Defense Health Program Department of Defense

Peer Review Medical Research Program Funding Opportunities for Fiscal Year 2021 (FY21)

The FY21 Defense Appropriations Act is anticipated to provide funding to the Department of Defense PRMRP to support research that will improve the health, care, and well-being of all military Service members, Veterans, and beneficiaries by encouraging, identifying, selecting, and managing medical research projects of clear scientific merit and direct relevance to military health. As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency J9, Research and Development Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for the anticipated Program Announcements/Funding Opportunities is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

FY21 PRMRP Program Announcements and General Application Instructions for the following award mechanisms are posted on the <u>Grants.gov</u> website.

Congressionally Directed Topic Areas: Applications submitted to the FY21 PRMRP must address at least one of the FY21 PRMRP Congressionally directed topic areas. As of the release date of this pre-announcement, the FY21 PRMRP Topic Areas have not been finalized. This pre-announcement should not be construed as an obligation by the Government to include any of these Topic Areas or others in the FY21 PRMRP. The potential FY21 PRMRP Topic Areas are as follows:

- · Arthritis
- Burn pit exposure
- Cardiomyopathy
- Congenital heart disease
- Diabetes
- Dystonia
- Eating disorders
- Emerging viral diseases
- · Endometriosis
- Epidermolysis bullosa
- Familial hypercholesterolemia
- Fibrous dysplasia
- · Focal segmental glomerulosclerosis
- Food allergies
- · Fragile X
- Frontotemporal degeneration
- Hemorrhage control
- Hepatitis B

- Hydrocephalus
- · Hypertension
- · Inflammatory bowel diseases
- · Malaria
- Metals toxicology
- Mitochondrial disease
- Myalgic encephalomyelitis/chronic fatigue syndrome
- Myotonic dystrophy
- Non-opioid therapy for pain management
- Nutrition optimization
- Pathogen-inactivated blood products
- Peripheral neuropathy
- · Plant-based vaccines
- Platelet like cell production
- Polycystic kidney disease
- · Pressure ulcers
- Pulmonary fibrosis
- · Respiratory health
- Rheumatoid arthritis
- · Sleep disorders and restriction
- · Suicide prevention
- Sustained release drug delivery
- Vascular malformations
- · Women's heart disease

https://cdmrp.army.mil/funding/prmrp

Clinical Trial Award - Preproposal due May 13, 2021

Assistant Professor level or above (or equivalent)

- Preproposal submission is required; application submission is by invitation only.
- Supports the rapid implementation of clinical trials of novel interventions with the potential to have a significant impact on patient care in the topic area(s) of interest.
- · Proposed projects may range from small proof-of-concept trials through large-scale, definitive trials.
- Two options will be offered:
 - Planning Phase with Clinical Trial Option: Provides support to prepare and submit an Investigational New Drug/Investigational Device Exemption (IND/IDE) application to the U.S. Food and Drug Administration (FDA) and requires FDA/regulatory approval or exemption to proceed before the Clinical Trial Award is made.
 - <u>Clinical Trial Only Option</u>: Provides support for the clinical trial. Investigational New Drug or Investigational Device Exemption applications to the Food and Drug

Administration (FDA), if needed, must be approved by the FDA **and** included in the application submission.

Clinical Trial:

- · Funding limit not defined; requested funding must be appropriate for the scope of work proposed
- · Maximum period of performance is 4 years for the clinical trial

Planning Phase with Clinical Trial Option:

- Maximum of \$500,000 for direct costs (plus indirect costs) for the Planning Phase Option
- · Maximum period of performance is **18 months** for the Planning Phase Option

Discovery Award - Letter of Intent Due April 29, 2021

Postdoctoral fellow or clinical fellow (or equivalent) and above

- · Supports the exploration of a highly innovative new concept or untested theory.
- · Not intended to support the logical progression of an already established line of questioning.
- Reviewers will be blinded to the identity of the Principal Investigator (PI), collaborators, and theirorganization(s).
- · Clinical trials will not be funded.
- · Maximum of \$200,000 for direct costs (plus indirect costs)
- · Maximum period of performance is **2** years

Focused Program Award - Preproposal due May 13, 2021

Full Professor level or above (or equivalent)

- · Preproposal submission is required; application submission is by invitation only.
- Supports a synergistic, multidisciplinary research program of at least four distinct but complementaryprojects addressing an overarching goal.
- Projects should work together to answer critical questions, resolve differing hypotheses, and translate laboratory findings to clinical applications.
- · Projects may range from exploratory/hypothesis-developing through small-scale clinical trialsthat together will address the overarching goal/question.
- Research team of highly qualified, multidisciplinary project leaders should be led by a PI with demonstrated success in directing large, focused projects.
- Maximum of \$7.2 million for direct costs (plus indirect costs)
- Maximum period of performance is 4 years

Investigator-Initiated Research Award – Preproposal due by April 28, 2021

Assistant Professor level or above (or equivalent)

- Preproposal submission is required; application submission is by invitation only.
- Supports research that will make an original and important contribution to the field of research or patientcare in the topic area(s) of interest.
- · Partnering PI Option available.
- · Clinical trials will not be funded.
- Maximum of \$1.6 million for direct costs (plus indirect costs)
- · Maximum of **\$2 million** for direct costs (plus indirect costs) for applications including a Partnering PIOption
- Maximum period of performance is 4 years

Technology/ Therapeutic Development Award - Preproposal due by April 28, 2021

Assistant Professor level or above (or equivalent)

- · Preproposal submission is required; application submission is by invitation only.
- · Supports the translation of promising preclinical findings into clinical applications for prevention, detection, diagnosis, treatment, or quality of life.
- · Product-oriented (e.g., device, drug, clinical guidelines). The product(s) to be developed may be a tangible item such as a pharmacologic agent (drugs or biologics) or device, or a knowledge-basedproduct.
- **New for FY21:** Two funding levels available, depending on the maturity of the product. The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under each funding level:
 - <u>Funding Level 1</u>: Supports research that is supported by significant preliminary data but has not advanced to the level of clinical translation.
 - <u>Funding Level 2</u>: Supports research that is in the final states of preclinical development with potential for near-term clinical development. Applications must provide relevant data that support the rationale for the proposed study. Funding Level 2 recipients must submit or obtain an IND/IDE application to the FDA, or must transition the product to clinical practice, within the period ofperformance.
- Clinical trials will not be funded.

Funding Level 1:

- Maximum of \$2 million for direct costs (plus indirect costs)
- · Maximum period of performance is 4 years

Funding Level 2:

- Maximum of \$4 million for direct costs (plus indirect costs)
- Maximum period of performance is 4 years

A pre-application is required and must be submitted through the electronic Biomedical Research Application Portal (eBRAP) at https://eBRAP.org prior to the pre-application deadline. All applications must conform to the final Program Announcements and General Application Instructions available for electronic downloading from the Grants.gov website. The application package containing the required forms for each award mechanism will also be found on Grants.gov. A listing of all CDMRP and other USAMRDC extramural funding opportunities can be obtained on the Grants.gov website by performing a basic search using CFDA Number 12.420.

For email notification when Program Announcements are released, subscribe to program-specific news and updates under "Email Subscriptions" on the eBRAP homepage at https://eBRAP.org. For more information about the PRMRP or other CDMRP-administered programs, please visit the CDMRP website(https://cdmrp.army.mil).

Point of Contact:

CDMRP Help Desk 301-682-5507 help@eBrap.org