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: HT942524PRCRPIPA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 21, 2024
- **Invitation to Submit an Application:** August 2, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, September 26, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 1, 2024
- **Peer Review:** November 2024
- **Programmatic Review:** January 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Peer Reviewed Cancer Research Program (PRCRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the PRCRP in 2009 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the PRCRP from FY09 through FY23 totaled $914.8 million (M). The FY24 appropriation is $130M.

The goal of the PRCRP is to improve 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. FY24 PRCRP Topic Areas

To be considered for funding, applications for the FY24 PRCRP Impact Award ***must*** address at least one of the congressionally directed FY24 PRCRP Topic Areas. Congressional language stipulates the FY24 PRCRP ***must not*** address research in melanoma, glioblastoma, or cancers originating in the breast, pancreas, prostate, ovary, kidney, or lung. In addition, FY24 PRCRP funds ***must not*** be used to study rare cancers except for subtypes of the FY24 PRCRP Topic Areas that are rare by definition. Applicants are directed to apply to the individual CDMRP cancer programs in those disease areas. The FY24 PRCRP Topic Areas are listed below.

- Bladder cancer
- Blood cancers
- Brain cancer (excluding glioblastoma)
- Colorectal cancer
- Endometrial cancer
- Esophageal cancer
- Germ cell cancers
- Liver cancer
- Lymphoma
- Mesothelioma
- Metastatic cancers
- Myeloma
- Neuroblastoma
- Pediatric, adolescent, and young adult cancers[1]
- Pediatric brain tumors
- Stomach cancer
- Sarcoma
- Thyroid cancer

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. ***Applications submitted under any PRCRP Topic Area, including the Metastatic cancers Topic Area, may not address or include research focused on cancers that originate in the breast, kidney, lung, pancreas, prostate, ovaries, or on melanoma, glioblastoma, or rare cancers (excluding relevant subtypes of the FY24 PRCRP Topic Areas) as part of the research study; such applications will be administratively withdrawn.***

II.A.2. FY24 PRCRP Military Health Focus Areas

In addition to addressing at least one of the required FY24 PRCRP Topic Areas, ***applications for theFY24 Idea Award must define how the research is relevant to Service Members and their Families by addressing at least one of the FY24 PRCRP Military Health Focus Areas listed below.***

It is central to the Vision and Mission of the PRCRP that applications are related to military health and mission readiness, and investigators must demonstrate how the proposed research will decrease the burden of cancer on Service Members, their dependents, Veterans, and other military beneficiaries (i.e., Family members of retirees) (https://cdmrp.health.mil/pubs/video/prc/prcrp_vision_video).

FY24 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

[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).

Health Concerns at https://www.publichealth.va.gov/exposures/health-concerns.asp or to the PRCRP website (https://cdmrp.health.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 FY24 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 member's) 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; 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)

- U.S. 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 (Refer to Appendix 2).

II.A.1. FY24 PRCRP Overarching Challenges

The PRCRP developed the Overarching Challenges as a strategy to address multiple issues in cancer research over the spectrum of different cancer topics. 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 17 FY24 PRCRP Overarching Challenges are classified in five different categories. The applicant must address at least one of the 17 FY24 PRCRP Overarching Challenges and not just select a category.***

- **Prevention**
    - Investigate primary, secondary, and tertiary prevention interventions/strategies to decrease cancer burden.
    - Determine the risk factors, etiology, or mechanisms underlying cancer development to improve prevention interventions.
- **Diagnostics/Prognostics**
    - Identify approaches to predict treatment resistance, recurrence, and the development of advanced disease.
    - Distinguish unique features driving cancer occurrence across the spectrum of ages.
    - Develop and improve minimally invasive methods for neoplasia detection, initiation, progression, and recurrence.
- **Therapeutics**
    - Transform cancer treatment, especially for advanced, recurrent, and metastatic disease.
    - Improve current therapies including systemic and local treatments.
    - Evaluate disease progression and/or treatment response over time.
    - Leverage the mechanisms of cancer development to improve treatment methods for all communities.
- **Patient Well-Being and Survivorship**
    - Study methods to address survivorship issues, including quality of life, wellness, mental health, psychological impact of recurrence, reproductive/sexual health, and/or disability.
    - Reduce short- and long-term treatment toxicities, including neurocognitive and physical effects.
    - Investigate ways to bridge gaps between treatment and survivorship, including alternative medicine, nutrition and lifestyle factors, and supportive care.
    - Understand and address the immediate and enduring burdens on caregivers, families, and communities.

- **Disparity**
    - Improve prevention strategies, diagnosis, treatment, and outcomes for patients in underserved or under recognized populations.
    - Study methods to improve accessibility to care and address survivorship.
    - Advance health equity and reduce disparities in cancer care, including telehealth.
    - Develop strategies to understand barriers to and improve communication amongst provider, patient, and care network.

II.B. Award Information

The FY24 PRCRP Impact Award supports high-impact research that can accelerate promising findings toward clinical applicability. 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 FY24 PRCRP Topic Areas and in at least one of the FY24 PRCRP Overarching Challenges.

The critical components of this award mechanism are:

- **Impact:** Research supported by the Impact Award will demonstrate the potential to accelerate promising findings and have a major impact in the near term on an area of paramount importance in cancer. The proposed study should demonstrate potential to improve patient outcomes in at least one of the FY24 PRCRP Topic Areas and in at least one of the FY24 PRCRP Overarching Challenges. 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 FY24 PRCRP Idea Award (HT942524PRCRPIA).***

- **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.

- **Clinical Trial, if applicable:** The clinical study must be initiated within the first year, including FDA Investigational New Drug/Investigational Device Exemption application submission plans within 60 days of the award.

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with the DoD and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2, DOD and VA Websites.

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique 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.

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, 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 FY24 PRCRP priorities.

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

Clinical trials are allowed.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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.

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

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition 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 assess 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 data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 PRCRP Impact Award should not exceed **$1.0M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $16.0M to fund approximately 10 Impact Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

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.

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or

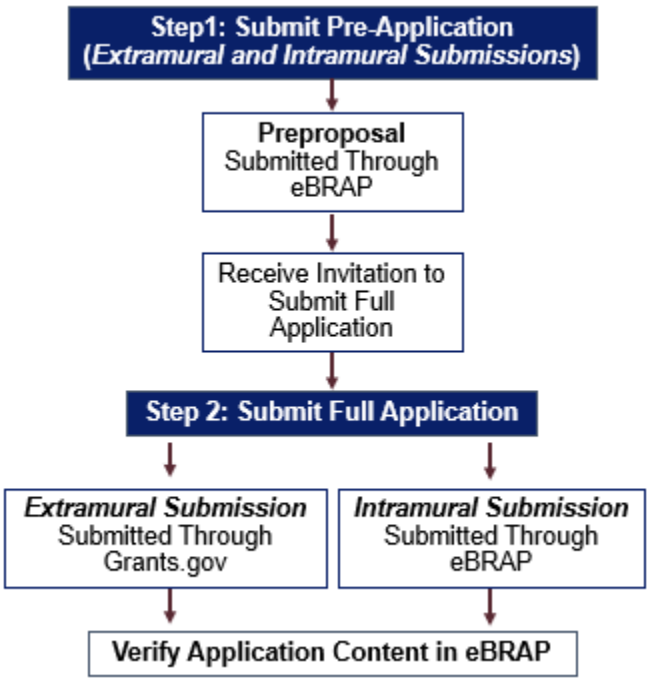
Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PRCRPIPA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PRCRPIPA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that 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).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 PRCRP Programmatic Panel members should not be involved in any pre-application or full 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.

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

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

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
No Clinical Trial	No Option
Clinical Trial	Clinical Trial Option

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

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

  The Preproposal Narrative should include the following:

  - State the FY24 PRCRP Topic Area(s) 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. If a clinical trial will be included, briefly describe the study including the intervention, study population, primary endpoints, and Phase of the trial. Describe the strategy to initiate the clinical study within the first year of the award. (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 FY24 PRCRP Topic Areas.
  - State the FY24 PRCRP Overarching Challenge(s) 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 FY24 PRCRP Military Health Focus Area(s).

- **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.

II.D.2.a.ii. 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 FY24 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 supports the hypothesis and specific aims of the project. If a Clinical Trial is proposed, whether the proposed intervention, population, and end points are appropriate for the phase of the trial.

- 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 FY24 PRCRP Topic Areas.

- To what degree the proposed research may lead to promising outcomes for one or more of the selected FY24 PRCRP Military Health Focus Areas.

- Whether an FY24 PRCRP Overarching Challenge is to be studied and to what degree the research will make a near-term impact.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full 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.

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

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **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 that expands 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 FY24 PRCRP Topic Areas ***and*** at least one of the FY24 PRCRP Military Health Focus Areas.

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

- **Research Strategy and Feasibility:** Describe the rationale, experimental design, and methodology appropriate to test the hypothesis and reach the final objective. Include preliminary data and reconcile it with objectives of the research proposed. Demonstrate how the research is based on strong preliminary data and/or previous clinical and/or translational research outcomes. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the PI or collaborators named on this application must be included. Describe potential problems and potential pitfalls and address alternative approaches. Demonstrate the availability of tissue, data, or human subjects, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the 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 described 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.

- If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the

proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.

  - **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 and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing 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.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

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

  Use of VA Resources *(if applicable)*: Provide a letter of support signed by 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. If the VA-affiliated non-profit corporation is not identified as the applicant organization 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.

- **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.*** 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. Clarity and completeness within the space limits are highly important.

- **Background:** State the FY24 PRCRP Topic Area(s) to be addressed by the proposed research. State the FY24 PRCRP Military Health Focus Area(s) 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 FY24 PRCRP Topic Areas. State the FY24 PRCRP Overarching Challenge(s) 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 FY24 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, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

  - State the FY24 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 FY24 PRCRP Overarching Challenge(s) 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".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  For the Impact Award, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Transition Plan (one-page limit): "Upload as Transition.pdf."** Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award (e.g., specific potential industry partners; specific funding opportunities to apply for). In addition, provide a plan to distribute the findings or intervention to the community.

- **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 FY24 PRCRP Programmatic Panel during programmatic review only.***

  - State the FY24 PRCRP Military Health Focus Area(s) 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 FY24 PRCRP Topic Area(s) 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 FY24 PRCRP Topic Areas.

  - State the FY24 PRCRP Overarching Challenge(s) 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 Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required.**

  - Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. 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.

  - 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.

  - Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug/Investigational Device Exemption application submission plans within 60 days of the award, if applicable. 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.

  - Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated

enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report, which is a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. Use the form to describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study.

- If applicable, describe the process for obtaining informed consent from human subjects and provide a draft, in English, of the Informed Consent Form.

- **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. 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 *(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 8, Section B, Representations.

- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V, for additional information and considerations. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

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

- **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".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 14.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period indicated in Section I, Overview of the Funding Opportunity. The full application cannot be modified once the application verification period ends.

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/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

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. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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 multi-institutional collaborations.
- Costs for one investigator to travel to two scientific/technical meetings per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the PRCRP Impact Award.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually 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 FY24 PRCRP Topic Areas.

- Whether the application selects an FY24 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.
- 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 FY24 PRCRP Topic Areas.
  - Whether the proposed research has the potential to have a major impact in the near term on an area of importance in cancer or cancer research.
  - 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)**
  - How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.

- How well the application demonstrates access to the study population, and ability to achieve recruitment goals.

- Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, 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.

- Whether the application describes plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity that are appropriate for the scientific goals of the study.

- Whether the process for obtaining Informed Consent and the Informed Consent Document are adequately disclosing information, including study risks.

- **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.

- In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored** criteria:

- **Transition Plan**
  - How the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.

- **Personnel**
  - Based on information in the biographical sketches, whether the research team's backgrounds are appropriate to study the specified FY24 PRCRP Topic Area(s), 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 extent the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.
  - If applicable, to what degree the intellectual and material property plan is appropriate.

- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 PRCRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Program portfolio composition
    - Programmatic relevance to the FY24 PRCRP Military Health Focus Areas
    - Programmatic relevance to the FY24 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.

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the PRCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of

funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office

of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, Institutional Review Board (IRB), or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

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 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report.

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.

PHS Inclusion Enrollment Reporting Requirement: ***(only required for clinical research studies and pilot 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 SAM 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 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission:

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of pre-application or full 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 the page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the full 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 Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 PRCRP Programmatic Panel members can be found at https://cdmrp.health.mil/prcrp/panels/panels24***.

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

- 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.

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, 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).

- 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.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The PI does not meet the eligibility criteria.
- The pre-application or application does not address at least one of the FY24 PRCRP Topic Areas.
- The pre-application or application does not address at least one of the FY24 PRCRP Military Health Focus Areas.
- The pre-application or application does not address at least one of the FY24 PRCRP Overarching Challenges.
- 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 glioblastoma, melanoma or cancers originating in the breast, kidney, lung, pancreas, prostate, ovary, or rare cancers except those that are subtypes of the FY24 PRCRP Topic Areas and rare by definition.

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. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Transition Plan – Attachment 6, upload as "Transition.pdf"	☐
Relevance to Military Health Statement – Attachment 7, upload as "MilHealth.pdf"	☐
Impact Statement **–** Attachment 8, upload as "Impact.pdf"	☐
Clinical Strategy Statement, *(if applicable)* – Attachment 9, upload as "Clinical.pdf"	☐
Statistical Plan and Data Analysis – Attachment 10, upload as "Stats.pdf"	☐
Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s), *(if applicable)* – Attachment 11, upload as "Access.pdf"	☐
Use of Hazardous Chemical or Biological Agents *(if applicable)* – Attachment 12, upload as "Hazardous.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 13, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 14, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐

Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
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
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
IPA	Impact Award
IRB	Institutional Review Board
M	Million
MB	Megabytes
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
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
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	U.S. Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DOD and VA areas of research interest, ongoing research, or potential opportunities for collaboration.

Air Force Office of Scientific Research
https://www.afrl.af.mil/AFOSR/

Air Force Research Laboratory
https://www.afrl.af.mil/

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://cccrp.health.mil/Pages/default.aspx

Congressionally Directed Medical Research Programs
https://cdmrp.health.mil/

Defense Advanced Research Projects Agency
https://www.darpa.mil/

Defense Health Agency
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/

Defense Suicide Prevention Office
https://www.dspo.mil/

Defense Technical Information Center
https://www.dtic.mil/

Defense Threat Reduction Agency
https://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program
https://midrp.health.mil/

Military Operational Medicine Research Program
https://momrp.health.mil/

Navy Bureau of Medicine and Surgery
https://www.med.navy.mil/

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

Naval Medical Research Command
https://www.med.navy.mil/Naval-Medical-Research-Command/

Office of Naval Research
https://www.nre.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
https://www.acq.osd.mil/

Telemedicine and Advanced Technology Research Center
https://www.tatrc.org/

Uniformed Services University of the Health Sciences
https://www.usuhs.edu

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

U.S. Army Combat Capabilities Development Command
https://www.army.mil/devcom

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

U.S. Army Medical Materiel Development Activity
https://usammda.health.mil/

U.S. Army Medical Research and Development Command
https://mrdc.health.mil/

U.S. Army Medical Research Institute of Infectious Diseases
https://usamriid.health.mil/

U.S. Army Research Institute of Environmental Medicine
https://usariem.health.mil/

U.S. Army Research Laboratory
https://www.arl.army.mil/

U.S. Army Sharp, Ready and Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.health.mil/

U.S. Department of Veterans Affairs, Office of Research and Development
https://www.research.va.gov/

U.S. Naval Research Laboratory
https://www.nrl.navy.mil/

Walter Reed Army Institute of Research
https://wrair.health.mil/