I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Impact Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-PRCRP-IPA

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), May 20, 2021
- **Invitation to Submit an Application:** July 8, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, September 8 2021
- **End of Application Verification Period:** 5:00 p.m. ET, September 15, 2021
- **Peer Review:** November 2021
- **Programmatic Review:** February 2022

This program announcement must be read in conjunction with the General Application Instructions, version 603. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2021 (FY21) Peer Reviewed Cancer Research Program (PRCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PRCRP was initiated in 2009 to provide support for research of exceptional scientific merit for the benefit of Service Members, their families, and the American public. Appropriations for the PRCRP from FY09 through FY20 totaled $539.8 million (M). The FY21 appropriation is $115.0M.

The goal of the PRCRP is to improve quality of life by decreasing the impact of cancer on active-duty Service Members, their families, Veterans, and the American public. The PRCRP is charged by Congress with the mission to investigate cancer risks and knowledge gaps that may be relevant to active-duty Service Members, their families, other military beneficiaries, and the American public.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY21 PRCRP Topic Areas

To be considered for funding, applications for the FY21 PRCRP Impact Award ***must*** address at least one of the FY21 PRCRP Topic Areas as directed by Congress. Congressional language for the FY21 PRCRP provides funds for research into cancers ***not*** addressed in the breast, kidney, lung, pancreatic, prostate, ovarian, rare cancer, and melanoma research programs. ***Research applications in the areas of breast, kidney, lung, pancreatic, prostate, ovarian, rare cancers, and melanoma are prohibited and will not be accepted***. The inclusion of the individual Rare Cancer Research Program ***shall not*** prohibit the PRCRP from funding the below mentioned cancers or cancer subtypes that may be rare by definition. The FY21 PRCRP Topic Areas are listed below.

- Bladder cancer
- Blood cancers
- Brain cancer
- ***New for FY21:*** Cancers associated with the use of beryllium
- Colorectal cancer
- ***New for FY21:*** Endometrial cancer
- Esophageal cancer
- ***New for FY21:*** Germ cell cancers
- Head and neck cancers
- Liver cancer
- ***Returning for FY21:*** Lymphoma
- Mesothelioma
- Metastatic cancers
- Neuroblastoma
- Pediatric, adolescent, and young adult cancers[1]
- Pediatric brain tumors
- Stomach cancer
- ***New for FY21:*** Sarcoma
- ***New for FY21:*** Thyroid cancer
- ***New for FY21:*** The link between scleroderma and cancer

For cancers associated with the use of beryllium, proposed research should target mechanistically the process of cancer risk, initiation, and be agnostic to the cancer type.

Metastatic cancer is cancer that has spread from its original location to another place in the body, representing what are known as stage III and stage IV cancer diagnoses. While recent research has revealed that there is a genetic basis for susceptibility or resistance to metastasis, more research is needed to develop a comprehensive understanding of this complex process.

Congressional language prohibits studies involving breast, kidney, lung, pancreatic, prostate, ovarian, rare cancers, and melanoma to be funded for any topic area included in the PRCRP.

II.A.2. FY21 PRCRP Military Health Focus Areas

In addition to addressing at least one of the required FY21 PRCRP Topic Areas, applications for the FY21 PRCRP Impact Award *must* also address at least one of the FY21 PRCRP Military Health Focus Areas. It is central to the Vision and Mission of the PRCRP that applications address how the proposed research is related to military health, mission readiness, and the cancer health needs of both deployed and non-deployed military personnel, their dependents, Veterans, and other military beneficiaries (i.e., family members of retirees) (https://cdmrp.army.mil/pubs/video/prc/prcrp_vision_video). The FY21 PRCRP ***requires all applications*** to address at least one of the Military Health Focus Areas listed below:

- ***Environmental exposure risk factors associated with cancer***
- ***Mission Readiness***

[1] The definition of adolescents and young adults is derived from the National Cancer Institute (https://www.cancer.gov/types/aya). Research should be targeted toward children (ages 0–14 years), adolescents (ages 15–24 years), and/or young adults (ages 25–39 years).

- Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public

- Gaps in quality of life and/or survivorship that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public

Environmental risk factors should be relevant to activities specific to the military such as deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.). For more information on military-related exposures and risk factors for cancer, applicants should refer to Exposure Related Health Concerns at https://www.publichealth.va.gov/exposures/health-concerns.asp or to the PRCRP website (https://cdmrp.army.mil/prcrp/default).

Examples of impact on mission readiness may include, but are not limited to, improvements in survival while minimizing late effects that would allow an active-duty Service Member to return to full duty; treatments that minimize a cancer patient's (either a Service Member's or their family members') time in the hospital, thus maximizing the time the Service Member is on duty; minimizing cancer relapse for Service Members or their families (in the event of a family member's relapse the active-duty Service Member is called home regardless of deployment status); and improvements in cancer detection that would lead to the earlier diagnosis, thus allowing for improved treatment of the Service Member and early return to duty. More information on mission readiness can be found here: https://cdmrp.army.mil/prcrp/pbks/prcrppbk2017.pdf.

Investigators are strongly encouraged to collaborate, integrate, and/or align their research projects with Department of Defense (DOD) and/or Department of Veterans Affairs (VA) research laboratories and programs.

II.A.3. FY21 PRCRP Overarching Challenges

***New for FY21*:** The PRCRP has developed a strategy to address multiple issues in cancer research over the spectrum of different cancer topics considered for funding. These Overarching Challenges are critical gaps in cancer research, care, and/or patient outcomes that, if addressed, will advance mission readiness of U.S. military members affected by cancer and improve quality of life by decreasing the burden of cancer on Service Members, their families, Veterans, and the American public. Simply identifying an Overarching Challenge is not sufficient. Applications must address at least one challenge in a way that can lead to or make a breakthrough and have a major impact.*

- Develop strategies and biomarkers to predict cancer risk, treatment resistance, recurrence, and advanced disease to mitigate risk in target populations.

- Improve prevention strategies, diagnosis, treatment, and outcomes for patients in underserved or under recognized populations (e.g., military populations, rural populations, communities of color, other minorities, and women).

- Transform cancer treatment through the identification of novel biomarkers and new targets especially for advanced disease (metastatic and/or recurrence); improve immunotherapy; and eliminate the risks of therapy-associated toxicity.

- Identify and understand the unique and novel features driving cancer presentation to improve outcomes across the spectrum of ages (e.g., children, adolescents, young adults, older adults).

- Identify and understand the mechanisms behind cancer epigenetics, biological development, etiology, and genetic basis.

- Develop strategies to improve ease of care/accessibility and to address survivorship issues including quality of life, long-term treatment effects, psychological impact of recurrence, neurocognitive deficits, and overall mental health.

- Develop and improve minimally invasive methods to detect cancer initiation, recurrence, and progression.

- Develop open access platform(s) or methods to coordinate and integrate multiple databases, biorepositories, and data sharing interfaces.

*Alternatively, with adequate justification, applications may identify and address another Overarching Challenge related to critical gaps in cancer research, care, and/or patient outcomes. Justification must be provided in the application.

II.B. Award Information

The FY21 PRCRP Impact Award supports hypothesis-driven, ***high-impact*** research. The Impact Award mechanism encourages applications with ***mature*** research projects that specifically focus on critical scientific or clinical cancer issues, which, if successfully addressed, have the potential to make a major ***near-term*** impact on at least one of the FY21 PRCRP Topic Areas. Important factors under consideration will be continuity of research, clinical applicability, and leveraging of clinical samples and trials. Through the Impact Award, the PRCRP seeks to build foundations in underfunded, understudied, and/or lethal militarily relevant cancer or research areas. The Impact Award supports identifying scientific outcomes through rigorous, robust research that are translatable toward treatment and/or preventive strategies. Research proposed should aim to accelerate promising findings toward clinical applicability and leverage research results to maximize impact.

The critical components of this award mechanism are:

- **Impact:** The Impact Award is intended to support research that demonstrates the potential to have a ***major impact in the near term*** on an area of paramount importance in cancer. The proposed study should demonstrate how the research will transform cancer research toward improved patient outcomes in at least one of the FY21 PRCRP Topic Areas and in at least one of the FY21 PRCRP Overarching Challenges in Section II.A.3 or another critical cancer area. Proposed projects may include translational or clinical research, including clinical trials. ***The potential impact of the proposed research is expected to be near-term, and it***

must be significant and go beyond an incremental advance. The applicant must articulate the potential impact the proposed work will have on cancer research and/or patient outcomes. The Impact Award is not intended for basic research. ***Applicants proposing more basic or long-term impact studies should apply to the FY21 PRCRP Idea Award (W81XWH-21-PRCRP-IA)***.

- **Preliminary Data:** The Impact Award is intended to support transformative investigations that leapfrog the cancer research field forward by utilizing previous research findings. ***Applications must include preliminary data to support feasibility of the study***. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member of the research team.

- **Continuity of Research:** The Impact Award is intended to support established projects that have moved beyond the realm of basic research and have the potential to result in a near-term impact in clinical research or the clinic.

- **Data Evaluation:** The proposed research should be rigorously designed to include a statistical plan and data analysis plan. The Impact Award is intended to have near-term relevance to patients; therefore, the statistical plan and data analysis plan should represent how significant the results and/or outcomes may be on patient outcomes.

- **Military Relevance:** The proposed research must address at least one of the FY21 PRCRP Military Health Focus Areas. The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public. For more information, review the following websites:

    - PRCRP Vision Video (https://cdmrp.army.mil/pubs/video/prc/prcrp_vision_video)

    - PRCRP (https://cdmrp.army.mil/prcrp/default)

    - Military Health System (MHS) (https://www.health.mil)

    - VA (https://www.va.gov/)

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

A congressionally mandated Metastatic Cancer Task Force was formed for the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address them, provided they are within the limitations of this funding opportunity and fit within the FY21 PRCRP priorities.

Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military families, and the American public.

The anticipated direct costs budgeted for the entire period of performance for an FY21 PRCRP IPA award will not exceed **$1.25M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information, refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $30.0M to fund approximately 15 Impact Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and

master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical Trials are allowed.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in Code of Federal Regulations, Title 32, Section 219 (32 CFR 219).

Clinical research is defined as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. ***Note:*** Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal

programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organization other than the DOD, and research institutes.

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to be named as the PI on the application.

Each investigator may be named on only one Impact Award application as a PI. ***This does not apply to collaborators named on the Impact Award applications***.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1, Full Application Guidelines).

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY21 PRCRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  - **Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

    The Preproposal Narrative should include the following:

    - State the FY21 PRCRP Topic Area(s) to be studied.

    - State the project's hypothesis, objectives, rationale, and specific aims. Describe the rationale, methodology, and experiment design to test the hypothesis and the specific aims of the project. Demonstrate how the research is based on strong preliminary data and/or previous clinical and/or translational research outcomes.

- Describe the hypothesis-driven, high-impact study. Describe the critical scientific or clinical issue that, if successfully addressed, will have a major impact on at least one of the FY21 PRCRP Topic Areas. Describe the ***potential near-term impact*** of the proposed research on at least one of the FY21 PRCRP Topic Areas.

- State the FY21 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make a near term impact. Alternatively, if a critical challenge is not identified from the FY21 PRCRP Overarching Challenges, justify the reasoning behind the new critical challenge to be addressed and state how the research will make a near term impact.

- Explain how the proposed research will lead to promising outcomes for one or more of the selected FY21 PRCRP Military Health Focus Area(s) in Section II.A.2.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (five-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PRCRP, pre-applications will be screened based on the following criteria:

  - Whether the proposed project addresses at least one of the FY21 PRCRP Topic Areas.

  - Whether the rationale, methodology, and experimental design will test the hypothesis and support the specific aims of the project. How well the preliminary data and/or previous clinical and/or translational research outcomes support the hypothesis and specific aims of the project.

- Whether the proposed research will study a critical scientific or clinical issue that, if successfully addressed, will have a major impact on at least one of the FY21 PRCRP Topic Areas.

- Whether an FY21 PRCRP Overarching Challenge in Section II.A.3 is to be studied and to what degree the research will make a near-term impact. Alternatively, if a critical challenge is not identified from the FY21 PRCRP Overarching Challenges, whether the reasoning behind the new critical challenge to be addressed in the pre-application is justified and to what degree the research will make a near-term impact.

- To what degree the proposed research may lead to promising outcomes for one or more of the selected FY21 PRCRP Military Health Focus Areas.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

Applications will not be accepted unless notification of invitation has been received.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (https://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of

Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-PRCRP-IPA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-PRCRP-IPA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DOD Submissions
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. ***Note:*** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

Extramural Submissions	Intramural DOD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

  SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. ***Inclusion of preliminary data is required.***

- **Background:** Describe the critical scientific or clinical issue that, if successfully addressed, will have a major impact on at least one of the FY21 PRCRP Topic Areas. Describe the rationale for the study in terms of clinical research gap or patient outcome gap.

- **Hypothesis and Objective:** State the hypothesis to be tested and the objective to be reached regarding a critical scientific of clinical issue relevant to at least one of the FY21 PRCRP Topic Areas in Section II.A.1 ***and*** at least one of the FY21 PRCRP Military Health Focus Areas in Section II.A.2.

- **Specific Aims:** State the specific aims of the study.

- **Research Strategy and Feasibility:** Describe the rationale, experimental design, and methodology appropriate to test the hypothesis and reach the final objective. Include preliminary data and reconcile it with objectives of the research proposed. Demonstrate how the research is based on strong preliminary data and/or previous clinical and/or translational research outcomes. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the PI or collaborators named on this application must be included. Describe potential problems and potential pitfalls, and address alternative approaches. Demonstrate the availability of tissue, data, or human subjects, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. Describe all animal studies and how the studies are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable. ***If funds for a clinical trial are requested, details regarding the Clinical Strategy must be outlined in Attachment 9.***

- Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. If women and minorities are excluded, to what extend the application provided a rational justification.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- **Intellectual Property:** Information can be found in 2 CFR 200.315, "Intangible Property."

    - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

        - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

    - **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

    - **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

    - **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

    - Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

    - **Background:** State the FY21 PRCRP Topic Area(s) in Section II.A.1 to be addressed by the proposed research. State the FY21 PRCRP Military Health Focus Area(s) in Section II.A.2 to be addressed. Present the ideas and reasoning behind the proposed work. If applicable, describe the previous clinical and/or translational research outcomes upon which the study is founded.

    - **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested.

- **Impact:** Briefly describe how the proposed project will have a near-term impact on at least one of the FY21 PRCRP Topic Areas. State the FY21 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and state how the research will make an impact. Alternatively, if a critical challenge is not identified from the FY21 PRCRP Overarching Challenges, state how the research will make an impact on a critical cancer area. .

- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Briefly describe the study design and methodology.

- **Relevance to Military Health:** Identify the FY21 PRCRP Military Health Focus Area(s) to be studied. Briefly describe how the proposed research is relevant to active-duty Service Members, Veterans, and other military beneficiaries.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. ***Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

  - State the FY21 PRCRP Topic Area(s) *and* Military Health Focus Area(s) to be addressed by the research project.

  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.

  - What types of patients will the research help, and how will it help them? What are the potential clinical applications, benefits, and risks? Describe the likely contributions of this study to advancing the field of cancer research and/or patient care?

  - Describe the near-term impact for patients and ultimate applicability of the research. What is the projected time it may take to achieve a patient-related outcome? What types of patients will it help, and how will it help them? What are the potential clinical applications, benefits, and risks?

  - State the FY21 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make an impact. Alternatively, if a critical challenge is not identified from the FY21 PRCRP Overarching Challenges, describe how the research will make an impact on a critical cancer area.

- Describe how the proposed research is relevant to active-duty Service Members, Veterans, and other military beneficiaries.

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** The suggested Statement of Work (SOW) format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the Impact Award mechanism, refer to the "***Suggested SOW Strategy Generic Research***" document for guidance on preparing the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

- **Attachment 6: Research Outcomes Plan: (one-page limit): Upload as "Outcomes.pdf".** Describe the anticipated research outcomes (e.g., knowledge products, clinical products for further development). Describe the methods and strategies (e.g., funding opportunities, collaborations, and intellectual property rights) proposed to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project. Detail the strategy to transition to the next level of investigation, development, and/or commercialization.

- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilHealth.pdf".** ***The Relevance to Military Health Statement will be evaluated by the FY21 PRCRP Programmatic Panel during programmatic review only.***

  - State the FY21 PRCRP Military Health Focus Area(s) in Section II.A.2 to be addressed in the study.

  - Identify the environmental and/or exposure risk factors associated with the FY21 PRCRP Topic Area(s) in Section II.A.1 to be studied and their short-term and long-term impact on the basic health, welfare, and/or psychosocial wellness of active-duty Service Members, Veterans, and other military beneficiaries.

    or

  - Identify how the proposed research will support mission readiness through filling a gap in cancer prevention, early detection/diagnosis, prognosis, treatment, quality of life and/or survivorship that may have a profound impact on the health and well-being of Service Members, their families, Veterans, or other beneficiaries.

  - Articulate how the proposed research will advance the knowledge and understanding of cancer, patient care, and/or treatment options in the MHS for the benefit of active-duty Service Members, Veterans, and other military beneficiaries.

  - Describe the anticipated short-term and/or long-term outcomes of the proposed research and their potential impact on the basic health, welfare, and/or psychosocial wellness of active-duty Service Members, Veterans, and other military beneficiaries.

- Describe how the study design will replicate field conditions, if appropriate. If active-duty Service Members, military families, or Veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population.

- If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the Veteran population).

- **Attachment 8: Impact Statement (one-page limit): Upload as "Impact.pdf".** ***The Impact Statement should be written in plain language for laypersons.***

  - Discuss the near-term clinical impact to patients. If the potential outcomes are relevant to clinical research, explain the impact for patients if successful.

  - State how the research will accelerate promising findings toward clinical applicability and leverage results to maximize impact. State explicitly how the proposed work addresses a critical problem in at least one of the FY21 PRCRP Topic Areas in Section II.A.1.

  - State the FY21 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make a near-term impact. Alternatively, if an FY21 PRCRP Overarching Challenge is not identified, justify the reasoning behind the new critical challenge to be addressed and describe how the research will make a near-term impact.

- **Attachment 9: Clinical Strategy Statement,** ***if applicable*** **(no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required.** Describe the rationale for the proposed clinical trial. Provide a description of the intervention, and the endpoints to be measured. Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug (IND)/Investigational Device Exemption (IDE) application submission plans within 60 days of the award, if applicable. Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page, fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. For phase 3 clinical trials, use the form to describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study.

  Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where

appropriate. Describe how the clinical trial will inform the correlative clinical research, if applicable. Describe the data management plans. If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that would be supported with funds from this award. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

Attachment 10: Statistical Plan and Data Analysis (five-page limit): Upload as "Stats.pdf". Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Describe how data will be evaluated for reproducibility and adjusted for confounding variables. Articulate how large datasets will be evaluated, if applicable. State whether large datasets will be accessible to the research community. Ensure sufficient information is provided to demonstrate the significance of anticipated outcomes for patient populations.

- **Attachment 11: Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human Anatomical Substances, Databases), *if applicable* (one-page limit per letter): Upload as "Access.pdf".** If the proposed research plan involves access to active-duty military and/or VA patient population(s) or resource(s), include a letter of support, signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

- **Attachment 12: Use of Hazardous Chemical or Biological Agents, *if applicable* (no page limit): Upload as "Hazardous.pdf".** The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information, such as Centers for Disease Control and Prevention registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate if agents to be used are purchased commercially, and, if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

- **Attachment 13: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/

public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 14: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (MHS facility, research laboratory, medical treatment facility, dental treatment facility, or DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

  Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

  - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

  - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

    - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

    - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

- **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that

determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business

Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **4** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **$1.25M.** If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **$1.25M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to two scientific/technical meetings per year. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the PRCRP Impact Award.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are of equal importance:

- **Research Strategy and Feasibility**
    - How well the proposed research addresses an important critical scientific or clinical issue relevant to at least one of the FY21 PRCRP Topic Areas in Section II.A.1.
    - How well the rationale is described for the study in terms of clinical research gap or patient outcome gap.
    - To what degree the experimental design and methodology is appropriate to test the hypothesis and reach the final objectives of the proposed research. Whether the included preliminary data reconciles with the objectives of the research proposed.
    - If applicable, to what extent the human subject population described is appropriate for the study and there is clear demonstration of access to the designated population.
    - To what degree the statistical plan with appropriate power analysis is appropriate and whether the power analysis supports the sample size.
    - How well the application acknowledges potential problems and potential pitfalls, and addresses alternative approaches.
    - Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.
    - Whether the application describes how the data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
    - Whether the application includes a plan for the recruitment of human subjects or the acquisition of samples and documents the experience of the PI and/or key collaborators in recruiting human subjects for similar projects, if applicable.
    - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable.

- **Impact**
    - How well the application articulates the near-term clinical impact to patients. How well the application demonstrated how laboratory outcomes are relevant to clinical research, and the impact for patients if successful.
    - To what extent the research, if successful, will accelerate promising findings toward clinical applicability to have maximize impact.
    - Whether the application selects an FY21 PRCRP Overarching Challenge to be studied and describes how the study will make an impact on the selected challenge. Alternatively, if an FY21 PRCRP Overarching Challenge is not selected, then to what degree the reasoning to study a new critical challenge is justified and whether it will make an impact.
    - Whether the application explicitly stated how the proposed work addresses a critical problem in at least one of the FY21 PRCRP Topic Areas in Section II.A.1.
- **Clinical Strategy (as applicable for applications proposing a clinical trial)**
    - Whether the application describes the strategy for the inclusion of women and minorities that is appropriate for the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.
    - Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity is included.
    - For phase 3 clinical trials, whether the application describes plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity that are appropriate for the scientific goals of the study.
    - Whether the application describes the rationale for the proposed clinical trial.
    - Whether the intervention and the endpoints to be measured are described in sufficient detail.
    - Whether the application provides detailed plans for initiating the clinical study within the first year, including FDA IND/IDE application submission plans within 60 days of the award, *if applicable*.
    - To what extent the application described access to the study population, recruitment plans, and inclusion/exclusion criteria.
    - Whether the type of clinical trial to be performed is indicated (e.g., prospective, randomized, controlled) and the methodology is outlined in sufficient detail to show a clear course of action.

- To what degree potential challenges and alternative strategies are described.
- How well the application articulated the data management plans.
- How data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan support an analysis of the study objectives.
  - To what degree the power analysis demonstrates that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies, if applicable.
  - If applicable, whether the approximate number of human subjects is stated. If multiple study sites are involved, whether the approximate number to be enrolled at each site is stated. If a subpopulation of a recruited sample population will be used for analysis, whether a statistical analysis to ensure appropriate power has been performed and whether it shows appropriate power for the study.
  - To what extent the data have been evaluated for reproducibility and adjusted for confounding variables.
  - Whether there is sufficient information to demonstrate significant outcomes for patient populations if the research is successful.
  - Whether there is a plan to evaluate large datasets, if applicable.
  - Whether large datasets will be accessible to the research community, if applicable.

In addition, the following **unscored** criteria will also contribute to the overall evaluation of the application:

- **Research Outcomes Plan**
  - Whether the application described the anticipated research outcomes (e.g. knowledge products, clinical products for development).
  - How well the application demonstrated methods (e.g., funding opportunities, collaborations, and intellectual property rights) to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project.
  - To what degree the application offers a well laid out strategy to transition to the next level of investigation, development, and/or commercialization.

- **Personnel**
    - Based on information in the biographical sketches, whether the research team's backgrounds are appropriate to study the specified FY21 PRCRP Topic Area(s) in Section II.A.1, with respect to the team's ability to perform the proposed work.
    - How appropriate the levels of effort are for successful conduct of the proposed work.
- **Budget**
    - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
    - Whether the budget is appropriate for the proposed research.
    - Whether there may be significant overlap with existing or pending awards of the PI or research team.
- **Environment**
    - To what degree the scientific environment is appropriate for the proposed research.
    - To what degree the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
    - To what degree the quality and extent of institutional support are appropriate.
    - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY21 PRCRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio balance and composition
    - Programmatic relevance to the FY21 PRCRP Military Health Focus Areas

- Programmatic relevance to the FY21 PRCRP Overarching Challenges
- Relative near-term impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.army.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the PRCRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when

determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. No commitment on the part of the government should be inferred from discussions with any other individual. **The award document signed by the Grants Officer is the official authorizing document.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D General Terms and Conditions; the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions; and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Inclusion Enrollment Reporting Requirement ***(only required for clinical research studies)***: Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value

greater than $10M are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 603a. The program announcement numeric version code will match the General Application Instructions version code 603.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- More than one Pre-application with the same PI will result in all but one being administratively rejected.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY21 PRCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY21 PRCRP Programmatic Panel members can be found at https://cdmrp.army.mil/prcrp/panels/panels21***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The invited application proposes a different research project than that described in the pre-application.

- The PI does not meet the eligibility criteria.

- The pre-application or application does not address at least one of the FY21 PRCRP Topic Areas in Section II.A.1.

- The pre-application or application does not address at least one of the FY21 PRCRP Military Health Focus Areas in Section II.A.2.

- The pre-application or application does not address at least one of the FY21 PRCRP Overarching Challenges in Section II.A.3.

- The applicant organization submits more than one pre-application or application with the same PI as the named investigator.

- An application proposing a clinical trial where Attachment 9: Clinical Strategy Statement is missing.

- The pre-application and/or the application does not adhere to Congressional language and proposes breast, kidney, lung, pancreatic, prostate, ovarian, rare cancers, and melanoma research.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Research Outcome Plan: Upload as Attachment 6 with file name "Outcomes.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "MilHealth.pdf"	
	Impact Statement: Upload as Attachment 8 with file name "Impact.pdf"	
	Clinical Strategy Statement: Upload as Attachment 9 with file name "Clinical.pdf", if applicable	
	Statistical Plan and Data Analysis: Upload as Attachment 10 with file name "Stats.pdf"	
	Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human/Animal Anatomical Substances, Databases): Upload as Attachment 11 with file name "Access.pdf" if applicable	
	Use of Hazardous Chemical or Biological Agents: Upload as Attachment 12 with file name "Hazardous.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf" if applicable	

Application Components	Action	Completed
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 14 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget **(intramural submissions only)**	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
PRCRP	Peer Reviewed Cancer Research Program
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs