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- Scholar Option

Announcement Type: Modified

Funding Opportunity Number: HT942524PRCRPCDASO

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 12, 2024
- Application Submission Deadline: 11:59 p.m. ET, July 26, 2024
- Confidential Letters of Recommendation Submission Deadline: 5:00 p.m. ET, July 31, 2024
- End of Application Verification Period: 5:00 p.m. ET, July 31, 2024
- **Peer Review:** September 2024
- **Programmatic Review:** November 2024

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

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

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

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

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

II.A.1. FY24 PRCRP Topic Areas

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

- Bladder cancer
- Blood cancers
- Brain cancer (excluding glioblastoma)
- Colorectal cancer
- Endometrial cancer
- Esophageal cancer

- Germ cell cancers
- Liver cancer
- Lymphoma
- Mesothelioma
- Metastatic cancers
- Myeloma

- Neuroblastoma
- Pediatric, adolescent, and young adult cancers¹
- Pediatric brain tumors
- Stomach cancer
- Sarcoma
- Thyroid cancer

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

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

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

In addition to addressing at least one of the required <u>FY24 PRCRP Topic Areas</u>, applications for the FY24 CDA-SO Award must define how the research is relevant to Service Members and their Families by addressing at least one of the FY24 PRCRP Military Health Focus Areas listed below.

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

(https://cdmrp.health.mil/pubs/video/prc/prcrp_vision_video). FY24 PRCRP Military Health Focus Areas:

• Environmental exposure risk factors associated with cancer

 Environmental and/or occupational risk factors should be relevant to activities specific to the military, such as deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.). For more information on militaryrelated exposures and risk factors for cancer, applicants should refer to Exposure-Related

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

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

• Mission Readiness and Gaps in Cancer Research

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

Mission readiness under the FY24 PRCRP Military Health Focus Areas refers to the impact of cancer on the Service Member. Decreasing the impact of cancer on active-duty Service Members and/or their Families protects the overall military missions. Some examples of relevant research to decrease the impact on mission readiness may include, but are not limited to:

- Studies on the improvement in survival while minimizing late effects that would allow an active-duty Service Member to return to full duty;
- Treatments to minimize a cancer patient's (either a Service Member's or their Family member's) time in the hospital, thus maximizing the time the Service Member is on duty;
- Effective ways to minimize cancer relapse for Service Members or their Families; and
- Research into improvements in cancer detection that would lead to earlier diagnosis, thus allowing for improved treatment of the Service Member and early return to duty.

For more information on military health and cancer:

- PRCRP Vision Video (https://cdmrp.health.mil/pubs/video/prc/prcrp_vision_video)
- PRCRP (https://cdmrp.health.mil/prcrp/default)
- Military Health System (MHS) (https://www.health.mil)
- U.S. Department of Veterans Affairs (VA) (https://www.va.gov/)

Investigators are strongly encouraged to collaborate, integrate, and/or align their research projects with Department of Defense (DOD) and/or VA research laboratories and programs (Refer to Appendix 2).

II.A.3. FY24 PRCRP Overarching Challenges

The PRCRP developed the Overarching Challenges as a strategy to address multiple issues in cancer research over the spectrum of different cancer topics. These Overarching Challenges are critical gaps in cancer research, care, and/or patient outcomes that, if addressed, will advance mission readiness of U.S. military members affected by cancer and improve quality of life by

decreasing the burden of cancer on Service Members, their Families, Veterans, and the American public. Simply identifying an Overarching Challenge is not sufficient. Applications must address at least one of the following Overarching Challenges in a way that can lead to or make a breakthrough and have a major impact. The 17 FY24 PRCRP Overarching Challenges are classified in five different categories. The applicant must address at least one of the 17 FY24 PRCRP Overarching Challenges and not just select a category.

Prevention

- o Investigate primary, secondary, and tertiary prevention interventions/strategies to decrease cancer burden.
- Determine the risk factors, etiology, or mechanisms underlying cancer development to improve prevention interventions.

• Diagnostics/Prognostics

- Identify approaches to predict treatment resistance, recurrence, and the development of advanced disease.
- o Distinguish unique features driving cancer occurrence across the spectrum of ages.
- Develop and improve minimally invasive methods for neoplasia detection, initiation, progression, and recurrence.

Therapeutics

- o Transform cancer treatment, especially for advanced, recurrent, and metastatic disease.
- o Improve current therapies including systemic and local treatments.
- Evaluate disease progression and/or treatment response over time.
- Leverage the mechanisms of cancer development to improve treatment methods for all communities.

Patient Well-Being and Survivorship

- Study methods to address survivorship issues, including quality of life, wellness, mental health, psychological impact of recurrence, reproductive/sexual health, and/or disability.
- Reduce short- and long-term treatment toxicities, including neurocognitive and physical effects.
- o Investigate ways to bridge gaps between treatment and survivorship, including alternative medicine, nutrition and lifestyle factors, and supportive care.
- Understand and address the immediate and enduring burdens on caregivers, families, and communities.

• Disparity

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

II.B. Award Information

The PRCRP is seeking to advance cancer research through development of early-career investigators. 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. Preliminary data are not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated. This award supports impactful research projects with an emphasis on discovery.

The CDA-SO supports an independent, highly accomplished early-career investigator (referred to as a Scholar) to conduct impactful research under the guidance of an experienced cancer researcher (i.e., Career Guide). Scholars are required to participate in the unique, interactive Virtual Cancer Center (VCC) focused on fostering the next generation of cancer researchers.

The overarching goal of the VCC is to develop successful, highly productive Scholars in a collaborative research and career developmental environment. The VCC will give Scholars opportunities to operate in a collegial, highly dynamic, and cutting edge research organization to lead cancer research to a new frontier. It is the intention that, through the VCC, collaborations will foster new growth to ensure the research advancements across different cancers.

The VCC directorship is awarded through a separate mechanism, the Virtual Cancer Center Director's Award (VCCDA). The VCCDA calls for two established investigators (Director and Deputy Director) to provide intensive mentoring, national networking, collaborations, and a peer group for Scholars. In addition to their Career Guide, Scholars are required to interact with the VCC Director, Deputy Director, and fellow Scholars to include required attendance at in-person meeting with VCC Members annually. *The intention of the Scholar Option is to support highly accomplished investigators toward the goal of leadership in cancer.*

The critical components of the Career Development Award:

• **Principal Investigator:** 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 for contributing to at least one of the FY24
PRCRP Topic Areas. The Scholar must be in a tenure-track position or equivalent position. The Scholar must demonstrate significant accomplishments, including first-author publications, extramural funding (beyond nominal), and show excellence in cancer research as supported by letters of recommendation. The Scholar must have independent laboratory space separate from the Career Guide's laboratory or other mentor's laboratory. For more information on the eligibility criteria for the Virtual Cancer Center Scholar Option, refer to Section II.C.1.

- Career Guide: The Scholar must designate a Career Guide. The Career Guide must be an experienced cancer researcher, as demonstrated by a strong record of funding and publications. In addition, the Career Guide must demonstrate a commitment to advancing the PI's career in cancer research and be committed to fully participating in the VCC and potentially serving on the VCC's Advisory Board as requested by VCC Leadership.
- Career Development Plan: A 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 FY24 PRCRP Topic Areas.
- Milestones: The Scholar must show career milestones and pathways toward achieving the
 milestones. The Scholar should demonstrate clear commitment to at least one of the <u>FY24</u>
 <u>PRCRP Topic Areas</u> through a career development plan designed to enhance further
 networking and collaboration.
- **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.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 PRCRP priorities.

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

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

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

Clinical trials are not allowed.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 PRCRP Career Development Award Scholar should not exceed \$800,000. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately \$15.36M to fund approximately 12 Career Development Award Scholar applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

II.C.1.b. Principal Investigator and Career Guide

Scholar:

- Independent investigator at or above the level of Assistant Professor or Instructor (or equivalent) and be on a *tenure track*.
- Evidence of an independent laboratory (should not be laboratory space in another investigator's laboratory).
- 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.
- PI must show a history of extramural funding and first-author publications.
- The PI's organization must demonstrate a commitment to the PI through confirmation of laboratory space and a commitment of no less than 25% effort to this award for the first 2 years.

Career Guide:

- 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.
- A Career Guide can only be a mentor to one CDA-SO applicant and must be willing to commit to participation in the Virtual Cancer Center.
- The Director and Deputy Director of the Virtual Cancer Center cannot be listed as a Career Guide.

The PI and the Career Guide do not need to 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.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

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

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

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

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

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

Step1: Submit Pre-Application (Extramural and Intramural Submissions) Letter of Intent Submitted Through eBRAP Step 2: Submit Full Application Submitted Through Grants.gov Intramural Submission Submitted Through eBRAP Verify Application Content in eBRAP

Application Submission Workflow

Extramural Submission: An application submitted by an <u>extramural organization</u> for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PRCRPCDASO from Grants.gov (https://grants.gov). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an <u>intramural DOD organization</u> for an investigator employed by that organization. Intramural DOD organizations <u>may</u> submit full applications to either eBRAP or Grants.gov. Download application package components for

HT942524PRCRPCDASO from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

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

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

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

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

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

FY24 PRCRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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

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

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

• Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY24 PRCRP 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. An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

List of Individuals Providing Confidential Letters of Recommendation: Enter contact information for the Career Guide and two additional references who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter.

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

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

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

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

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

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

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

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

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

Describe the proposed project in detail using the outline below.

- Principal Investigator: Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY24 PRCRP Topic Areas, including 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. Describe how the PI's career goals and plans will promote an independent, sustainable career. Discuss how the research would support the highly accomplished investigator toward the goal of leadership in cancer. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research. Demonstrate that the PI has independent laboratory space. Must commit no less than 25% effort to this award for the first 2 years.
- 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 FY24 PRCRP Topic Areas. Articulate how the proposed research will advance the field in at least one of the FY24 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 the proposed project uses human subjects or human biological samples, include a

detailed plan for the recruitment of subjects or the acquisition of 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.
- Commitment to the PRCRP's VCC: Describe the Scholar's motivation and commitment to participating in the VCC, to include opportunities for networking and collaborating with the other Scholar/Career Guide pairs and the VCC Leadership. More detailed information regarding the PI's commitment should be provided in Attachment 11.
- Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf". Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of

- support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- Intellectual Property: Information can be found in the 2 CFR 200.315, "Intangible Property."
 - Intellectual and Material Property Plan (*if applicable*): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - 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.
- DOD Data Management Plan (two-page limit is recommended): Describe the data management plan in accordance with Section 3.c, Enclosure 3, <u>DoD Instructions</u> 3200.12. Do not duplicate the Data and Research Resources Sharing Plan. Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- Data and Research Resources Sharing Plan: Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

- Use of DOD Resources (*if applicable*): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- Inclusion Enrollment Plan (if applicable): Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf". The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- Personnel: Describe the PI's potential for a career at the forefront of cancer research in at least one of the <u>FY24 PRCRP Topic Areas</u> and at least one of the <u>FY24 PRCRP Overarching Challenges</u>. 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, and addresses issues of particular interest to the affected community. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Do not duplicate the technical abstract.

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

- Describe the scientific objective and rationale for the proposed project.
- Describe the PI's career goals in cancer research. How will the award advance the PI's career in at least one of the <u>FY24 PRCRP Topic Areas</u>? How will the proposed research move the field toward better patient care and/or outcomes with respect to at least one of the <u>FY24 PRCRP Overarching Challenges</u>? 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". Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

For the CDA-SO refer to "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- Attachment 6: Relevance to Military Health Statement (one-page limit): Upload as "MilHealth.pdf". The Relevance to Military Health Statement will be evaluated by the FY24 PRCRP Programmatic Panel during programmatic review only.
 - State the <u>FY24 PRCRP Military Health Focus Area(s)</u> 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 exposure risk factors associated with the <u>FY24</u>
 <u>PRCRP Topic Area(s)</u> 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 activeduty 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 FY24 PRCRP Topic Areas and at least one of the FY24 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. The relevance of all research including basic should relate to the outcomes of how it benefits those affected by cancer. Describe how the patient community will be engaged. The Impact Statement should be written in plain language for lay persons.
- Attachment 8: Career Development Plan (two-page limit): Upload as "CareerDev.pdf".
 - Clearly describe and outline the individualized career development plan that focuses on at least one of the <u>FY24 PRCRP Topic Areas</u>. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY24 PRCRP Topic Area(s) and at least one of the <u>FY24 PRCRP</u> 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 <u>FY24 PRCRP Topic Area(s)</u>. 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, 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.
- Clearly describe how the PI demonstrates a commitment to and the potential to be a leader in at least one of the <u>FY24 PRCRP Topic Areas</u> through the VCC and through engagement with patient communities or organizations.
- 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. 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 at no less than 25% of the PI's time for cancer research.
- Attachment 10: Productivity Statement (two-page limit): Upload as "Productivity.pdf". State how long the PI has been on tenure track. Discuss the PI's record of accomplishments (e.g., awards, honors, first-author publications, publications in high-impact journals, presentations/ speaking engagements, committees) that demonstrates their potential for becoming an independent investigator in cancer research in at least one of the FY24 PRCRP Topic Areas and at least one of the FY24 PRCRP Overarching Challenges. List up to five first-author papers that support the PI's candidacy for VCC Scholar Option. Demonstrate extramural funding support for the candidate. Describe the productivity of the PI since receipt of their terminal degree. Productivity may also include other outcomes, such as presentations, abstracts, and patent applications.
- Attachment 11: Integration Statement (two-page limit): Upload as "Integration.pdf". Describe the PI's motivation and commitment to participating in the

- VCC with the other Scholar/Career Guide pairs and the VCC Leadership. Describe how the PI will engage with the patient community. Describe how the career goals outlined in the Career Development Plan will be impacted by the integration into the VCC.
- Attachment 12: Letters Confirming Access to Target Military or VA Patient Population(s) or Resources (e.g., Human/Animal Anatomical Substances, Databases), if applicable (one-page limit per letter): Upload as "Access.pdf". If the proposed research plan involves access to active-duty military and/or VA patient population(s) or resource(s), include a letter of support, signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).
- Attachment 13: Representations (Extramural Submissions Only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/ public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 14: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The total costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
 - o **PI Biographical Sketch (five-page limit):** Upload as "Biosketch LastName.pdf".
 - **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support LastName.pdf".
- (e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
 - Budget Justification (no page limit): For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (*if applicable, Extramural Submissions Only*): Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
 - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
 - Intramural DOD Subaward: Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 14.

II.D.2.b.iii. Additional Application Components

In addition to the complete application package, CDA-SO Award applications also require the following components:

(a) Confidential Letters of Recommendation

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 July 31, 2024. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the preapplication. The PI will not be able to view the letters.

- 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 researcher development and mentorship. The Career Guide's letter of recommendation should describe:
 - The PI's potential to become a successful leading researcher in at least one of the FY24 PRCRP Topic Areas. The relevance of the proposed research project to the PI's development as a researcher in at least one of the FY24 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.
- The Career Guide should describe commitment to participation in the Virtual Cancer Center.
- 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 FY24 PRCRP Topic Areas. 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 at the forefront of cancer research.
 - The relevance of the proposed research project to the PI's development as a researcher in at least one of the FY24 PRCRP Topic Areas.

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

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

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

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

II.D.5. Funding Restrictions

The maximum period of performance is 4 years.

The application's direct costs budgeted for the entire period of performance should not exceed \$800,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

For this award mechanism, direct costs:

Must be requested for:

• Travel costs for the Scholar to attend an in-person meeting with the VCC Leadership and other VCC members, annually.

May be requested for (not all-inclusive):

- Costs associated with participating in the VCC (e.g., hardware and/or software for the audioor video-teleconferencing or web-based communications).
- Costs for one investigator to travel to two scientific/technical meetings per year in addition to
 the required meeting described above. The intent of travel costs to scientific/technical
 meetings is to present project outcomes or to attend a workshop as designated in the Career
 Development Plan of the FY24 PRCRP Career Development Award.

Must not be requested for:

Clinical trial costs

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

• Principal Investigator

- Whether the PI meets the eligibility requirements. How long the PI has been on tenure track.
- Whether the productivity of the PI since receipt of their terminal degree supports the candidacy for the VCC Scholar Option.
- How well the PI's record of accomplishments (e.g., awards, honors, first-author publications, publications in high-impact journals, presentations/speaking engagements, committees) demonstrate their potential for becoming an independent investigator in cancer research in at least one of the <u>FY24 PRCRP Topic Areas</u> in and at least one of the <u>FY24 PRCRP Overarching Challenges</u>.
- How relevant the research would be to support a highly accomplished investigator toward the goal of leadership in cancer.
- Whether the application demonstrates other sources of extramural funding support for the candidate.
- Whether the Scholar demonstrated independent laboratory space.
- o To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research.
- The extent to which the PI is motivated and committed to participating in the VCC with the other Scholar/Career Guide pairs and the VCC Leadership.

• Career Development Plan and Environment

- 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
 FY24 PRCRP Topic Areas and at least one of the FY24 PRCRP Overarching Challenges.
- 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 <u>FY24 PRCRP Topic Area(s)</u>, including information on collaborations with other investigators.
- Whether there is a clear organizational commitment for independent laboratory space and a minimum commitment of 25% effort by the PI for the first 2 years of the award.
- How well the research requirements are supported by the availability and accessibility to facilities and resources (including collaborative arrangements).
- Whether the PI demonstrates a commitment to and the potential to be a leader in at least one of the <u>FY24 PRCRP Topic Areas</u> including through engagement with patient communities or organizations.
- Whether the Career Guide 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.
- If applicable, how well the plan recognizes 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.
- 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.
- Whether the Career Guide demonstrates a willingness to participate on the VCC's Advisory Board as requested by the VCC Director and Deputy Director.

Research Strategy and Feasibility

- How well the proposed research addresses an important clinical and/or translational question relevant to at least one of the <u>FY24 PRCRP Topic Areas</u> and at least one of the <u>FY24 PRCRP Overarching Challenges</u>.
- 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 <u>FY24 PRCRP Topic Areas</u> and at least one of the <u>FY24 PRCRP Overarching Challenges</u>.
- 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.
- To what extent the application demonstrates that the PI will engage with the patient community.

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

Personnel

- How appropriate the levels of effort are for successful conduct of the proposed work.
- 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.

• Budget

• Whether the budget is appropriate for the proposed research.

• Application Presentation

To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 PRCRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity
 - Program portfolio composition
 - o Programmatic relevance to the FY24 Military Health Focus Areas
 - Programmatic relevance to the FY24 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 <u>Section II.E.1.b</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.*

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

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

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

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

In-person presentations may be requested.

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

Email: support@grants.gov

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

An FY24 PRCRP Programmatic Panel member is named as being involved in the research
proposed or is found to have assisted in the pre-application or application processes including,
but not limited to, concept design, application development, budget preparation, and the
development of any supporting documentation, including letters of support/recommendation.

A list of the FY24 PRCRP Programmatic Panel members can be found at https://cdmrp.health.mil/prcrp/panels/panels24.

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- Clinical trial is proposed.
- The named Career Guide does not meet the eligibility criteria.
- The application does not address at least one of the <u>FY24 PRCRP Topic Areas</u>.
- The application does not address at least one of the <u>FY24 PRCRP Military Health Focus</u> Areas.
- The application does not address at least one of the FY24 PRCRP Overarching Challenges.
- The application does not adhere to congressional language and includes primary breast, kidney, lung, pancreatic, prostate, ovarian, or rare cancers (excluding relevant subtypes of the FY24 PRCRP Topic Areas), melanoma, or glioblastoma as part of the research study.

• The application does not include <u>Attachment 10, Productivity Statement</u> and/or <u>Attachment 11, Integration Statement</u>.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance (Extramural submissions only)	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	
Statement of Work – Attachment 5, upload as "SOW.pdf"	
Relevance to Military Health Statement – Attachment 6, upload as "MilHealth.pdf"	
Impact Statement – Attachment 7, upload as "Impact.pdf"	
Career Development Plan – Attachment 8, upload as "CareerDev.pdf"	
Letter of Eligibility – Attachment 9, upload as "Eligibility.pdf"	
Productivity Statement – Attachment 10, upload as "Productivity.pdf"	
Integration Statement – Attachment 11, upload as "Integration.pdf"	
Letters Confirming Access to Target Military or VA Patient Population(s) or Resources (if applicable) – Attachment 12, upload as "Access.pdf"	
Representations (<i>Extramural submissions only</i>) – Attachment 13, upload as "RequiredReps.pdf"	
Suggested Intragovernmental/Intramural Budget Form (<i>if applicable</i>) – Attachment 14, upload as "IGBudget.pdf"	
Research & Related Personal Data	
Research & Related Personal Data	
Research & Related Senior/Key Person Profile (Expanded)	
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	
Research & Related Budget (Extramural submissions only) Include budget justification	
Budget (Intramural submissions only) Include budget justification	
Project/Performance Site Location(s) Form	
DOD FY24 Peer Reviewed Cancer Career Development Award	30

Research & Related Subaward Budget Attachment(s) Form (if applicable)	
Additional Application Components	
Confidential Letters of Recommendation	

APPENDIX 1: ACRONYM LIST

ACOS/R&D Associate Chief of Staff for Research and Development

CDA-SO Career Development Award – Virtual Cancer Center Scholar 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

ET Eastern Time
FY Fiscal Year
LOI Letter of Intent

M Million

MB Megabytes

MHS Military Health System

MIPR Military Interdepartmental Purchase Request

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

PRCRP Peer Reviewed Cancer Research Program

SAM System for Award Management

SOW Statement of Work

UEI Unique Entity Identifier
URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA U.S. Department of Veterans Affairs

VCC Virtual Cancer Center

VCCDA Virtual Cancer Center Director's Award

APPENDIX 2: DOD AND VA WEBSITES

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

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

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

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

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

Congressionally Directed Medical Research Programs

https://cdmrp.health.mil/

Defense Advanced Research Projects Agency

https://www.darpa.mil/

https://midrp.health.mil/

Military Operational Medicine Research Program

https://momrp.health.mil/

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

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

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

Naval Medical Research Command https://www.med.navy.mil/Naval-Medical-Research-Command/ Defense Health Agency https://health.mil/About- MHS/OASDHA/Defense-Health-Agency/

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

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

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

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

Military Infectious Diseases Research Program

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

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

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

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

U.S. Army Aeromedical Research Laboratory https://usaarl.health.mil/ U.S. Army Combat Capabilities Development Command https://www.army.mil/devcom

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

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

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

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

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

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

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

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

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

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

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