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

Career Development Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-PRCRP-CDA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 25, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, August 10, 2023
- **Confidential Letters of Recommendations Deadline (Resident Option Only):** 11:59 p.m. ET, August 10, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, August 16, 2023
- **Peer Review:** October 2023
- **Programmatic Review:** December 2023

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."

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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 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. FY23 PRCRP Topic Areas

To be considered for funding, applications for the FY23 PRCRP Career Development 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 Career Development 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.health.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 FY23 PRCRP 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

[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.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 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 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 (in the event of a family member's relapse and the active-duty Service Member being 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**
    - Investigate innovative prevention strategies and early detection methods to decrease cancer burden.
    - Elucidate the mechanisms underlying cancer development to improve prevention methods.
- **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 to detect cancer initiation, progression, and recurrence.
- **Therapeutics**
    - Transform cancer treatment, especially for advanced disease and metastasis.
    - Improve current therapies including systemic and local treatments.
    - Research longitudinal evaluation of disease progression and/or treatment response.
    - Elucidate the mechanisms of cancer development to improve treatment methods.
- **Patient Well-Being and Survivorship**
    - Study methods to address survivorship issues, including quality of life, overall mental health, psychological impact of recurrence, and/or survivor permanent disability.
    - Reduce short- and long-term treatment effects, including neurocognitive deficits.
    - Investigate ways to bridge gaps between treatment and survivorship, including alternative medicine, nutrition and lifestyle factors, and supportive care.
- **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 through research.

II.B. Award Information

The PRCRP is seeking to advance cancer research through development of early-career investigators. Depending on the career path of the candidates, the PRCRP will offer two distinct early-career development options: the Career Development Award-Fellow Option (CDA-FO) and the Career Development Award-Resident Option (CDA-RO). Under this award mechanism, the early-career investigator is considered the Principal Investigator (PI), and the application should focus on the PI's research and career development. ***The Career Development Award – Virtual Cancer Center Scholar Option is not being offered this fiscal year.*** Logical reasoning and a sound scientific rationale for the proposed research must be demonstrated. ***Preliminary data are not required.*** This award supports impactful research projects with an emphasis on discovery.

- **Fellow Option:** The PI must be an early-career researcher or physician-scientist (referred to as a Fellow) within 7 years after completion of their terminal degree by the time of the application deadline (excluding time spent in residency, clinical training, or on family medical leave). PIs suitable for the Fellow Option include investigators who may not be on a tenure track and may share laboratory space not completely separate from a more established investigator. ***The intention of the Fellow Option is to support the early-career investigators toward wider independence and success***. One research funding level is available for the Fellow Option.

- **Resident Option:** The PI must be an early-career clinician during the time of their residency. PIs suitable for the Resident Option include investigators interested in a career path toward becoming a physician-scientist. The intention of the Resident Option is to support the early-career investigators research development with strong scientific career development. Two research funding levels are available for the Resident Option. The Resident must be able to commit 1 or 2 years within the time frame from approximately June 2024-2026 toward research with level of effort on the proposed research appropriate for the research funding level and the project.

It is the responsibility of the PI to select the option that best aligns with their current career path. The option should be selected based on the eligibility defined in the program announcement. ***It is incumbent upon the early-career investigator to select the suitable option***.

The critical components of the Career Development Award:

- **Principal Investigator**
    - **Fellow Option:** The PI must be an early-career researcher or physician-scientist within 7 years after completion of their terminal degree by the time of the application deadline (excluding time spent in residency, clinical training, or on family medical leave). Time spent as a postdoctoral fellow is ***not*** excluded. ***Postdoctoral fellows are not eligible for***

this award mechanism. The PI's record of accomplishments and the proposed research will be evaluated regarding their potential to contribute to at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Previous and/or current career development funding outside of institutional startup funds will be taken into consideration when evaluating the need for further developmental funds. ***The Fellow Option is intended for candidates that have been named on only nominal career development funding. Applications are strongly encouraged to demonstrate protection of the PI's time for cancer research***. For more information on the eligibility criteria for the Fellow Option, refer to Section II.C.1.

- **Resident Option:** The PI must be an early-career clinician during the time of their residency. PIs suitable for the Resident Option include investigators interested in a career path toward becoming a physician-scientist. The Resident must articulate a clear plan to accomplish a scientifically rigorous project of either 1 year or 2 years. The PI must demonstrate a commitment to a career as an investigator at the forefront of one of the FY23 PRCRP Topic Areas and clinical practice; however, the PI is not required to have previous cancer research experience. ***Applications are strongly encouraged to demonstrate protection of the PI's time for cancer research***. Two research funding levels are available for the Resident Option. The Resident must be able to commit 1 or 2 years within the time frame from approximately June 2024-2026 toward research with level of effort on the proposed research appropriate for the research funding level and the project.

  - **Resident Research Level 1:** A 1-year research project under the guidance of the designated Career Guide must be proposed. The 1-year research project application must include a hypothesis, objectives/aims, and experimental design. Research focused on early hypotheses or conceptual ideas are appropriate for Research Level 1.

  - **Resident Research Level 2:** A 2-year research project under the guidance of the designated Career Guide must be proposed. The 2-year research project application must be more extensive and include a hypothesis, objectives/aims, an experimental design, and proposed outcomes. Research focused on more developed ideas and hypotheses are appropriate for Research Level 2.

The Research Level chosen by the Resident must be justified by the complexity of the research project. It is incumbent upon the early-career investigator to select the suitable research level.

- **Career Guide:** Both the Fellow and the Resident must designate a Career Guide. For the Fellow, the Career Guide must be an experienced cancer researcher, as demonstrated by a strong record of funding and publications. For the Resident, the Career Guide must be an experienced physician-scientist with a strong record of funding and publications in cancer. Under both options, the Career Guide must demonstrate a commitment to advancing the PI's career in cancer research.

- **Career Development Plan**

    - **Fellow Option:** A individualized career development plan is required and should be prepared with appropriate guidance from the Career Guide. The career development plan should include a clearly articulated strategy for acquiring the necessary skills, competence, further independence, and expertise to advance their career at the forefront of cancer research in at least one of the FY23 PRCRP Topic Areas.

    - **Resident Option:** An individualized career development plan is required and should be prepared with appropriate guidance from the Career Guide. The career development plan should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project (level 1 or 2) and foster the PI's development as an independent physician-scientist in at least one of the FY23 PRCRP Topic Areas. An environment appropriate to the proposed mentoring and research project must be clearly described.

- **Impact:** The applicant must articulate the potential impact the proposed work will have on cancer research and/or patient care. Impactful research will accelerate the movement of promising ideas in cancer research into clinical applications.

- **Preliminary data are not required.** Any preliminary data included in the application is subject to evaluation and review. Research proposed should be based on strong scientific reasoning and relevant literature.

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's 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.

The anticipated direct costs budgeted for the entire period of performance for an **FY23 PRCRP CDA-FO Award** should not exceed **$400,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The anticipated direct costs budgeted for the entire period of performance for an **FY23 PRCRP CDA-RO Award Research Level 1** should not exceed **$200,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The anticipated direct costs budgeted for the entire period of performance for an **FY23 PRCRP CDA-RO Award Research Level 2** should not exceed **$400,000**. 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 $3.84M to fund approximately six CDA-FO Award applications. The CDMRP expects to allot approximately $1.28M to fund approximately three CDA-RO Research Level 1 Award applications and $2.56M to fund approximately three CDA-RO Research Level 2 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.

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. ***Clinical trials are not allowed***.

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 CDA-FO and CDA-RO 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

Each investigator may be named on only one Career Development Award application as a PI. The applicant must select either the Fellow Option or the Resident Option. The applicant is responsible for selecting which option is appropriate for the named PI of the application.

- **Fellow Option**
    - Investigator (early-career researcher or physician-scientist) at or above the level of Research Assistant Professor or Instructor (or equivalent).
    - Within 7 years after completion of their terminal degree by the time of the application submission deadline (excluding time spent in residency, clinical training, or on family medical leave). Time spent as a postdoctoral fellow is ***not*** excluded. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.
    - Postdoctoral fellows are ***not*** eligible.
    - The PI is ***not*** required to show a history of extramural funding. Any funding obtained should be nominal. Nominal funding may include startup funds, collaboration funding

from an award held by another investigator, and/or only one career development type of award. Eligibility for the Fellow Options does not include investigators named as the PI on major non-career development grants such as a National Institutes of Health (NIH) RO1, etc.

- Applications are strongly encouraged to demonstrate protection of the PI's time for cancer research.

- **Resident Option**
  - The Resident must be in an accredited graduate medical education program with an institutional letter of support.
  - The Resident must be able to commit 1 or 2 years within the time frame from approximately June 2024-2026 toward research with the level of effort on the proposed research appropriate for the research funding level and the project.
  - The Resident's organization must demonstrate a commitment to the Resident through confirmation of laboratory space.
  - Postdoctoral fellows are ***not*** eligible.
  - The Resident is ***not*** required to show a history of extramural funding. Any funding obtained should be nominal. Eligibility for the Resident Option does ***not*** include investigators named as the PI on major non-career development grants such as an NIH RO1, etc.
  - Applications are strongly encouraged to demonstrate protection of the Resident's time for the research project.

- **Career Guide**
  - **Fellow Option:**
    - The Career Guide must hold a position at or above the level of an Associate Professor (or equivalent).
    - The Career Guide must have a proven publication and funding record in cancer research.
    - ***The Fellow and the Career Guide do not need to be located at the same organization***.
  - **Resident Option:**
    - The Career Guide must hold a position at or above the level of an Associate Professor (or equivalent).

- The Career Guide must be an experienced physician-scientist with a strong record of funding and publications in cancer. ***It is strongly encouraged the Resident and the Career Guide be located at the same organization***.

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/).

The applicant organization and associated PI (and mentor) 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 multiple options for the Career Development Award:

  - Fellow Option – Applications name an early-career investigator within 7 years from their terminal degree at the level of Research Assistant Professor, Instructor, or equivalent.
  - Resident Option Research Level 1 – Applications name a resident to do cancer research for 1 year within the time frame from approximately June 2024-2026. Research will include a single year with an appropriate level of effort for the proposed research project.
  - Resident Option Research Level 2 – Applications name a resident to do cancer research for 2 years within the time period of approximately June 2024-2026. Research will include a 2-year project with an appropriate level of effort for the proposed research.

- **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 applicants 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**

  - **Letter of Intent (LOI) (one-page limit):**

    - **Fellow Option:** Provide a brief description of the research to be conducted. Include the Topic Area under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is ***not*** required.

    - **Resident Option:** The LOI must indicate Research Level 1 or Research Level 2. Provide a brief description of the research to be conducted. Include the Topic Area under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is ***not*** required.

  - **Confidential Letters of Recommendation (*Resident Option only*):** Enter contact information for the Career Guide, the Department Head, and one additional reference who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter.

- **Tab 6 – Submit Pre-Application**

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

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

An invitation to submit a full application to the Career Development Award ***is not*** required.

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.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23- PRCRP-CDA 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-CDA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DOD Submissions
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. 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.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***

Extramural Submissions	Intramural DOD Submissions
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 number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

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

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

- **Attachment 1: Project Narrative (page limit – see each option): 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.

  Fellow Option (eight-page limit):

  - **Principal Investigator:** Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1, including the qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as a cancer researcher and how the proposed effort will advance their career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research. Demonstrate that the candidate has been named on only nominal career development funding opportunities.

  - **Background:** Present the ideas and strong scientific rationale behind the proposed research; include relevant literature citations. Preliminary data are not required.

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

  - **Specific Aims:** State the project's specific aims. If this application is part of a larger study, ***present only tasks that this award would fund***.

  - **Research Strategy and Feasibility:** Describe how the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Articulate how the proposed research will advance the field in at least one of the FY23 PRCRP Overarching Challenges. Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for evaluation. Address potential problem areas and pitfalls, and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Verify access to human biological samples. ***This award cannot be used to conduct clinical trials.***

- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Detail a statistical analysis plan for the resulting outcomes. If applicable, include a power analysis for the study that adequately represents an assessment of the population or subpopulation proposed.

Resident Option - Research Level 1 (four-page limit):

- **Principal Investigator:** Describe the PI's potential for a career at the forefront of cancer research as a physician-scientist in at least one of the FY23 PRCRP Topic Areas in Section II.A.1, including the qualifications and achievements that make the PI an ideal candidate for this award. Demonstrate the PI's strong personal commitment to advancing as an independent physician-scientist in at least one of the FY23 PRCRP Topic Areas. Describe the PI's career goals as a physician-scientist and how the proposed effort will advance their career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research during residency.

- **Background:** Present the ideas and strong scientific rationale behind the proposed research; include relevant literature citations. Describe the clinical rationale for the research project.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached. ***Clinical trials are not allowed***. ***Projects at Research Level 1 involving human subjects or specimens must be exempt under 32 CFR 219.104(d)***.

- **Specific Aims:** State the project's specific aims.

- **Methods:** Describe the experimental design, methods, and analyses, including appropriate controls, if applicable. If human biological samples will be used, describe the sources for biospecimen samples (if applicable). Articulate how the proposed research will advance the field in at least one of the FY23 PRCRP Overarching Challenges. Address potential problem areas and present alternative methods and approaches. Include a statistical analysis plan for the proposed research and a power analysis to support the design and sample size (if applicable).

Resident Option - Research Level 2 (eight-page limit):

- **Principal Investigator:** Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1, including the qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as a physician-scientist and how the proposed effort will advance their career. Demonstrate the PI's strong personal commitment to advancing as an independent physician-scientist in at least one of the FY23 PRCRP Topic Areas. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research during residency.

- **Background:** Present the ideas and strong scientific rationale behind the proposed research; include relevant literature citations. Preliminary data are not required.

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

- **Specific Aims:** State the project's specific aims. If this application is part of a larger study, ***present only tasks that this award would fund***.

- **Research Strategy and Feasibility:** Describe how the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Articulate how the proposed research will advance the field in at least one of the FY23 PRCRP Overarching Challenges. Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for evaluation. Address potential problem areas and pitfalls, and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Verify access to human biological samples. ***This award cannot be used to conduct clinical trials.***

- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Detail a statistical analysis plan for the resulting outcomes. If applicable, include a power analysis for the study that adequately represents an assessment of the population or subpopulation proposed.

- **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, ***support protected time for cancer research***, 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's 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.

- **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.

    - **Personnel:** Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1 and at least one of the FY23 PRCRP Overarching Challenges. Describe the Career Guide's background and experience in cancer research.

    - **Career Development:** Describe how the award will provide the PI with the opportunity to advance their career at the forefront of cancer research.

    - **Background:** Present the ideas and reasoning behind the proposed project.

    - **Objective/Hypothesis:** State the hypotheses/study questions and overall objective(s) to be reached.

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

    - **Study Design:** Briefly describe the study design, including appropriate controls.

- **Relevance to Military Health:** Briefly describe how the proposed research is relevant to active-duty Service Members, Veterans, and other military beneficiaries.

- **Impact:** Summarize the proposed project's potential impact on advancing the current state of cancer research and/or patient care.

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

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

  - 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***.

  - Describe the PI's career goals in cancer research. How will the award advance the PI's career in at least one of the FY23 PRCRP Topic Areas in Section II.A.1? How will the proposed research move the field toward better patient care and/or outcomes with respect to at least one of the FY23 PRCRP Overarching Challenges? How do the research and career development plans support the PI in attaining these goals?

  - In lay persons' terms, describe the ultimate applicability of the research. What types of patients will it help and how will it help them? What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field. What is the projected time it may take to achieve a clinically relevant outcome? What are the likely contributions of this study to advancing the field of cancer research and/or patient care? If the research is basic, describe the long-term goals that are related to patient care, outcomes, or survivorship. Basic research should be framed toward the goal of the betterment of the cancer patient or family, etc.

  - Describe how the proposed research will benefit 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 CDA-FO and CDA-RO, refer to the ***"Suggested SOW Strategy Generic Research"***, and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

- **Attachment 6: 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 exposure 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 7: Impact Statement (one-page limit): Upload as "Impact.pdf".** State explicitly how the proposed work addresses a critical problem in at least one of the FY23 PRCRP Topic Areas and at least one of the FY23 PRCRP Overarching Challenges. Describe the pathway to making an impact on cancer research and/or patient care and explain how the PI's specific research goals would fit into that pathway. Articulate how the research benefits those affected by cancer in the short and/or long term. The relevance of all research, including basic, should relate to the outcomes of how it benefits those affected by cancer.

- **Attachment 8: Career Development Plan (page limit indicated in the option and research level below): Upload as "CareerDev.pdf".** ***Members of the FY23 PRCRP Programmatic Panel must not be involved.***

  Fellow Option (two-page limit):

  - Clearly describe and outline the individualized career development plan that focuses on at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY23 PRCRP Topic Area(s) and at least one of the FY23 PRCRP Overarching Challenges.

  - Describe how the PI's level of effort for the proposed project is sufficient to ensure successful completion of the SOW. Articulate the appropriateness of the levels of effort by the Career Guide and other key personnel to ensure the success of this research effort.

  - Indicate specifically how the individualized career development plan will provide the PI with an opportunity to advance their independent career in cancer research.

  - Describe how the career development plan is supported by the research environment and guidance from the Career Guide, including a description of ongoing cancer research at the institution in the relevant FY23 PRCRP Topic Area(s). Include information on collaborations with other investigators.

  - Articulate the Career Guide's commitment to an individualized plan for interaction between the Career Guide and the PI for further career development.

  - Describe the Career Guide's track record for training early-career investigators. Articulate the Career Guide's (and co-Career Guide's, if applicable) experience as an independent, established researcher in cancer research (including their record of publications, patents, and/or funding history). If the Career Guide and PI are located at different organizations, describe how appropriate direction and oversight will be accomplished.

  Resident Option-Research Level 1 (one-page limit): ***Members of the FY23 PRCRP Programmatic Panel must not be involved.***

  - Clearly describe how the 1-year project will develop research and analytical skills for the candidate physician-scientist. Outline the individualized clinical research career development plan that focuses on at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY23 PRCRP Topic Area(s) and at least one of the FY23 PRCRP Overarching Challenges.

  - Indicate how the individualized researcher development plan will provide the PI with an opportunity to investigate a problem or question in the cancer field and effectively prepare the PI for a career as an independent physician-scientist.

- Describe how the career development plan is supported by the environment and mentorship, including a description of ongoing cancer research at the institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities for professional interaction with leaders in the cancer field.

- Articulate the Career Guide's commitment to an individualized plan for interaction between the Career Guide and the PI for further career development.

Resident Option-Research Level 2 (two-page limit): ***Members of the FY23 PRCRP Programmatic Panel must not be involved.***

- Clearly describe and outline the individualized career development plan that focuses on at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY23 PRCRP Topic Area(s) and at least one of the FY23 PRCRP Overarching Challenges.

- Describe how the PI's level of effort for the proposed project is sufficient to ensure successful completion of the SOW. Articulate the appropriateness of the levels of effort by the Career Guide and other key personnel to ensure the success of this research effort.

- Indicate specifically how the individualized career development plan will provide the PI with an opportunity to advance their independent career in cancer research.

- Describe how the career development plan is supported by the research environment and guidance from the Career Guide, including a description of ongoing cancer research at the institution in the relevant FY23 PRCRP Topic Area(s). Include information on collaborations with other investigators.

- Articulate the Career Guide's commitment to an individualized plan for interaction between the Career Guide and the PI for further career development.

  Describe the Career Guide's track record for training early-career investigators. Articulate the Career Guide's (and co-Career Guide's, if applicable) experience as an independent, established researcher in cancer research (including their record of publications, patents, and/or funding history).

- **Attachment 9: Letter of Eligibility (one-page limit): Upload as "Eligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements have been met.

  - **Fellow Option:** The letter should verify that the PI is no more than 7 years from their terminal degree (refer to Section II.C, Eligibility Information). Include the organizational commitment for independent laboratory space and protection of time for cancer research.

- **Resident Option:** The letter must verify the resident participates in an accredited graduate medical education program, the resident is able to commit 1 or 2 years within the time frame approximately June 2024-2026 toward research with level of effort on the proposed research appropriate for the research funding level and the project. Include the organizational commitment for independent laboratory space and protection of time for cancer research.

- **Attachment 10: Letter from Career Guide *(Fellow Option applicants only)*: (two-page limit): Upload as "GuideLetter.pdf".** Provide a signed letter from the Career Guide indicating recommendation, support, and planned interactions with the PI for the proposed work. The letter from the Career Guide should detail individualized interaction between the Career Guide and the PI for further career development in at least one of the FY23 PRCRP Topic Areas in Section II.A.1 and at least one of the FY23 PRCRP Overarching Challenges. Include information on the Career Guide's record of preparing early-career investigators for careers in cancer research.

  The Resident Option is required to have three letters of recommendations uploaded by the Career Guide and two other investigators (see Additional Application Components).

- **Attachment 11: Inclusion of Women and Minorities (if applicable) (four-page limit): Upload as "Inclusion.pdf".** Attachment 11 is only applicable and required for applications that propose clinical research and are ***not exempt under 32 CFR 219.104(d).*** 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, provide a justification. 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 Public Health Service (PHS) Inclusion Enrollment Report format is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Attachment 12: 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 13: 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 NIH 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 13. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

Resident Option Only – Application Components

In addition to the complete application package, ***Career Development Award-Resident Option only*** applications also require the following components:

- **Three Confidential Letters of Recommendations (two pages per letter):**

  The three letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the Confidential Letters of Recommendation Submission deadline of August 10, 2023. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the pre-application; however, the PI will not be able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  - **Confidential letter(s) of recommendation from the Career Guide:** The PI's Career Guide must submit a letter describing the Career Guide's commitment to the PI's

physician-scientist development. The Career Guide's letter of recommendation should describe:

- The PI's potential to become a productive, independent physician-scientist in at least one of the FY23 PRCRP Topic Areas in Section II.A.1. The relevance of the proposed research project to the PI's development as a physician-scientist in at least one of the FY23 PRCRP Topic Areas.

- The Career Guide's commitment to the career development and mentorship of the PI, including details of their proposed interactions with the PI and how they intend to support the PI's research endeavors.

- **Additional confidential letter(s) of recommendation:** The remaining letter(s) should be from independent researchers with scientific knowledge of and interaction with the PI. The letters should highlight the PI's potential for success in pursuing a career in at least one of the FY23 PRCRP Topic Areas in Section II.A.1. Specifically, each letter should include the writer's perspective on:

  - The PI's qualifications, characteristics, and achievements

  - The PI's potential for productivity and desire for establishing a successful career as a physician-scientist.

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 requested funding level should be aligned with the eligibility and the funding level descriptions. The government reserves the right to fund an application at a lower funding level.

Fellow Option:

The maximum period of performance is up to **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$400,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

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.

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

For this award mechanism, direct costs may be requested for:

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meeting(s) is to present project outcomes or to attend a workshop as designated in the career development plan of the PRCRP Career Development Award.

Must not be requested for:

- Clinical trial costs

Resident Option – Research Level 1:

A maximum period of performance of 1 year.

The application's direct costs budgeted for the entire period of performance should not exceed **$200,000.** 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.

For this award mechanism, direct costs may be requested for:

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting. The intent of travel costs to scientific/technical meeting(s) is to present project outcomes or to attend a workshop as designated in the career development plan of the PRCRP Career Development Award.

Must not be requested for:

- Clinical trial costs

Resident Option- Research Level 2:

A maximum period of performance of 2 years.

The application's direct costs budgeted for the entire period of performance should not exceed **$400,000.** 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.

For this award mechanism, direct costs may be requested for:

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meeting(s) is to present project outcomes or to attend a workshop as designated in the career development plan of the PRCRP Career Development Award.

Must not be requested for:

- Clinical trial costs

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:

Fellow Option:

- **Principal Investigator**
    - Whether the PI meets the eligibility requirements.
    - To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research.

- How relevant the research would be to support the early-career investigator toward wider independence and success.

- To what extent the PI's record of accomplishments and letters of support demonstrate their potential for advancement as a productive, independent investigator in cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1 and at least one of the FY23 PRCRP Overarching Challenges.

- Whether the application demonstrates that the candidate has been named on and awarded nominal career development funding.

- **Career Development Plan, Environment, and Career Guide**

  - How well the PI has outlined a detailed, individualized career development plan that will effectively advance their independent career as a cancer researcher in at least one of the FY23 PRCRP Topic Areas.

  - Appropriateness of the levels of effort by the PI, Career Guide, and other key personnel to ensure the success of this research effort.

  - To what extent the career development plan is supported by the research environment and guidance from the Career Guide, including a description of ongoing cancer research at the institution in the relevant FY23 PRCRP Topic Area(s), include information on collaborations with other investigators.

  - Whether there is a clear organizational commitment for laboratory space (***does not have to be independent space***) and protection of PI's time for cancer research.

  - How well the research requirements are supported by the availability and accessibility to facilities and resources (including collaborative arrangements).

  - Whether the Career Guide (and co-Career Guide, if applicable) is an independent, experienced, established researcher in cancer research as demonstrated by a record of publications, patents, and/or funding history.

  - To what degree the Career Guide's commitment demonstrates an individualized plan for interaction between the Career Guide and the PI for further career development.

  - To what degree the Career Guide's track record in training early-career investigators indicates the potential for successful mentorship and advancement of the PI's independent research career.

  - If applicable, how well the plan recognizes the impediments of distance mentoring if the Career Guide and PI are located at different organizations and describes how appropriate direction and oversight will be accomplished.

  - Whether there is evidence of support from other career development awards besides institutional startup funds.

- **Research Strategy and Feasibility**
    - How well the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY23 PRCRP Topic Areas in Section II.A.1 and articulates how the proposed research will advance the field in at least one of the FY23 PRCRP Overarching Challenges.
    - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data *(if included)*, and logical reasoning.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
    - How well the application acknowledges potential problems and addresses alternative approaches.
    - Whether the applicants demonstrate the availability of tissue, data, or human subjects, if applicable.
    - If applicable, to what degree the intellectual and material property plan is appropriate.
    - To what degree the statistical plan is appropriate for the experimental methodology being used.
    - If applicable, whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.
    - 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.
- **Impact**
    - To what degree the proposed work addresses a critical problem in at least one of the FY23 PRCRP Topic Areas and at least one of the FY23 PRCRP Overarching Challenges.
    - Whether the PI's described pathway toward making an impact on cancer research and/or patient care, including the PI's specific research goals, would support the pathway.
    - Whether all research, including basic, relates to how it benefits those affected by cancer in the short and/or long term.

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

- **Personnel**
    - To what degree the background and expertise of the research team based on biographical sketches (other than the PI or Career Guide) are appropriate to accomplish the proposed research.
    - How appropriate the levels of effort as justified in the budget 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.
- **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.

Resident Option – Research Level 1:

- **Principal Investigator:**
    - Whether the PI meets the eligibility requirements.
    - To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research as a physician-scientist in at least one of the FY23 PRCRP Topic Areas in Section II.A.1.
    - To what degree the PI's qualifications and achievements make the PI an ideal candidate for this award.
    - To what extent the PI's letters of recommendation demonstrate their potential for advancement as a productive, independent physician-scientist in cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1.
    - How well the PI's career goals as a physician-scientist support the advancement their career.

- Whether level of effort of the PI show commitment to conduct of the proposed research during residency.

- **Career Development Plan, Environment, and Career Guide:**
  - How well the 1-year project supports the development of research and analytical skills for the candidate physician-scientist.
  - To what degree the individualized career development plan will provide the PI with an opportunity to investigate a problem or question in the cancer field and effectively prepare the PI for a career as an independent physician-scientist.
  - How well the unique features of the career development plan show support to develop the physician-scientist specifically in cancer research for FY23 PRCRP Topic Area(s).
  - How well the career development plan is supported by the environment and mentorship, including whether the Resident will benefit from the ongoing cancer research at the institution.
  - Whether the career development is supported by collaborations with other investigators, seminars, workshops, and other opportunities for professional interaction with leaders in the cancer field.
  - To what extent the Career Guide has demonstrated a commitment to an individualized plan for interaction between the Career Guide and the PI for further career development.
- **Scientific Merit:**
  - To what extent the ideas and scientific rationale behind the proposed research (laboratory or clinical) demonstrate strong scientific reasoning.
  - To what degree the stated hypothesis to be tested or the objective will be achieved with consideration to the methods proposed and the PI's rationale. ***Clinical trials are not allowed. Projects at Research Level 1 involving human subjects or specimens must be exempt under 32 CFR 219.104(d).***
  - Whether the project's specific aims support an investigation into the hypothesis and/or objectives.
  - To what extent the experimental design, methods, and analyses, including appropriate controls, support the investigation into the hypothesis and/or objectives.
  - If applicable, whether the application shows the source for human biological samples to be used and verifies access to the human biological samples to be used.
  - To what extent the application demonstrated how the proposed research will advance the field in at least one of the FY23 PRCRP Topic Areas.

- How well the application addresses potential problem areas and presents alternative methods and approaches.
- How well a statistical analysis plan for the proposed research is integrated into the study.
- If applicable, whether a power analysis is presented to support the design and sample size.
- If applicable, 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.

- **Impact**
  - To what degree the proposed work addresses a critical problem in at least one of the FY23 PRCRP Topic Areas and at least one of the FY23 PRCRP Overarching Challenges.
  - Whether the PI's described pathway toward making an impact on cancer research and/or patient care, including the PI's specific research goals, would support the pathway.
  - Whether all research, including basic, relates to how it benefits those affected by cancer in the short and/or long term.

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

- **Personnel**
  - To what degree the background and expertise of the research team based on biographical sketches (other than that of the PI or Career Guide) are appropriate to accomplish the proposed research.
  - How appropriate the levels of effort as justified in the budget 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.

- **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.

Resident Option – Research Level 2:

- **Principal Investigator**
    - Whether the PI meets the eligibility requirements.
    - To what degree the PI's qualifications and achievements make the PI an ideal candidate for this award.
    - To what degree the PI's career goals as a physician-scientist support the proposed research effort will advance their career.
    - Whether the level of effort of the PI will support their successful conduct of the proposed research during residency
    - To what extent the PI's letters of recommendation demonstrate their potential for advancement as a productive, independent physician-scientist in cancer research in at least one of the FY23 PRCRP Topic Areas in Section II.A.1.
- **Career Development Plan, Environment, and Career Guide**
    - How well the PI has outlined a detailed, individualized career development plan that will effectively advance their independent career as a cancer researcher in at least one of the FY23 PRCRP Topic Areas.
    - Appropriateness of the levels of effort by the PI, Career Guide, and other key personnel to ensure the success of this research effort.
    - To what extent the career development plan is supported by the research environment and guidance from the Career Guide, including a description of ongoing cancer research at the institution in the relevant FY23 PRCRP Topic Area(s), include information on collaborations with other investigators.
    - Whether there is a clear organizational commitment and protection of PI's time for cancer research.
    - How well the research requirements are supported by the availability and accessibility to facilities and resources (including collaborative arrangements).
    - Whether the Career Guide (and co-Career Guide, if applicable) is an independent, experienced, established researcher in cancer research as demonstrated by a record of publications, patents, and/or funding history.

- To what degree the Career Guide's commitment demonstrates an individualized plan for interaction between the Career Guide and the PI for further career development.

- To what degree the Career Guide's track record in training early-career investigators indicates the potential for successful mentorship and advancement of the PI's independent research career.

- **Research Strategy and Feasibility**

  - How well the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY23 PRCRP Topic Areas in Section II.A.1 and articulates how the proposed research will advance the field in at least one of the FY23 PRCRP Overarching Challenges.

  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data *(if included)*, and logical reasoning.

  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.

  - How well the application acknowledges potential problems and addresses alternative approaches.

  - Whether the applicants demonstrate the availability of tissue, data, or human subjects, if applicable.

  - If applicable, to what degree the intellectual and material property plan is appropriate.

  - To what degree the statistical plan is appropriate for the experimental methodology being used.

  - If applicable, whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.

  - 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.

- **Impact**

  - To what degree the proposed work addresses a critical problem in at least one of the FY23 PRCRP Topic Areas and at least one of the FY23 PRCRP Overarching Challenges.

- Whether the PI's described pathway toward making an impact on cancer research and/or patient care, including the PI's specific research goals, would support the pathway.
- Whether all research, including basic, relates to how it benefits those affected by cancer in the short and/or long term.

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

- **Personnel**
  - To what degree the background and expertise of the research team based on biographical sketches (other than the PI or Career Guide) are appropriate to accomplish the proposed research.
  - How the levels of effort, as justified in the budget, are appropriate 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.
- **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 Defense Health Program and FY23 PRCRP, as evidenced by the following:

  Fellow and Resident Options:
  - Adherence to the intent of the award mechanism

- Program portfolio composition
- Programmatic relevance to the FY23 Military Health Focus Areas
- Programmatic relevance to the FY23 PRCRP Overarching Challenges
- Relative 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 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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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

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

II.F.2. Administrative and National Policy Requirements

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

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

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

Refer to full text of the latest DoD R&D General Terms and Conditions 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.

PHS Inclusion Enrollment Reporting Requirement ***(only required for clinical research studies)***: 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 applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds the 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 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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- The PI named on the application does not meet the eligibility criteria for the specific option selected by the applicant.
- The named Career Guide does not meet the eligibility criteria.
- The application does not address at least one of the FY23 PRCRP Topic Areas in Section II.A.1.
- The application does not address at least one of the FY23 PRCRP Military Health Focus Areas in Section II.A.2.
- The application does not address at least one of the FY23 PRCRP Overarching Challenges in Section II.A.3.
- The application does not adhere to congressional language and proposes breast, kidney, lung, pancreatic, prostate, ovarian, rare cancer, and melanoma research.

- 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.

- ***For Resident Option Research Level 1; The application does not meet exempt status under 32 CFR 219.104(d)***

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"	
	Relevance to Military Health Statement Upload as Attachment 6 with file name "MilHealth.pdf".	
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"	
	Career Development Plan: Upload as Attachment 8 with file name "CareerDev.pdf"	
	Letter of Eligibility: Upload as Attachment 9 with file name "Eligibility.pdf"	
	Letter from Career Guide (Fellow Option Only): Upload as Attachment 10: GuideLetter.pdf"	
	Inclusion of Women and Minorities (if applicable) upload as Attachment 11 "Inclusion.pdf"	
	Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	Completed
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	
Additional Application Components	**Action**	**Completed**
Confidential Letters of Recommendation (Resident Option only)	Confirm upload to eBRAP	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDA-FO	Career Development Award-Fellow Option
CDA-RO	Career Development Award-Resident Option
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
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
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
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