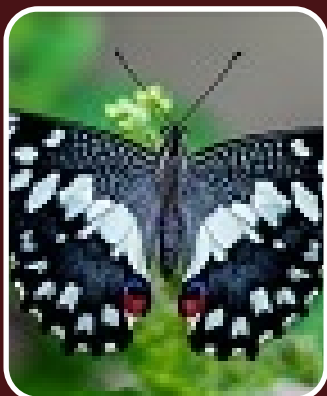
FY22 PRCRP Funding Opportunities Available

Letter of Intent – No Invitation needed



Behavioral Health Science Award

- \$1M in direct costs (4 year period of performance)
- Independent investigator with a faculty-level appointment (or equivalent)
- Supports research that spans the spectrum of behavioral health science including prevention, survivorship, quality of life, and psychosocial research related to cancer – Pilot Clinical Trials allowed



Translational Team Science Award

- \$2.5M in direct costs (4 year period of performance)
- At least 2-3 PIs (at the level of Assistant Professor or equivalent)
- Supports translational studies associated with an ongoing or completed clinical trial that can lead to a future clinical trial or clinical application in cancer research – Clinical Trials allowed

Career Development Award

Virtual Cancer Center Scholar Option



- \$800,000 in direct costs (4 year period of performance)
- Fully independent, tenure track Assistant Professor (< 7 yrs terminal degree)
- Supports the addition Scholars to the unique, interactive Virtual Cancer Center
- Provides intensive mentoring, national networking, and a peer group for junior faculty
- Must address FY22 Topic Areas, Military Health Focus Areas, and Overarching Challenges

Fellow Option

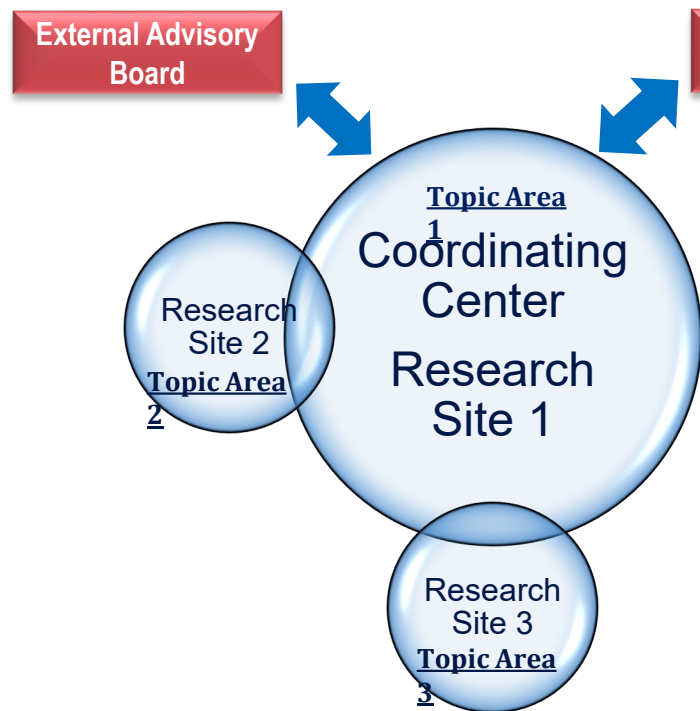


- \$400,000 in direct costs (3 year period of performance)
- Independent investigators at level of Research Assistant Professor, Instructor (<7 yrs terminal degree)
- Supports early-career investigators toward further independence to conduct impactful research with the mentorship of an experienced cancer researcher
- Must address FY22 Topic Areas, Military Health Focus Areas, and Overarching Challenges

FY22 PRCRP Funding Opportunities Available

Letter of Intent – No Invitation needed

Convergent Science Cancer Consortium Development Award



**One Overarching
Challenge**

- ◆ \$2.5M direct costs 2 year period of performance
- ◆ PI for Coordinating Center (Consortium Director):
Investigators at or above the level of Associate Professor; **Co-PI for the Research Site:**
Investigators at or above the level of Assistant Professor
- ◆ Supports novel approaches to ending cancer
- ◆ Proof of principle (convergent science) research projects support
- ◆ Emphasis is on the development of a convergent science infrastructure
- ◆ Address 3 FY22 PRCRP Topic Areas
- ◆ Address FY22 PRCRP Military Health Focus Area
- ◆ Address 1 FY22 PRCRP Overarching Challenge

FY22 PRCRP Funding Opportunities Available

Preproposal – Invitation Required



Idea Award

- \$400,000 direct costs (2 year period of performance)
- Independent investigator/ faculty-level appointment
- Supports innovative, untested, high-risk/ potentially high-reward concepts, theories, paradigms, and/or methods in cancer
- Must address FY22 Topic Areas, Military Health Focus Areas, and Overarching Challenges

Impact Award

- \$1M direct costs 3 year period of performance
- Independent investigators at or above the level of Assistant Professor
- Supports research projects that, if successfully addressed, have the potential to make a *near-term, major impact*
- Clinical Trials allowed
- Must address FY22 Topic Areas, Military Health Focus Areas, and Overarching Challenges

Dates to Remember Submission Deadlines

Funding Opportunity	LOI or Pre-proposal/ Date		Invitation to Submit	Full Application Deadline
Behavioral Health Science	LOI	12 July 2022	Not needed	2 August 2022
Career Development Award – Scholar Option	LOI	12 July 2022	Not needed	2 August 2022
Career Development Award – Scholar Option	LOI	12 July 2022	Not needed	2 August 2022
Translational Team Science	LOI	12 July 2022	Not needed	2 August 2022
Convergent Science Cancer Consortium Development	LOI	17 August 2022	Not needed	7 September 2022
Idea	Pre-proposal	25 May 2022	11 July 2022	7 September 2022
Impact	Pre-proposal	25 May 2022	11 July 2022	7 September 2022

PRCRP Select Outcomes

Products, Outcomes, and Discoveries

XPOVIO® (selinexor)

For relapsed/refractory
multiple myeloma and diffuse
large B-cell lymphoma



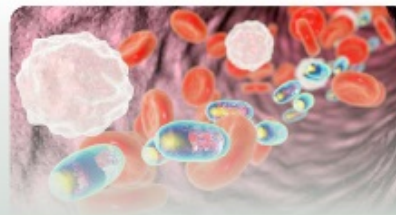
NVN1000

Topical nitric oxide therapy to treat
cervical neoplasias and prevent
HPV-associated cancers

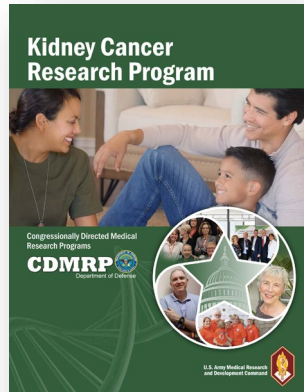
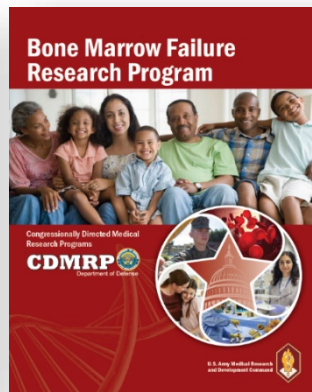
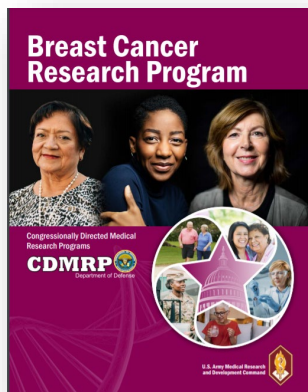


SYMPHONY

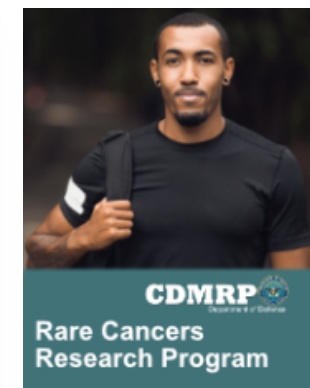
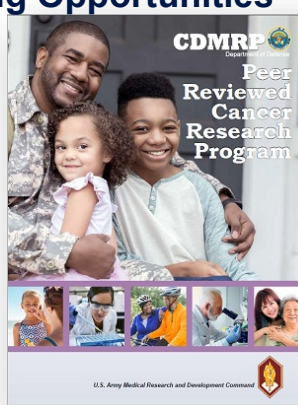
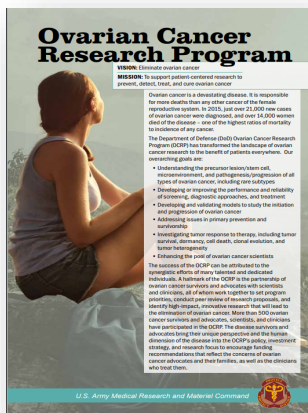
Immunotherapy and
photothermal nanotherapy
combination for bladder cancer



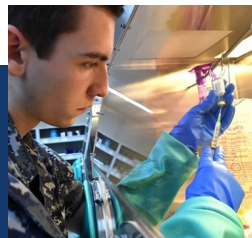
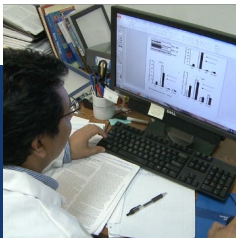
CDMRP Cancer Programs



<https://cdmrp.army.mil/researchprograms>
FY22 Funding Opportunities



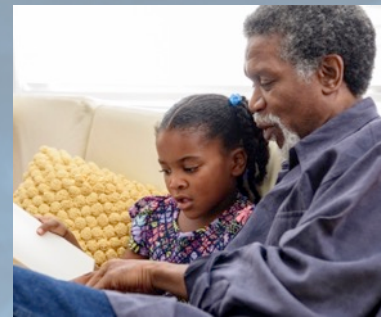
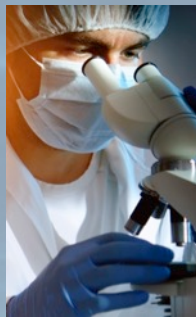
For more information, please visit:
<https://cdmrp.army.mil/prcrp>



Traumatic Brain Injury and Psychological Health Research Program (TBIPHRP)

CUTTING EDGE RESEARCH

Dwayne Taliaferro, Ph.D.
Program Manager, TBIPHRP



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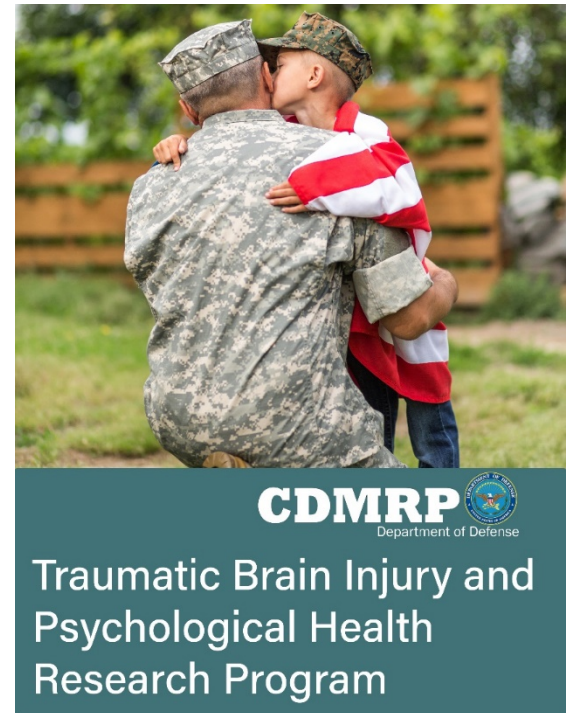
TBIPHRP Vision and Mission

◆ Vision

- ❖ Optimize psychological health and reduce or eliminate the effects of traumatic brain injury and traumatic stress

◆ Mission

- ❖ Fund research to understand, prevent and treat traumatic brain injury and psychological health conditions that accelerates solutions to improve health and healthcare of Service Members, DOD beneficiaries, Veterans, and the American public

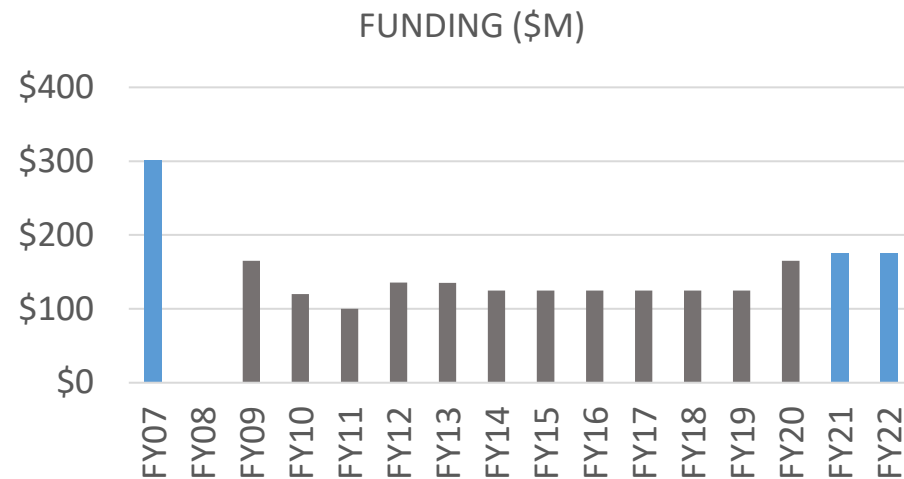


<https://cdmrp.army.mil/tbiphrp/>

TBIPHRP Introduction

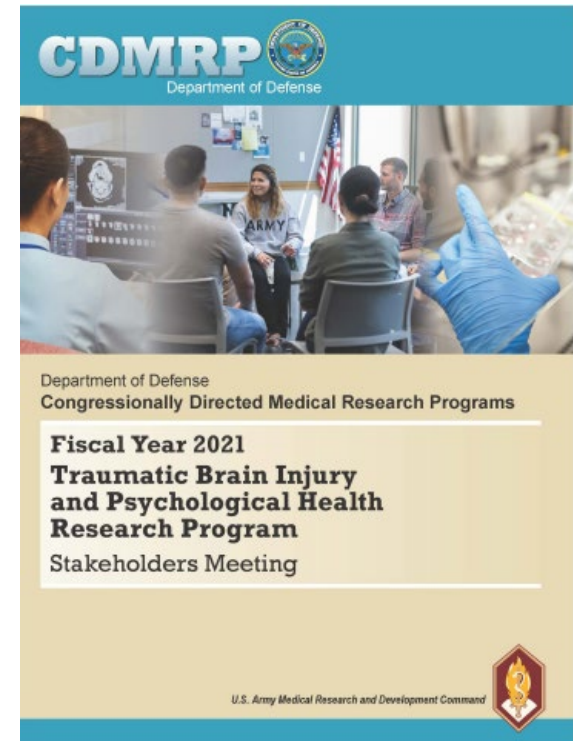
◆ Brief History

- ❖ In Fiscal Year 2007 (FY07), Congress appropriated funds for traumatic brain injury (TBI) and psychological health (PH)
 - The Congressionally Directed Medical Research Programs (CDMRP) managed those funds as the Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)
- ❖ In FY09–FY20, programmatic oversight for the PH/TBIRP was provided by the Joint Program Committees
 - The CDMRP provided execution management support for some PH/TBIRP funds
- ❖ In FY21, the CDMRP began



Strategic Guidance, Gaps, and Emerging Needs

- ◆ Congressional Language
- ◆ Portfolio Analysis
- ◆ Clinical Practice Guidelines/Recommendations
- ◆ Direct Stakeholder Engagement
- ◆ Stakeholders Meeting
- ◆ Vision Setting Meeting



FY21 TBIPHRP Strategic Goals

Provided for information purposes only. May not reflect the FY22 TBIPHRP goals

◆ Understand

- ❖ Research will address knowledge gaps in foundational science, epidemiology, and the etiology of TBI and PH
 - Four Focus Areas

◆ Prevent

- ❖ Research will address the prevention or progression of TBI or PH conditions through population, selective, and indicated prevention approaches. Efforts that focus on primary prevention (including protection), screening, diagnosis, and prognosis are within scope
 - Five Focus Areas

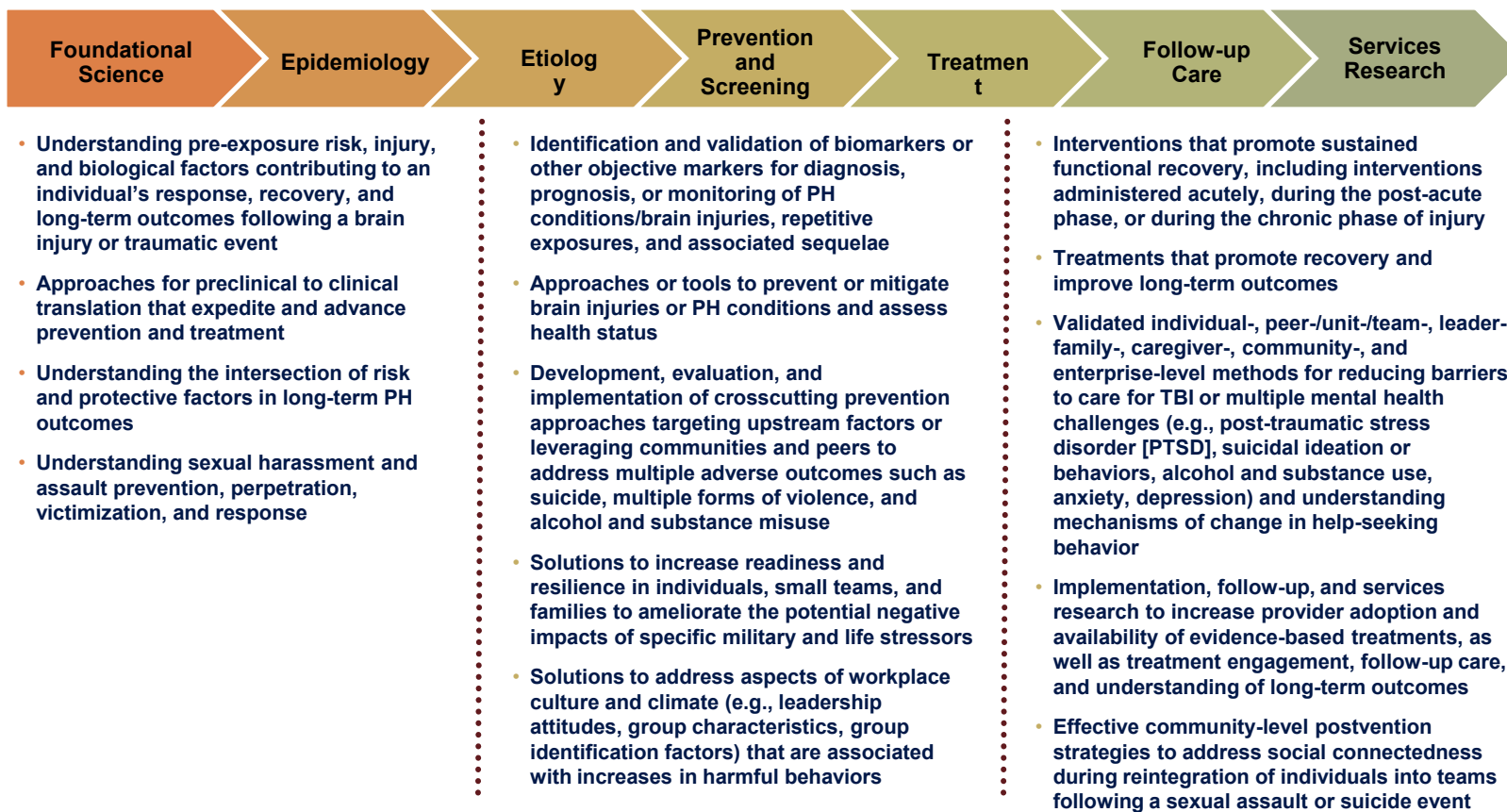
◆ Treat

- ❖ Research will address immediate and long-term treatments and improvements in systems of care, including access to and delivery of healthcare services. Treatment topics may include novel treatments and interventions, personalized medicine approaches, length and durability of treatment, rehabilitation, relapse, and relapse prevention
 - Five Focus Areas

TBIPHRP Strategic Goals → FY21 Focus Areas

Provided for information purposes only. May not reflect the FY22 TBIPHRP Focus Areas

Major Focus Areas

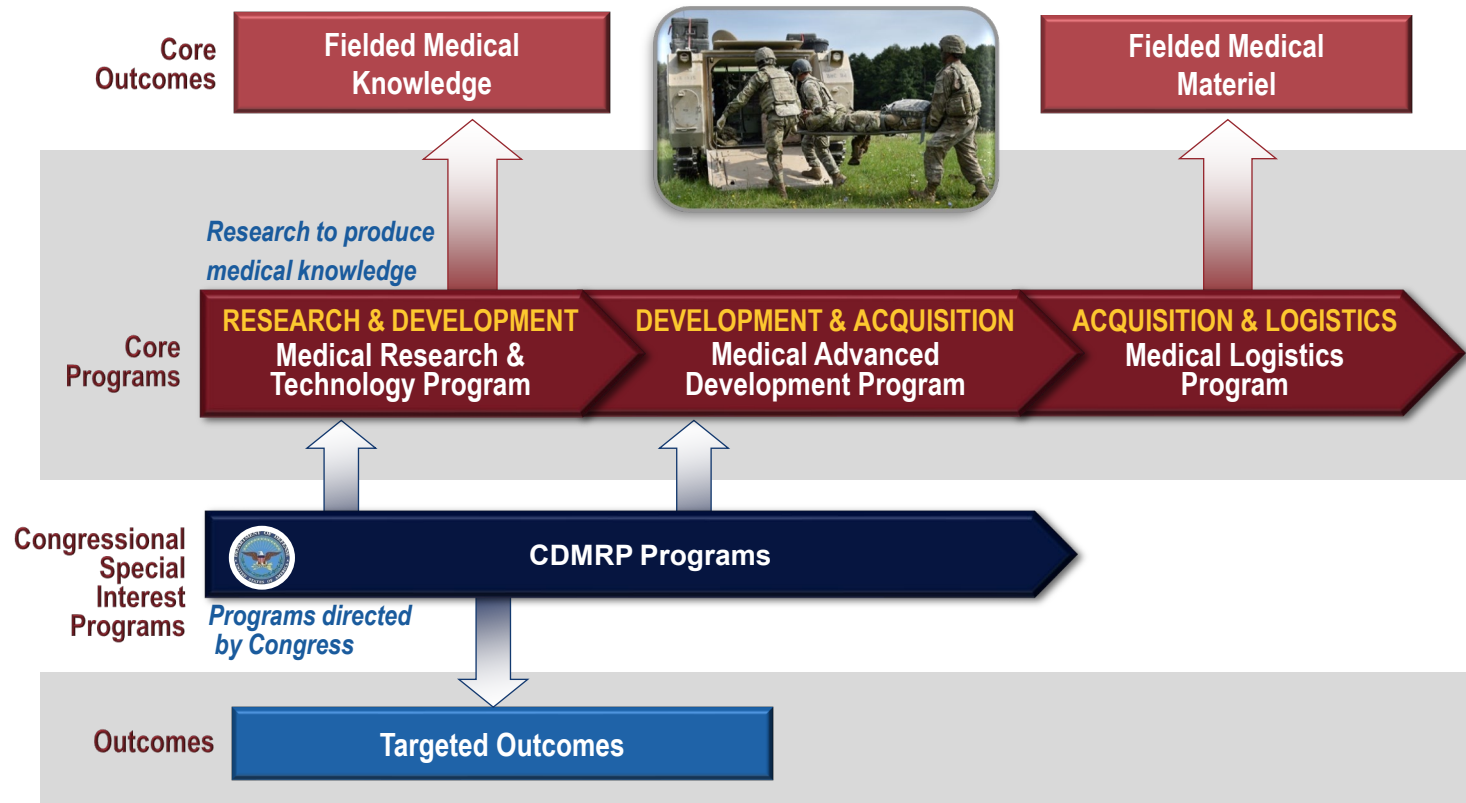


Example: Linking TBI-Specific Focus Areas to Research Gaps

Provided for information purposes only. May not reflect the FY22 TBIPHRP Focus Areas

Goal	Focus Area	Gap(s)	Source(s)
Understand	Understanding pre-exposure risk, injury, and biological factors contributing to an individual's response, recovery, and long-term outcomes following a brain injury or traumatic event	Identify clinical endophenotypes and biomarker profiles that will allow testing of clinical management interventions Not enough validated devices are deployed at scale (implementation science) Characterize the profiles (e.g., injury history, demographics, genetics) of treatment responders versus treatment non-responders to identify indicators of successful recovery following TBI	FY21 TBIPHRP Stakeholders Meeting FY20–FY22 Traumatic Brain Injury Center of Excellence Research Gaps and Priorities
Treat	Interventions that promote sustained functional recovery, including interventions administered acutely, during the post-acute phase, or during the chronic phase of injury	Increased Warfighter cognitive performance that enables effective execution of mission essential tasks Implement mechanisms to improve cognitive performance The ability to enhance and protect Warfighters' brain health and cognitive performance	FY21 TBIPHRP Stakeholders Meeting Warfighter Brain Health Capabilities-Based Assessment

CDMRP and the USAMRDC Strategic Process



Research to produce medical knowledge

RESEARCH & DEVELOPMENT

Medical Research & Technology Program

Medical Research & Technology Program

DEVELOPMENT & ACQUISITION
Medical Advanced
Development Program

Medical Advanced Development Program

ACQUISITION & LOGISTICS

Medical Logistics Program

Medical Logistics Program

Congressional Special Interest Programs



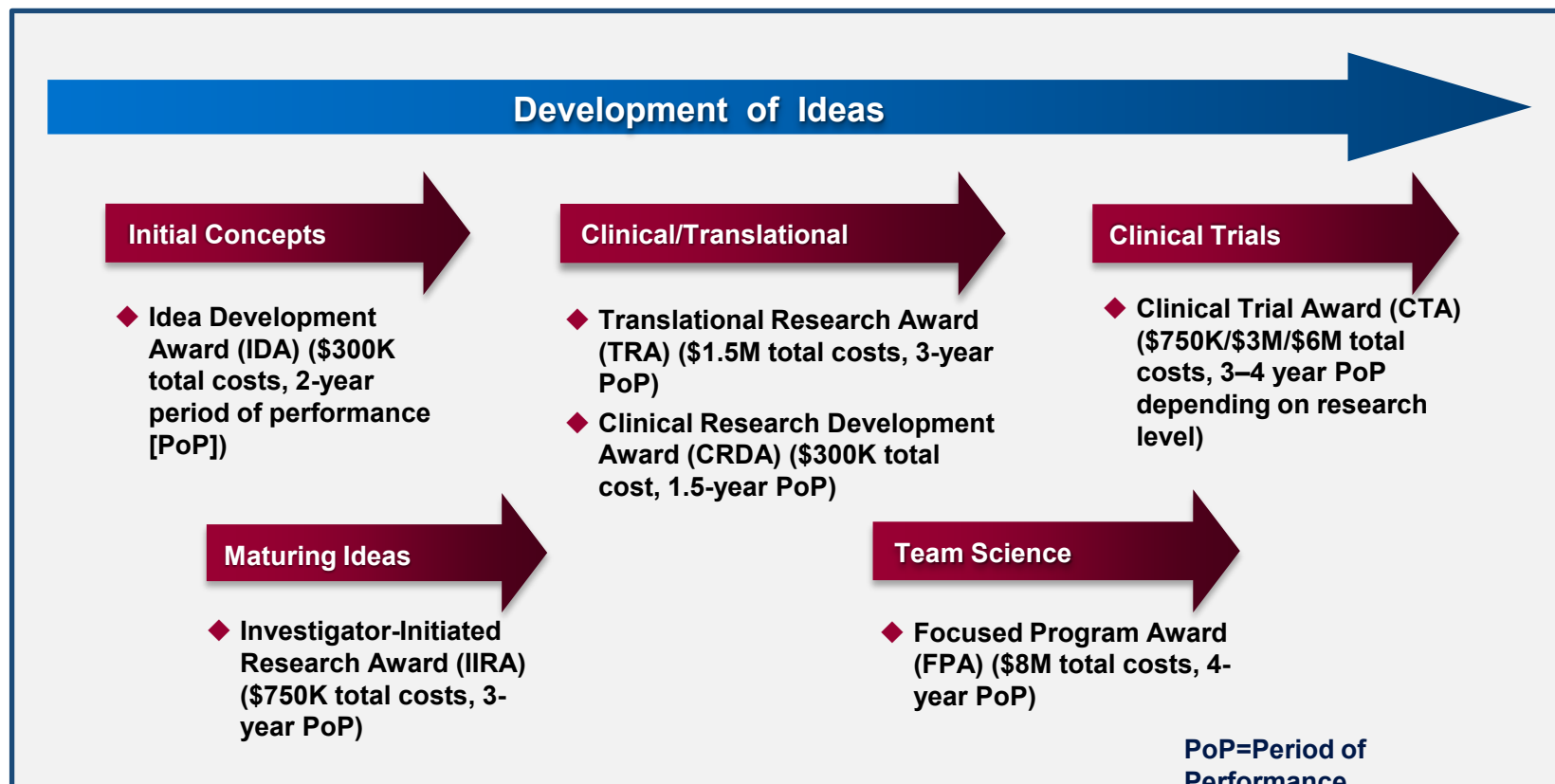
Programs directed by Congress

Outcomes

Targeted Outcomes

FY21 Funding Opportunities

Provided for information purposes only. May not reflect the FY22 TBIPHRP funding opportunities



FY21 Cycle Mechanism Features

Provided for information purposes only. May not reflect the FY22 TBIPHRP funding opportunities

◆ Maximize reproducibility and translational potential → Animal Research Plan (with associated review criteria)

- ❖ Requires applicants to validate or corroborate animal studies to human data/populations
- ❖ Take steps to reduce possibility that animal findings cannot be translated to humans



◆ Improve impact and stakeholder engagement → Community-Based Participatory Research (CBPR)

- ❖ Enables establishment and utilization of lived experience subject matter experts, care providers, and community-based organizations in the design and execution of research



FY21 Cycle Mechanism Features (cont.)

Provided for information purposes only. May not reflect the FY22 TBIPHRP funding opportunities

◆ Relevance to Service Members, Veterans, and the American public

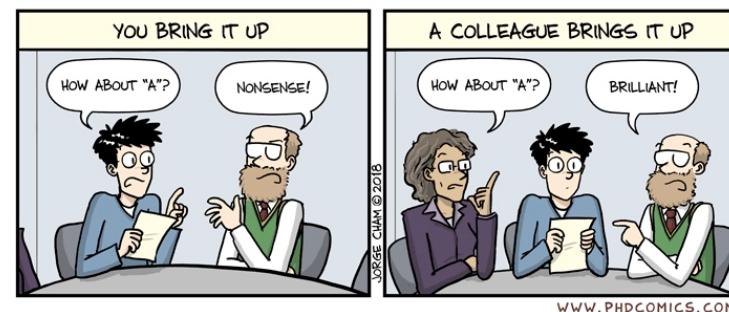
- ❖ Investigators are required to identify the target population and how the proposed research will benefit their health and healthcare needs.

◆ Bring new ideas/perspectives → Early-Career Investigator Partnering Principal Investigator (PI) Option

- ❖ Pairs established Investigator and an early-career investigator as partners
 - Receive independent awards and work together to complete the same Statement of Work
 - Investigators at the level of Assistant Professor, Instructor, or Assistant Research Professor (or equivalent) and less than 10 years from a terminal degree (excluding time spent in medical residency/fellowship or family medical leave) at the time of application submission deadline

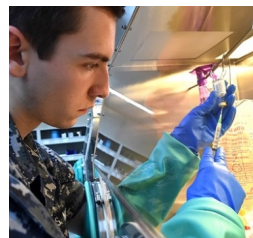


HOW GOOD YOUR IDEA IS IF...



Legacy PH/TBI Portfolio Composition

Provided for information purposes only. Does not reflect the FY21+ TBIPHRP research portfolio



Legacy PH/TBIRP TBI Landscape Overview

Provided for information purposes only. Does not reflect the FY21+ TBIPHRP research portfolio

◆ Acute TBI Management

- ❖ Emergency/point-of-injury care
- ❖ Hemodynamics

◆ Blast, Trauma, and Injury Modeling

- ❖ Modeling, blast modeling, or other TBI-related modeling studies

◆ Brain Structure, Function, and Health

- ❖ Functionality, structure, mechanism, systems, and physiological consequences of brain tissue after TBI
- ❖ Measure/evaluate, facilitate, and/or rehabilitate cognitive function after TBI

◆ Sensory

- ❖ Auditory, visual, vestibular, or combination sensory

◆ Other

- ❖ Quality of life
- ❖ Locomotion/movement
- ❖ Pain
- ❖ Other studies (clinical resources, unable to classify)

◆ Clinical Disorders/PTSD

- ❖ Addressing mental health disorders, including PTSD, depression, anxiety, adjustment disorder, etc., either occurring as a result of military Service or impacting mission readiness/return to duty

◆ Military Family Well-Being

- ❖ Understanding the impact of military Service on families, addressing sequelae of military Service, and promoting family resilience

◆ Psychological Resilience

- ❖ Understanding risk/protective factors for negative mental health outcomes (to include those impacting minority populations such as LGBT individuals) and enhancing individuals' abilities to cope and bounce back in the face of adversity

◆ Substance Misuse and Abuse

- ❖ Understanding and preventing the misuse of alcohol and other substances and treating alcohol and substance use disorders

◆ Suicide Prevention

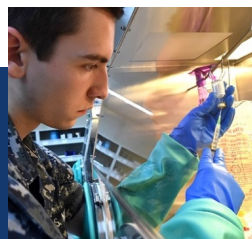
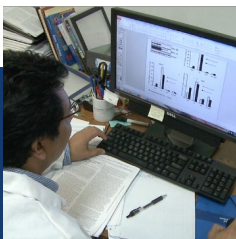
- ❖ Understanding, preventing, detecting, and treating suicidality and addressing postvention

◆ Violence Prevention

- ❖ Addressing sexual assault/harassment, workplace violence, intimate partner violence, hazing/bullying, etc.

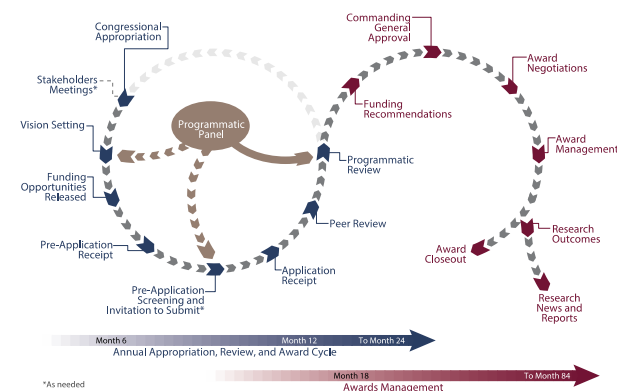
Data presented may not be a complete representation of the CDMRP-managed PH/TBIRP portfolio and may not be used for audit purposes.

For more information, please visit:
<https://cdmrp.army.mil/tbiphrrp/>



FY21 Program Cycle Overview

Activity	CRDA, IDA, and IIRA	FPA, CTA, and TRA
Release	6 August 2021	6 August 2021
Pre-Application Receipt	22 September 2021 (Letter of Intent)	1 November 2021
Invite Letter	N/A	5 November 2021
Full Application Receipt	7 October 2021	16 December 2021
Peer Review	December 2021	February 2022
Programmatic Review	February 2022	April 2022



Idea Development Award

- ◆ **Eligibility:** Independent investigators at all academic levels (or equivalent)
- ◆ **Period of Performance:** Up to 2 years
- ◆ **Total Costs:** Up to \$300K
- ◆ **Anticipated # of awards:** ~18
- ◆ **Intent**
 - ❖ To support innovative, non-incremental, high-risk/high-reward research that will provide new insights, paradigms, technologies, or clinical applications
- ◆ **Key Features**
 - ❖ Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, leverage unique study populations, or exhibit other highly creative qualities
 - ❖ Preliminary data are allowed but not required
 - ❖ Research must be relevant to the healthcare needs of Service Members, Veterans, military beneficiaries, and the American public
 - ❖ Clinical research or clinical trials are not allowed



Clinical Research and Development Award

- ◆ **Eligibility:** Independent investigators at all academic levels (or equivalent)
- ◆ **Period of Performance:** Up to 18 months
- ◆ **Total Costs:** Up to \$300K
- ◆ **Anticipated # of awards:** ~10
- ◆ **Intent**
 - ❖ To support planning and development activities necessary to initiate a future clinical study with the potential to have a significant impact on TBI and/or psychological health. The future study to be developed at the conclusion of the award may be clinical research or a clinical trial
- ◆ **Key Features**
 - ❖ Preclinical or clinical research or clinical trials are not allowed; HOWEVER, may be used to support the generation of preclinical data specifically requested by the Food and Drug Administration (FDA) (i.e., needed to lift a clinical hold)
 - ❖ Relevance to Military Health: Research must be relevant to the healthcare needs of Service Members, Veterans, military beneficiaries, and the American public



Investigator-Initiated Research Award

- ◆ **Eligibility:** Independent investigators at all academic levels (or equivalent); Early-Career Investigator Partnering Option (ECIPO): Investigator must be within 10 years of completion of their terminal degree
- ◆ **Period of Performance:** Up to 3 years
- ◆ **Total Costs:** Up to \$750K
- ◆ **Anticipated # of awards:** ~15



◆ Intent

- ❖ To support studies that will make an important contribution toward understanding, preventing, and treating TBI and/or PH conditions
- ❖ To support research with the potential to yield highly impactful discoveries or major advancements
- ❖ Research projects may focus on any phase of research from basic laboratory research through translational research

◆ Key Features

- ❖ **Impact:** The application should clearly describe the project's potential near-term and long-term outcome(s)/product(s) and how they will impact a critical problem or question in the field of research and/or patient care
- ❖ Clinical research is allowed; however, clinical trials are not supported
- ❖ Data Sharing using Common Data Elements (CDEs) is required for human subjects research

Translational Research Award

- ◆ **Eligibility:** Independent investigators at all academic levels (or equivalent); ECIPO: Investigator must be within 10 years of completion of their terminal degree
- ◆ **Period of Performance:** Up to 4 years
- ◆ **Total Costs:** Up to \$1.5M
- ◆ **Anticipated # of awards:** ~24



◆ Intent

- ❖ Supports both preclinical to clinical translational research (e.g., studies of pharmaceuticals and medical devices in preclinical systems) as well as clinical research to clinical care translation (e.g., comparative effectiveness, implementation science, healthcare services research)

◆ Key Features

- ❖ Clinical research and trials are allowed; however, clinical trials for new interventions or new indications are NOT allowed
- ❖ Impact: The application should clearly describe the project's potential near- and long-term outcome(s)/product(s) and how they will impact a critical problem or question in the field of research and/or patient care
- ❖ Data Sharing using CDEs is required for human subjects research

Clinical Trial Award

- ◆ **Eligibility:** Independent investigators at all academic levels (or equivalent); ECIPO: Investigator must be within 10 years of completion of their terminal degree
- ◆ **Period of Performance:** Up to 3 or 4 years based on Research Funding Level
- ◆ **Total Costs:** Up to \$750K, \$3M, or \$6M based on Research Funding Level
- ◆ **Anticipated # of awards:** ~28
- ◆ **Intent**
 - ❖ Projects may range from small proof-of-concept trials through large-scale trials
 - ❖ Encourage innovative clinical trial design approaches (e.g., Bayesian, adaptive, clinical bio-equivalence, seamless, exploratory/phase 0, basket, stepped wedge) that improve efficiency and ability to determine clinical benefit while maintaining validity, integrity and ethical considerations
 - ❖ Targeted Broad Agency Announcement: Allows the generation of either contracts and assistance agreements (grants and cooperative agreements)
- ◆ **Key Features**
 - ❖ If required, FDA IND or IDE needs to be obtained by the application submission deadline
 - ❖ Community Collaboration: Inclusion of CBPR approaches is required
 - ❖ Data Sharing using CDEs is required



Focused Program Award

- ◆ **Eligibility:** Independent investigator at or above the level of Full Professor (or equivalent)
- ◆ **Period of Performance:** 4 years
- ◆ **Total Costs:** \$8M
- ◆ **Anticipated # of awards:** ~5
- ◆ **Intent**



- ❖ Supports the development of a synergistic, multidisciplinary research program with the potential to have a significant impact on TBI and/or PH
- ❖ Targeted Broad Agency Announcement: Allows the generation of either contracts and assistance agreements (grants and cooperative agreements)
- ◆ **Key Features**
 - ❖ Overarching Challenge: The projects must describe a unifying, overarching challenge that will be addressed by the set of research projects proposed
 - ❖ Research Project: Recommend minimum of four, distinct research projects led by individual project leaders that address complementary aspects of the overarching challenge
 - ❖ The overall project is led by a PI with demonstrated success in leading large, focused project, with identified project leaders for each of the complementary and synergistic research projects
 - ❖ Implementation: detailed implementation plan that identifies critical milestones

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 funding opportunity



Key Features of CDMRP Funding

- ❖ No “pay line” (portfolio balance)
- ❖ Funds obligated up-front; limited out-year budget commitments (but milestones imposed)
- ❖ No continuation funding

Video and additional information available at:
<https://cdmrp.army.mil/about/2tierRevProcess>

Peer Review Criteria

	IDA	IIRA	CRDA
Scored	Equal Importance <ul style="list-style-type: none"> • Innovation • Research Strategy and Feasibility • Statistical Plan and Data Analysis (Biostatistician) • Impact (Consumer) 	Equal Importance <ul style="list-style-type: none"> • Research Strategy and Feasibility • Data and Research Resources Sharing Plan • Statistical Plan and Data Analysis (Biostatistician) • Impact and Relevance to Military Health (Consumer) • Ethical Considerations (HS only) (Bioethicist) • Transition Plan (Technology Transfer Specialist) • Personnel • Partnership Statement 	Equal Importance <ul style="list-style-type: none"> • Rationale for Future Clinical Study • Impact and Relevance to Military Health (Consumer) • Development Plan Strategy and Feasibility (Biostatistician) • Personnel
Unscored	<ul style="list-style-type: none"> • Personnel • Budget • Environment • Application Presentation 	<ul style="list-style-type: none"> • Budget • Environment • Application Presentation 	<ul style="list-style-type: none"> • Budget • Environment • Application Presentation

Peer Review Criteria

TRA		CTA	
Scoring	Scored	<ul style="list-style-type: none"> Research Strategy and Feasibility Statistical Plan and Data Analysis (Biostatistician) Ethical Considerations (<i>HS only</i>) (Bioethicist) Data and Research Resources Sharing Plan Impact and Relevance to Military Health (Consumer) Transition Plan (Technology Transfer Specialist) Personnel Partnership Statement (<i>ECIPO only</i>) 	<ul style="list-style-type: none"> Impact and Relevance to Military Health (Consumer) Research Strategy and Feasibility Intervention Regulatory Strategy (Technology Transfer Specialist) Transition Plan (Technology Transfer Specialist) Human Subject Recruitment Statistical Plan and Data Analysis (Biostatistician) Ethical Considerations (Bioethicist) Personnel and Communication Partnership Statement (<i>ECIPO only</i>) Data and Research Resources Sharing Plan
	Unscored	<ul style="list-style-type: none"> Budget Environment Application Presentation 	<ul style="list-style-type: none"> Environment Budget Application Presentation

Peer Review Criteria

	FPA			
	Overall Program		Project	
Scored	Equal Importance <ul style="list-style-type: none"> Overall Program Leadership Implementation Plan Impact and Relevance to Military Health (Consumer) Regulatory Strategy and Transition Plan (Technology Transfer Specialist) 	Equal Importance <ul style="list-style-type: none"> Research Strategy and Feasibility Ethical Considerations (<i>HS and CT only</i>) (Bioethicist) Data and Research Resources Sharing Plan Statistical Plan (Biostatistician) Personnel 		
Unscored	<ul style="list-style-type: none"> Budget Application Presentation 		n/a	

Programmatic Review Criteria

- ◆ **Ratings and evaluations of the peer reviewers**
- ◆ **Relevance to the mission of the Defense Health Program and FY21 TBIPHRP, as evidenced by the following:**
 - ❖ Adherence to the intent of the award mechanism
 - ❖ Program portfolio composition
 - ❖ Relative impact and relevance to military health



**Outcome:
Funding
Recommendations**