Fiscal Year 2021 Peer Reviewed Medical Research Program (PRMRP) Reference Table of Award Mechanisms and Submission Requirements

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Clinical Trial Award Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-21-PRMRP-CTA	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: <u>Planning Phase with Clinical Trial</u> <u>Option</u>: Provides support to prepare and submit an 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 Device Exemption applications to the Food and Drug Administration (FDA), if needed, must be approved by the FDA and included in the application submission. 	 <u>Clinical Trial</u>: 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 <u>Planning Phase with Clinical</u> <u>Trial Option</u>: 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 	Pre-Application (Preproposal): May 13, 2021 5:00 p.m. Eastern time Application: August 26, 2021 11:59 p.m. Eastern time
Discovery Award Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-21-PRMRP-DA	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 their organization(s). Clinical trials will not be funded. 	 Maximum of \$200,000 for direct costs (plus indirect costs) Maximum period of performance is 2 years 	Pre-Application (Letter of Intent): April 29, 2021 5:00 p.m. Eastern time Application: May 13, 2021 11:59 p.m. Eastern time

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Focused Program Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-21-PRMRP-FPA	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 complementary projects 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 trials that 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 	Pre-Application (Preproposal): May 13, 2021 5:00 p.m. Eastern time Application: August 26, 2021 11:59 p.m. Eastern time
Investigator-Initiated Research Award Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-21-PRMRP-IIRA	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 patient care 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 PI Option Maximum period of performance is 4 years 	Pre-Application (Preproposal): April 28, 2021 5:00 p.m. Eastern time Application: September 2, 2021 11:59 p.m. Eastern time
Technology/Therapeutic Development Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-21-PRMRP-TTDA	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, and/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-based product. New for FY21: Two funding levels are available, depending on the maturity of the 	 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 	Pre-Application (Preproposal): April 28, 2021 5:00 p.m. Eastern time Application: September 2, 2021 11:59 p.m. Eastern time

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		 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 of performance. Clinical trials will not be funded. 		