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: HT9425-23-PRCRP-IPA

**Assistance Listing 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 25, 2023

- **Invitation to Submit an Application:** June 29, 2023

- **Application Submission Deadline:** 11:59 p.m. ET, September 12, 2023

- **End of Application Verification Period:** 5:00 p.m. ET, September 19, 2023

- **Peer Review:** November 2023

- **Programmatic Review:** January 2024

This program announcement must be read in conjunction with the General Application Instructions, version 802. 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."

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2023 (FY23) Peer Reviewed Cancer Research Program (PRCRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). 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 FY22 totaled $784.8 million (M). The FY23 appropriation is $130M.

The goal of the PRCRP is to increase mission readiness and quality of life by decreasing the burden of cancer on 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. FY23 PRCRP Topic Areas

To be considered for funding, applications for the FY23 PRCRP Impact Award ***must*** address at least one of the congressionally directed FY23 PRCRP Topic Areas. Congressional language stipulates the FY23 PRCRP must not fund research into breast, kidney, lung, pancreatic, prostate, ovarian, rare cancer, and melanoma. Applicants are directed to apply to the individual CDMRP cancer programs those disease areas. ***Research applications in the areas of breast, kidney, lung, pancreatic, prostate, ovarian, rare cancer, or melanoma are prohibited and will be rejected***. The inclusion of the individual Rare Cancers Research Program ***shall not*** prohibit the funding of the FY23 PRCRP congressionally directed cancers or cancer subtypes that may be rare by definition. The FY23 PRCRP Topic Areas are listed below.

- Bladder cancer
- Blood cancers
- Brain cancer
- Colorectal cancer
- Endometrial cancer
- Esophageal cancer
- Germ cell cancers
- Head and Neck cancer

- Liver cancer
- Lymphoma
- Mesothelioma
- Metastatic cancers
- Myeloma
- Neuroblastoma
- Pediatric, adolescent, and young adult cancers[1]

- Pediatric brain tumors
- Stomach cancer
- Sarcoma
- Thyroid cancer
- Von Hippel-Lindau syndrome malignancies (excluding cancers of the kidney and pancreas)

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 cancer, and melanoma to be funded for any Topic Area included in the PRCRP.

II.A.2. FY23 PRCRP Military Health Focus Areas

In addition to addressing at least one of the required FY23 PRCRP Topic Areas, applications for the FY23 PRCRP Impact Award *must* define how the research is relevant to Service Members and their families. 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 FY23 PRCRP *requires all applications* to demonstrate the relevance of the research to at least one of the Military Health Focus Areas listed below and show how the research will decrease the burden of cancer on Service Members, their families, and Veterans.

FY23 PRCRP Military Health Focus Areas:

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

  Environmental and /or occupational 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

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[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 pediatric (ages 0–14 years), adolescents (ages 15–24 years), and/or young adults (ages 25–39 years).

Concerns at https://www.publichealth.va.gov/exposures/health-concerns.asp or to the PRCRP website (https://cdmrp.army.mil/prcrp/default).

- ***Mission Readiness and Gaps in Cancer Research***

  - 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.

Mission readiness under the FY23 PRCRP Military Health Focus Areas refers to the impact of cancer on the Service Member. Decreasing the impact of cancer on active-duty Service Members and/or their families protects the overall military missions. Some examples of relevant research to decrease the impact on mission readiness may include, but are not limited to:

- Studies on the improvement in survival while minimizing late effects that would allow an active-duty Service Member to return to full duty;

- Treatments to 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;

- Effective ways to minimize 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

- Research into improvements in cancer detection that would lead to earlier diagnosis, thus allowing for improved treatment of the Service Member and early return to duty.

For more information on military health and cancer:

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

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

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

- Department of Veterans Affairs (VA) (https://www.va.gov/)

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

II.A.3. FY23 PRCRP Overarching Challenges

The PRCRP developed a strategy to address multiple issues in cancer research over the spectrum of different cancer topics considered for funding under the PRCRP. 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 of the following Overarching Challenges in a way that can lead to or make a breakthrough and have a major impact. ***The 15 FY23 PRCRP Overarching Challenges are classified in five different categories. The applicant must address at least one of the 15 FY23 PRCRP Overarching Challenges and not just select a category.***

- **Prevention**

    o   Investigate innovative prevention strategies and early detection methods to decrease cancer burden.

    o   Elucidate the mechanisms underlying cancer development to improve prevention methods.

- **Diagnostics/Prognostics**

    o   Identify approaches to predict treatment resistance, recurrence, and the development of advanced disease.

    o   Distinguish unique features driving cancer occurrence across the spectrum of ages.

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

- **Therapeutics**

    o   Transform cancer treatment, especially for advanced disease and metastasis.

    o   Improve current therapies including systemic and local treatments.

    o   Research longitudinal evaluation of disease progression and/or treatment response.

    o   Elucidate the mechanisms of cancer development to improve treatment methods.

- **Patient Well-Being and Survivorship**

    o   Study methods to address survivorship issues, including quality of life, overall mental health, psychological impact of recurrence, and/or survivor permanent disability.

    o   Reduce short- and long-term treatment effects, including neurocognitive deficits.

    o   Investigate ways to bridge gaps between treatment and survivorship, including alternative medicine, nutrition and lifestyle factors, and supportive care.

- **Disparity**

    o   Improve prevention strategies, diagnosis, treatment, and outcomes for patients in underserved or under recognized populations.

o Study methods to improve accessibility to care and address survivorship.

o Advance health equity and reduce disparities in cancer care through research.

II.B. Award Information

The FY23 PRCRP Impact Award supports hypothesis-driven, high-impact research. The intent of the Impact Award mechanism is to ***fund mature research projects*** that specifically focus on critical scientific or clinical cancer issues, which have the potential to make a major near-term impact on at least one of the [FY23 PRCRP Topic Areas](#). Important factors under consideration will be continuity of research, clinical applicability, and leveraging of clinical samples and trials. The Impact Award supports identifying scientific outcomes that, through rigorous, robust research, 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 [FY23 PRCRP Topic Areas](#) and in at least one of the FY23 PRCRP Overarching Challenges in [Section II.A.3](#). 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 while it fundamentally may include the next step in research, 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 generating preliminary data, basic research, high-risk/high-gain studies should apply to the FY23 PRCRP Idea Award (W81XWH-22-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.

A congressionally mandated Metastatic Cancer Task Force was formed with 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, the 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 these recommendations provided they are within the limitations of this funding opportunity and fit within the FY23 PRCRP priorities.

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.

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 FY23 PRCRP Impact Award should not exceed **$1.0M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $17.6M to fund approximately 11 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 FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human

data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), 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 application submission is *not* required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of *all required and complete* documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research *must* rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based 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 a placebo or another 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 the 32 CFR 219.*

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. *For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.* Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual.

Note: Studies that meet the requirements for exemption under §46.104(d)(4) of the Common Rule are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military and/or VA 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 research funded by the FY23 PRCRP Impact Award involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO, 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 organizations 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:* **An** ***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.***

The 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.

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

The CDMRP strongly 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).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

The electronic Biomedical Research Application Portal (eBRAP) (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (https://grants.gov), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

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

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.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 eBRAP 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 eBRAP 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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.

  There are two options for the Impact Award:

  ○ Impact Award

    – Applications do *not* include a clinical trial and do *not* require the Clinical Trial Strategy (Attachment 9). Refer to the definition of a clinical trial in Section II.B., Award Information.

  ○ Impact Award – Clinical Trial Option

    – Applications *do* include a clinical trial and *do* require the Clinical Trial Strategy (Attachment 9). Refer to the definition of a clinical trial in Section II.B., Award Information.

  It is incumbent on the *investigator* to select the correct option. Failure to correctly select the correct option may affect the review of the application.

- **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.

  FY23 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 eBRAP 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 (one-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 FY23 PRCRP Topic Area(s) in Section II.A.1 to be studied.

- State the project's hypothesis, objectives, rationale, and specific aims. Describe the 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 that may include previous clinical and/or translational research outcomes. State whether a clinical trial will be included in the study (Refer to the definition of a clinical trial in Section II.B., Award Information).

- Describe the *potential near-term impact* of the proposed research on at least one of the FY23 PRCRP Topic Areas.

- State the FY23 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make an impact.

- Explain how the proposed research will lead to promising outcomes for one or more of the selected FY23 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 Defense Health Program (DHP) and the PRCRP, pre-applications will be screened based on the following criteria:

○ Whether the proposed project addresses at least one of the FY23 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 FY23 PRCRP Topic Areas.

○ Whether an FY23 PRCRP Overarching Challenge in Section II.A.3 is to be studied 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 FY23 PRCRP Military Health Focus Areas.

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

Following the pre-application screening, PIs will be notified as to whether 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://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.

<div align="center">

Table 1. Full Application Submission Guidelines

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Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-PRCRP-IPA from Grants.gov (https://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 HT9425-23-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.
Application Package Submission	
Create a Grants.gov Workspace.	**Submit package components to eBRAP (https://ebrap.org).**

Extramural Submissions	Intramural DOD Submissions
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 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.***	**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.
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	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Extramural Submissions	Intramural DOD Submissions
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.	

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 megabytes (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 (uniform resource locators) 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 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 FY23 PRCRP Topic Areas in Section II.A.1 *and* at least one of the FY23 PRCRP Military Health Focus Areas in Section II.A.2.

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

- **Relevance to the Impact Award Intent:** Explain how the proposed research has the potential to have a *major impact in the near term* on an area of paramount importance in cancer and how the research will transform cancer research.

- **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 Trial Strategy must be outlined in Attachment 9. Only those proposed studies measuring safety, effectiveness, and/or efficacy of an intervention are considered clinical trials and should submit a Clinical Trial Strategy.* Refer to the definition of a clinical trial in Section II.B., Award Information.

- *Statistical Plan and Data Analysis for all applications must be submitted in Attachment 10.*

- If applicable, 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 extent the application provided a 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 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 demonstrating 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 the 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.

- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c Enclosure 3, [DoD Instructions 3200.12](#).

    - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.

    - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.

- **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.

Technical abstracts should be written using the outline below.

– **Background:** State the FY23 PRCRP Topic Area(s) in Section II.A.1 to be addressed by the proposed research. State the FY23 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. If applicable describe the clinical trial to be performed.

– **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 FY23 PRCRP Topic Areas. State the FY23 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make an impact.

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

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

– **Relevance to Military Health:** Identify the FY23 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. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

– State the FY23 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 FY23 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make an impact.

- 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, refer to either the "*Suggested SOW Strategy for Clinical Research_Clinical Trial*" or "*Suggested SOW Strategy Generic Research*", whichever format is most appropriate for the proposed effort, 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 FY23 PRCRP Programmatic Panel during programmatic review only.*

  - State the FY23 PRCRP Military Health Focus Area(s) in Section II.A.2 to be addressed in the study.

– Based on published literature of the impact of cancer on military populations, articulate the relevance of the research proposed and show how it will decrease the burden of cancer on Service Members, their families, and Veterans.

– Identify the environmental and/or occupational risk factors associated with the FY23 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

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

– 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 FY23 PRCRP Topic Areas in Section II.A.1.

– State the FY23 PRCRP Overarching Challenge(s) in Section II.A.3 to be studied and describe how the research will make a near-term impact.

– Describe the pathway from the proposed research to making a near-term impact on patient outcomes and/or caregiver issues. Explain how the application's specific research goals would fit into the pathway of achieving clinical applicability.

○ **Attachment 9: Clinical Trial Strategy, if applicable (no page limit): Upload as "Clinical.pdf".** If funds for a clinical trial are requested, this attachment is required. Only those proposed studies measuring safety, effectiveness, and/or efficacy of an intervention are considered clinical trials and should submit a Clinical Trial Strategy.

– Describe the rationale for the proposed clinical trial. Demonstrate how the proposed clinical trial is supported by strong preliminary data and relevant literature citations. Provide a description of the intervention, and the endpoints to be measured. Articulate the type of clinical trial to be performed (e.g., randomized, cohort, case-

control, cross-sectional) and outline the proposed methodology in sufficient detail to show a clear course of action. Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug/Investigational Device Exemption (IND/IDE) application submission plans within 60 days of the award, if applicable. Define the study population and indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria, include a justification for the plans and alternatives strategies if issues arise. Describe the informed consent process.

– 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 is a one-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

– 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.

– 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".** *All applicants are required to submit a Statistical Plan and Data Analysis.* Describe the statistical methodology and plan including how it supports the stated hypothesis or objective. If an existing dataset is to be used, describe the dataset and how it supports the aims of the project. State the inclusion and exclusion criteria for the subjects with sound rationale for the criteria, if applicable. Describe the power analysis and whether it determined population numbers; if not, justify why the power analysis is not essential to the statistical evaluation. State whether the study will include univariate, bivariate, or multivariate analyses. State the variables to be used in the main analysis; include covariates and how the data will be adjusted to account for covariates, if applicable. Stratification of data (if applicable) should be described and justified. Describe how the study will conform to the 1996 Health Insurance Portability and Accountability Act, if applicable. Explain data capture, verification, disposition, if applicable. Describe how data will be evaluated for reproducibility and adjusted for confounding variables. Articulate how large datasets will be evaluated, if applicable. For laboratory projects, describe the organization and maintenance of large datasets, if applicable.

○ **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 a 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".

  – 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.

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 14](). (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. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. ***As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.*** Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

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 **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed
$1.0M. If indirect cost rates have been negotiated, indirect costs are to be budgeted in
accordance with 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 **3** 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 FY23 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:

- **Impact**

  ○ Whether the application explicitly stated how the proposed work addresses a critical problem in at least one of the FY23 PRCRP Topic Areas in Section II.A.1.

  ○ Whether the application selects an FY23 PRCRP Overarching Challenge to be studied and describes how the study will make an impact on the selected challenge.

  ○ Whether the application demonstrated a pathway from the proposed research to making a near-term impact on patient outcomes and/or caregiver issues. How well the application's specific research goals would fit into the pathway of achieving clinical applicability.

  ○ To what extent the research will accelerate promising findings toward clinical applicability to have maximize impact.

- **Research Strategy and Feasibility**

  ○ How well the proposed research addresses an important critical scientific or clinical issue relevant to at least one of the FY23 PRCRP Topic Areas in Section II.A.1.

- Whether the proposed research has the potential to have a major impact in the near term on an area of paramount importance in cancer and how the research will transform cancer research.

- 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.

- 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.

- **Clinical Trial Strategy (applicable for applications proposing funding for a clinical trial)**

  - To what extent the application justifies the rationale for the proposed clinical trial.

  - To what degree the proposed clinical trial and proposed intervention is supported by strong preliminary data and relevant literature citations.

  - How well the endpoints to be measured are justified for the described clinical trial.

  - Whether the proposed type of clinical trial to be performed (e.g., randomized, cohort, case-control, cross-sectional) is supported by the methodology to be used.

  - Whether there are 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.

- Whether the study population is clearly defined and whether access to the study population, recruitment plans, and inclusion/exclusion criteria including justification for the plans and alternatives strategies if issues arise. Whether the informed consent process is clearly articulated.

- 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.

- If applicable, whether the application shows how the data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA.

- To what degree potential challenges and alternative strategies are addressed.

- How well the clinical trial will inform correlative clinical research, if applicable.

- **Statistical Plan and Data Analysis**

  - To what extent the statistical methodology and plan supports the stated hypothesis or objective.

  - If applicable, how well the described dataset supports the aims of the project.

  - If applicable, whether the inclusion and exclusion criteria for the subjects is sound and rationale for the criteria.

  - How well the application describes the power analysis and whether it determined population numbers. If applicable, how well the application justified why a power analysis is not essential to the statistical evaluation.

  - Whether the application states whether the analyses will be univariate, bivariate, or multivariate.

  - How well the variables are described and how well any covariates are identified (if applicable). How well the application accounts for covariates and whether the adjustment is justified (if applicable).

  - If applicable, how well the stratification of data is described and if it is justified.

  - How well the data management is described and justified to include all methods for data collection (e.g., identifiers, confidentiality).

  - To what extent the data management plans support the generation, analyses, standardization and storage of data.

- How well the application explains the data capture, verification, disposition, if applicable.

- If applicable for laboratory projects, to what extent evaluations to be made, storage of samples, and organization and maintenance of large datasets are described and justified.

- To what extent the data have been evaluated for reproducibility and adjusted for confounding variables.

- Whether there is a plan to evaluate large datasets, if applicable.

- Whether the application describes plans to conform to the 1996 Health Insurance Portability and Accountability Act, if applicable.

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

- **Research Outcomes Plan**

  - Whether the application describes the anticipated research outcomes (e.g., knowledge products, clinical products for development).

  - How well the application demonstrates 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 FY23 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.

  - Whether the lay abstract and impact statement were written with clarity for lay persons.

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 FY23 PRCRP, as evidenced by the following:

  - Adherence to the intent of the award mechanism

  - Program portfolio balance and composition

  - Programmatic relevance to the FY23 PRCRP Military Health Focus Areas

  - Programmatic relevance to the FY23 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. ***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.health.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 200.1, 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 FY23 funds are anticipated to be made no later than September 30, 2024. 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 the 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 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.

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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 and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;

- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and

- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

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 whether additional and/or 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 whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

Awards resulting from this program announcement may entail 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. These 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. eBRAP 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 eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). 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 eBRAP 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 802a. The program announcement numeric version code will match the General Application Instructions version code 802.

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.

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.

- Applications submitted to the wrong option (inclusion of clinical trial or not) may be moved to the correct option without prior notification. It is incumbent upon the applicant to select the correct option**.**

II.H.2.c. Withdrawal

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

- An FY23 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 FY23 PRCRP Programmatic Panel members can be found at https://cdmrp.health.mil/prcrp/panels/panels23.***

- 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 FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.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.

- Application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for application withdrawal.

- 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 named on the application does not meet the eligibility criteria.

- The pre-application or application does not address at least one of the FY23 PRCRP Topic Areas in Section II.A.1.

- The pre-application or application does not address at least one of the FY23 PRCRP Military Health Focus Areas in Section II.A.2.

- The pre-application or application does not address at least one of the FY23 PRCRP Overarching Challenges in Section II.A.3.

- 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 cancer, 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 Outcomes 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"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 14 with file name "MFBudget.pdf" if applicable	

Application Components	Action	Completed
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
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
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
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MB	Megabytes
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRCRP	Peer Reviewed Cancer Research Program
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