

Program Announcement for the Department of Defense Defense Health Program

Peer Reviewed Cancer Research Program

Career Development Award – Fellow and Resident Option

Funding Opportunity Number: HT942525PRCRPCDAFRO

Pre-Application Due: June 20, 2025

Application Due: July 3, 2025

Content

	Before You Begin	3
1	Basic Information Contains a <u>summary of the funding opportunity</u> , <u>funding details</u> , and <u>submission/review dates</u>	4
2	Eligibility Details the factors that determine applicant organization and Principal Investigator eligibility	5
3	Program Description Describes the <u>program mission</u> and <u>intent of the Career Development Award – Fellow and Resident Option</u> , provides <u>key award information</u> and <u>Considerations</u> , and outlines <u>funding restrictions</u>	7
4	Application Contents Introduces the two-step <u>application process</u> and provides instructions for preparing a <u>preapplication</u> and <u>full application</u>	19
5	Submission Requirements Provides <u>locations for application packages</u> , instructions for submitting <u>pre-applications</u> and <u>full applications</u> , and describes <u>application verification</u>	30
6	Application Review Information Outlines the processes associated with application compliance review, pre-application and full application selection/notification, and risk assessment. Also details the complete review criteria for pre-application screening and both tiers of the CDMRP's application review process, Peer Review and Programmatic Review	33
7	Federal Award Notices Outlines what a successful applicant can expect to receive if recommended for funding	41
8	Post-Award Requirements References policy requirements for funded research, outlines reporting requirements, and restrictions related to Principal Investigator changes or institutional award transfers	42
9	Other Information Outlines criteria for administrative actions including application <u>rejection</u> , <u>modification</u> , <u>withdrawal</u> and <u>withhold</u>	44
	Appendix 1 Includes a checklist for all full application components to facilitate application submission	46
	Appendix 2 Acronym List	47
	Appendix 3 DOD and VA Websites	49

Before You Begin

- Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission. User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- Read the funding opportunity announcement in the order it is written before beginning to prepare application materials. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.

Who to Contact for Support

eBRAP Help Desk

301-682-5507 help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

800-518-4726 International: 1-606-545-5035 support@grants.gov

> Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

<u>Basic Information</u> | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2025 (FY25) Peer Reviewed Cancer Research Program (PRCRP) Clinical Development Award - Fellow and Resident Option (CDA-FRO) supports the advancement of 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. The proposed research should address a critical problem in at least one of the FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals and should be designed to advance cancer research and/or improve patient care.

Distinctive Features: There are two distinct early-career development options: the Fellow Option and the Resident Option. For the Fellow Option the PI must be an early-career researcher or physician-scientist (referred to as a Fellow) within seven 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). For the Resident Option the PI must be an early-career clinician performing their residency with an interest in becoming a physician-scientist.

Career Guide: Inclusion of a Career Guide, experienced cancer researcher, as demonstrated by a strong record of funding and publications, is required for both the Fellow Option and the Resident Option. The Career Guide must demonstrate a commitment to advancing the PI's career in cancer research.

Funding Details: (New for FY25) Funding limits are now listed as <u>total cost limits</u>, which is <u>the combination of both direct and indirect costs</u>.

The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$6.72 million (M) to fund approximately 12 Career Development Award – Fellow and Resident Option applications with total cost caps of \$280,000 for the Resident Option – Research Level 1 and \$560,000 for the Fellow Option and Resident Option – Research Level 2. The maximum period of performance is 3 years for the Fellow Option, 1 year for the Resident Option – Research Level 1, and 2 years for the Resident Option – Research Level 2. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

• **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 20, 2025

Application Submission Deadline: 11:59 p.m. ET, July 3, 2025

• End of Application Verification Period: 5:00 p.m. ET, July 8, 2025

• Peer Review: September 2025

Programmatic Review: November 2025

Announcement Type: Modified

Funding Opportunity Number: HT942525PRCRPCDAFRO

Assistance Listing Number: 12.420

Basic Information | <u>Eligibility</u> | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply, *including foreign and domestic organizations, for-profit and non-profit organizations, and public or private entities*.

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

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

2.1.2. Principal Investigator

Fellow Option:

- Investigator (early-career researcher or physician-scientist) at or above the level of Research Assistant Professor or Instructor (or equivalent).
- Within seven 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) R01, 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 one or two years within the time frame from approximately September 2026-2028 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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 R01, 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.
- o The Career Guide must have mentorship experience.
- 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 have a proven publication and funding record in cancer research.
- The Career Guide must have mentorship experience.
- It is strongly encouraged the Resident and the Career Guide be located at the same organization.

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

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

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the PRCRP. 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 FY24 totaled \$1.04 billion. The FY25 appropriation is \$130M.

Congressional language stipulates the FY25 PRCRP must be relevant to Service Members, and address at least one of the congressionally directed FY25 PRCRP topic areas listed below.

_	R	lac	44	er	~~	n	٦
•	В	121	1(1	eı	CH	110	:01

Blood cancers

Brain cancer

Colorectal cancer

Endometrial cancer

Esophageal cancer

Germ cell cancers

Kidney cancer

Liver cancer

Lung cancer

Lymphoma

Mesothelioma

Metastatic cancers

Myeloma

Neuroblastoma

Neuroendocrine tumors

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

Research proposed to the PRCRP must not address research in melanoma, or cancers originating in the breast, prostate, or ovary. In addition, FY25 PRCRP funds must not be used to study rare cancers except FY25 PRCRP topic area cancer types that are rare by definition.

FY25 PRCRP Portfolios and Strategic Goals

To meet the intent of the funding opportunity, all applications for FY25 PRCRP funding must specifically address one of the FY25 PRCRP topic areas as directed by the U.S. Congress and have direct relevance to military health. Additionally, the PRCRP implements a portfoliodriven approach by grouping related topic areas with strategic goals as a framework within which to address critical gaps in cancer research and patient care. All applications must address one of the FY25 PRCRP strategic goals as it relates to the portfolio-assigned FY25 PRCRP topic area. Topic areas may be included in more than one portfolio, but the application must be aligned to the strategic goals of the portfolio in which a topic area is included. If the proposed research does not specifically address one FY25 PRCRP topic area and one FY25 PRCRP strategic goals from a single portfolio, then the government reserves the right to administratively withdraw the application. The government reserves the right to reassign the application's topic area if submitted to an incorrect topic area. The table below lists the FY25 PRCRP topic areas and strategic goals in each PRCRP portfolio category.

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).

Portfolio: Bloo	d Cancers			
All application listed below.	s under this portfolio must address one topic area and one strategic goal			
Topic Areas: Blood, Lymphoma, Myeloma				
Strategic Goal				
Prevention	Improve risk assessment of precancerous conditions			
and Etiology	 Develop early intervention strategies to prevent initiation and/or progression 			
	 Investigate autoimmune disorders as risk factors for lymphoma to inform surveillance strategies 			
	 Understand the role of cancer stem cells and the tumor microenvironment in the development of blood cancers 			
Diagnosis and Prognosis	 Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification 			
	Develop more cost-effective molecular diagnostics			
	 Identify biomarkers to predict progression from indolent disease 			
	 Identify unique prognostic factors in pediatric, adolescent, and young adult malignancies 			
Treatment	Develop new, less toxic therapies			
	Develop methods to predict therapeutic vulnerabilities			
	Develop therapies that don't require hospitalization			
	Develop therapies employing gene editing technologies and cell therapies			
	 Identify contribution of immune niche to initial treatment response and relapse 			
	Develop therapeutic options for patients who fail last line therapies			
Survivorship	Develop strategies to minimize and mitigate treatment toxicities			
	Improve quality of life for survivors and/or caregivers			
	 Identify long-term effects of gene editing and cell therapies and develop risk-based standards for surveillance of treated patients 			
	Improve understanding of the effects of long-term immunosuppression			
Epidemiology	Design population-based studies to identify and characterize risk factors related to malignancy			

Portfolio: Gas	stroenterological Cancers				
All applications under this portfolio must address one topic area and one strategic goal listed below.					
Topic Areas: Colorectal, Esophageal, Liver, Stomach, Pancreatic cancer					
Strategic Goa					
Prevention and Etiology	 Identify modifiable and non-modifiable risk factors to inform prevention strategies 				
	Identify factors driving the increasing rates of early-age onset disease				
	 Identify environmental and genetic factors associated with an increased cancer risk 				
	Identify key drivers of conversion from precancerous lesions into cancer				
	 Explore the interplay between the microbiome and infectious agents in cancer initiation and progression 				
	Conduct integrative studies that analyze stool, blood, and the microbiome as they impact disease onset and patient outcomes				
Diagnosis and	 Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification 				
Prognosis	Develop cost-effective and minimally invasive tools for early detection				
	Develop preclinical models to study disease development				
Treatment	Develop new, less toxic therapies				
	Develop effective treatments for advanced disease				
	Develop immunotherapies and novel targeting therapies				
	Identify combination therapies to improve patient outcomes				
	Identify predictive biomarkers to determine treatment response				
	 Develop integrated treatment plans to address short and long-term impacts of cancer 				
Survivorship	Develop strategies to minimize and mitigate treatment toxicities				
	Improve quality of life for survivors and/or caregivers				
	Improve post treatment surveillance guidelines				
	Develop validated tools to measure patient quality of life				
Epidemiology	 Design population-based studies to identify and characterize risk factors related to malignancy 				
	 Implement systems to analyze disease patterns and track patient outcomes to inform best practices 				
	Examine the influence of familial genetics and geographic location on disease onset and treatment outcome				

Portfolio: Ne	urological Cancers			
All applications under this portfolio must address one topic area and one strategic goal listed below.				
	Brain cancer, Pediatric Brain Tumors			
Strategic Go				
Prevention and Etiology	 Identify biological and environmental exposures, including maternal exposures during pregnancy, that increase risk 			
Diagnosis	Develop early detection methods that avoid diagnostic uncertainties			
and Prognosis	Develop effective monitoring for recurrence/refractory disease			
	Develop less invasive diagnostic procedures			
Treatment	Develop new, less toxic therapies			
	Prevent or overcome treatment resistance			
	 Develop personalized oncological care and synergistic multi-modal therapies 			
	 Identify protective therapies to be used in conjunction with toxic therapies to reduce treatment-related damage 			
	Develop less invasive treatment options			
	Develop therapies that cross the blood-brain-barrier			
Survivorship	Develop strategies to minimize and mitigate treatment toxicities			
	 Improve quality of life for survivors and/or caregivers 			
	 Develop effective screening, monitoring, and provision of psychosocial support/care for the patient and family 			
	 Develop care for patients as they transition from pediatric to adult survivors 			
Epidemiology	Analyze and assess the incidence/prevalence of brain tumors over time to identify changes in trends			
Technology Development	 Advance the development or adoption of technologies in areas including artificial intelligence and machine learning, human microbiota, genomics, nanoparticles, and robotics 			

Portfolio: Ped	diatr	ic Adolescent and Young Adult Cancers (PAYAC)
All application listed below.	ns u	under this portfolio must address one topic area and one strategic goal
		AC, Germ cell cancers, Neuroblastoma, Sarcoma, Thyroid cancer
Strategic Goa		
Prevention and Etiology		Determine the molecular basis of cancer predisposition syndromes
and Ellology		Determine the extent to which development of disease is attributable to genetic versus environmental differences
		Increase understanding of epigenetic influences on cancer development and progression
		Identify biological and environmental exposures, including maternal exposures during pregnancy, that increase risk
	•	Investigate the role of microbiome composition in cancer risk and outcomes
Diagnosis and		Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification
Prognosis		Develop noninvasive techniques for monitoring progression and recurrence
	•	Identify biomarkers present in early-stage disease
	•	Develop preclinical models that accurately mimic disease
	•	Improve accurate and rapid diagnosis of sub-types of disease
Treatment	•	Develop new, less toxic therapies
		Develop treatments for relapse/recurrence, metastatic, and advanced disease
		Increase the number of clinical trials, including ones that may not be curative but may improve the quality of life for terminal patients
		Generate evidence-based treatment and surveillance strategies to preserve fertility
	•	Reduce secondary cancers arising from treatment regimen
Survivorship	•	Develop strategies to minimize and mitigate treatment toxicities
	•	Improve quality of life for survivors and/or caregivers
		Develop strategies to improve the full implementation of survivorship guidelines
		Develop survivorship guidelines based on current/modern therapeutic agents
Epidemiology		Design population-based studies to identify and characterize risk factors related to malignancy

Portfolio: Solid Tumors				
All applications under this portfolio must address one topic area and one strategic goal listed below.				
	Bladder cancer, Endometrial cancer, Mesothelioma, Sarcoma, Germ cell roid cancer, Kidney cancer, Lung cancer, Neuroendocrine tumors			
Strategic Goa				
Prevention	Develop methods that mitigate or identify risk			
and Etiology	Develop prevention strategies			
	 Explore the mechanistic relationship between novel and known risk factors and oncogenesis 			
	 Identify convergent etiologies underlining the development of malignancies 			
Diagnosis and	 Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification 			
Prognosis	 Investigate the interactions of pre-existing autoimmune disease and cancer 			
Treatment	Develop new, less toxic therapies			
	Develop feasible precision medicine approaches			
	 Identify ways to tailor therapeutic strategies to minimize toxicity 			
Survivorship	Develop strategies to minimize and mitigate treatment toxicities			
	Improve quality of life for survivors and/or caregivers			
Epidemiology	 Design population-based studies to identify and characterize risk factors related to malignancy 			

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Portfolio: Metastatic Disease					
All applications under this portfolio must address one topic area and one strategic goal listed below.					
	Topic Area: Metastatic cancers, limited to PRCRP topic area cancers				
Strategic Go	als				
Prevention and Etiology	•	Identify biomarkers in primary disease that could predict metastatic potential			
	•	Prevent immune evasion by circulating tumor cells			
	•	Identify how dormant, disseminated tumor cells (DTCs) persist			
	•	Identify drivers that initiate DTCs progression to metastatic colonies			
	•	Prevent metastatic colonization by maintaining dormancy of DTCs			
	•	Investigate clonal divergence of primary tumor cells between metastatic sites to immunological disease			
Diagnosis	•	Improve early detection of metastasis and dormant residual disease			
and Prognosis	•	Develop biomarkers that predict and monitor treatment efficacy			
Treatment	•	Develop new, less toxic therapies			
	•	Revert metastatic cells to a dormant state			
	•	Identify strategies to prevent or overcome treatment resistance			
	•	Investigate abscopal effects of primary disease treatment			
	•	Determine optimal sequencing of treatments			
	•	Eliminate chemotherapy-induced metastasis			
Survivorship	•	Develop strategies to alleviate treatment toxicities			
	•	Improve quality of life for survivors and/or caregivers			

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 melanoma or cancers that originate in the breast, prostate, or ovaries, or rare cancers (excluding relevant subtypes of the FY25 PRCRP topic areas) as part of the research study; such applications will be administratively withdrawn.

FY25 PRCRP Military Health Focus Areas

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., Retirees and their Family members) (https://cdmrp.health.mil/pubs/video/prc/prcrp_vision_video).

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

In addition to addressing at least one of the required FY25 PRCRP Topic Areas and FY25 Strategic Goals, applications for the FY25 Career Development Award must define how the research is relevant to Service Members and their Families by addressing at least one of the FY25 PRCRP Military Health focus areas listed below.

FY25 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 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 FY25 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 effects that would allow an activeduty 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 DOD and/or VA research laboratories and programs (Refer to Appendix 3).

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

3.1. Intent of the Career Development Award – Fellow and Resident Option

The PRCRP supports advancement of cancer research through development of early-career investigators. Depending on the career path of the candidates, this mechanism 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 PI, and the application should focus on the PI's research and career development. The proposed research should address a critical problem in at least one of the FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals and should be designed to advance cancer research and/or improve patient care. 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 intention of the Fellow Option is to support early-career investigators or physician-scientists toward wider independence and success. Postdoctoral fellows are not eligible for this award mechanism.
- **Resident Option:** The intention of the Resident Option is to support the early-career clinician investigators research development with strong scientific career development. Two research funding levels are available for the Resident Option depending on the level of effort and time commitment of the Resident.

For those interested in applying to be a Scholar with the Virtual Cancer Center (VCC), the Career Development Award – Scholar Option (CDA-SO) mechanism will be offered this year and is available in a separate program announcement: HT942525PRCRPCDASO. The VCC is not available under the CDA-FRO.

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.

3.1.1. Key Elements for the CDA-FRO

- **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;** however, research proposed should be based on strong scientific reasoning and relevant literature.
- One research funding level is available for the <u>Fellow Option</u>. The Fellow Option is intended for candidates that have been named on only nominal career development funding (e.g., approximately \$300,000 or less in Federal funding). The Pl's record of accomplishments and the proposed research will be evaluated regarding their potential to contribute to at least one of the FY25 PRCRP topic areas. 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. Applications are strongly encouraged to demonstrate protection of the Pl's time for cancer research.
- Two research funding levels are available for the <u>Resident Option</u>. The Resident must be able to commit one or two years within the time frame from approximately June 2026-2028 toward research with level of effort on the proposed research appropriate for the research funding level and the project.

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- Resident Research Level 1: A one-year research project under the guidance of the designated Career Guide must be proposed. The one-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 two-year research project under the guidance of the designated Career Guide must be proposed. The two-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. Applications to the Resident Option are strongly encouraged to demonstrate protection of the PI's time for cancer research. The Resident must articulate a clear plan to accomplish a scientifically rigorous project of either one year or two years. The PI must demonstrate a commitment to a career as an investigator at the forefront of one of the FY25 PRCRP Topic Areas and clinical practice; however, the PI is not required to have previous cancer research experience.

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.

An individualized career development plan is required and should be prepared with appropriate guidance from the Career Guide who will act as a mentor to the PI and oversee their career development plan progress. For the **Fellow Option**, 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 FY25 PRCRP topic areas. For the **Resident Option**, 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 FY25 PRCRP topic areas. An environment appropriate to the proposed mentoring and research project must be clearly described.

3.1.2. Other Important Considerations for the CDA-FRO

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.

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

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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. An *intervention* includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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.

3.2. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the PRCRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

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 <u>recommendations</u> and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY25 PRCRP priorities.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment and improved health outcomes of 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.

The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

3.3. Funding Instrument

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

3.4. Funding Details

Period of Performance: The maximum period of performance is 3 years for the Fellow Option, 1 year for the Resident Option – Research Level 1, and 2 years for the Resident Option – Research Level 2.

New for FY25: Funding limits are now listed as total cost limits, which is the combination of both direct and indirect costs. This is a change from prior years which listed funding limits for direct costs only.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed \$560,000 for the Fellow Option, \$280,000 for the Resident Option – Research Level 1, and \$560,000 for the Resident Option – Research Level 2. 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 noted above.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY25 PRCRP CDA-FRO.

Must not be requested for:

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

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (<u>eBRAP</u>) and a *full application* submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

When starting the pre-application, applicants will be asked to select the following:

- Select the FY25 PRCRP portfolio addressed by the proposed research.
- Select the primary FY25 PRCRP topic area addressed by the proposed research.
- Select the FY25 portfolio classification and strategic goal to be studied.
- When applicable, a secondary FY25 PRCRP topic area should be selected. The secondary topic area may be any topic regardless of selected portfolio. Examples include, (not allinclusive):
 - Applications addressing more than one cancer type should select the two most applicable.
 - Applications addressing a topic area that is the subtype of another topic area (e.g. Lymphoma and Blood Cancers) should select both.
 - Applications addressing a cancer type in PAYAC populations, should select both the cancer type and the PAYAC topic area.
 - Applications addressing metastatic disease in a cancer type should select both the metastatic disease and cancer type category.
- Select the FY25 PRCRP Military Health Focus Area to be studied.

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the topic area(s) and corresponding strategic goal 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

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter.

4.3. Step 2: Full Application Components

Each application submission must include the completed full application package for this program announcement. See <u>Appendix 1</u> for a checklist of the full application components.

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

<u>IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number</u> assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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 (see each option for 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.

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 FY25 PRCRP Topic Areas, 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: Describe how the proposed research addresses an important question relevant to at least one of the FY25 PRCRP topic areas and corresponding strategic goals and articulate how the proposed research will improve the lives of patients and/or advance cancer research. 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

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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 FY25 PRCRP Topic Areas, 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 FY25 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.
- 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: Describe how the proposed research addresses an important question relevant to at least one of the FY25 PRCRP topic areas and corresponding strategic goals and articulate how the proposed research will improve the lives of patients and/or advance cancer research. 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.

Resident Option – Research Level 2 (<u>eight</u>-page limit):

- Principal Investigator: Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY25 PRCRP Topic Areas 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 FY25 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.
 Describe the clinical rationale for the research project.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached. Clinical trials are not allowed.
- 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: Describe how the proposed research addresses an important question relevant to at least one of the FY25 PRCRP topic areas and corresponding strategic goals and articulate how the proposed research will improve the lives of patients and/or advance cancer research. 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. 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 Support (recommended) (two-page limit per letter is recommended):
 Provide individual letters signed by collaborating individuals and/or organizational

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

officials demonstrating that the PI has the support and resources necessary for the proposed work.

- The Career Guide must provide a signed letter 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 FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals. The letter should include a brief overview of the Career Guide's record of preparing early-career investigators for careers in cancer research.
- If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- Inclusion Enrollment Plan (only required if clinical research is proposed): 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. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, sex, ethnicity or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- Data and Research Resources Sharing Plan: Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial 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 & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- Use of DOD Resources or VA Resources (if applicable): If the proposed research involves access to military and/or VA patient populations and/or DOD or VA

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 3, for additional considerations.

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 Pl's potential for a career at the forefront of cancer research in at least one of the FY25 PRCRP topic areas. 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: State the <u>FY25 PRCRP Topic Area(s)</u> and <u>FY25 Strategic Goal</u> to be addressed by the proposed research. Present the ideas and reasoning behind the proposed work.
- Hypothesis/Objective(s): State the hypothesis/study questions to be tested and/or objective(s) to be reached.
- Specific Aims: State the specific aims of the study.
- Study Design: Describe the study design, including appropriate controls.
- Impact: Summarize the proposed project's potential impact on advancing the current state of cancer research and/or patient care.
- Relevance to Military Health: Identify the FY25 PRCRP Military Health focus area(s) to be studied. Briefly describe how the proposed research is relevant to active-duty Service Members, Veterans and other military beneficiaries.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf". The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Do not duplicate the technical abstract.

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

Describe the PI's career goals in cancer research. How will the award advance the PI's career in at least one of the FY25 PRCRP topic areas? How will the proposed research move the field toward better patient care and/or outcomes with respect to at least one of the FY25 PRCRP strategic goals? How do the research and career development plans support the PI in attaining these goals?

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- State the FY25 PRCRP topic area(s) and FY25 strategic goal to be addressed by the research project.
- Describe the scientific objective and rationale for the proposed research.
- Describe what types of patients the research will help and how it will help them. What are the potential clinical applications, benefits and risks?
- Describe the likely contributions of this study to advancing the field of cancer research and/or patient care.
- State the FY25 PRCRP Military Health focus area(s) to be addressed by the research project. Describe how the proposed research is relevant to active-duty Service Members, Veterans, and other military beneficiaries.
- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to eBRAP for the "Suggested SOW Format".
 - For the CDA-FRO, refer to the <u>"Example: Assembling a Generic Statement of Work"</u> for guidance on preparing the SOW.
- 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 FY25 PRCRP Programmatic Panel during programmatic review only.
 - State the FY25 Military Health Focus Area(s) to be addressed in the study.
 - Based on published literature of the impact of cancer on military populations, articulate the relevance of the research proposed and show how it will decrease the burden of cancer on Service Members, their Families, and Veterans.
 - Identify the environmental and/or exposure risk factors associated with the <u>FY25</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 FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals. 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.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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 (page limit indicated in the option and research level below): Upload as "CareerDev.pdf".

Fellow Option (two-page limit):

- Clearly describe and outline the individualized career development plan that focuses on at least one of the <u>FY25 PRCRP Topic Areas</u>. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY25 PRCRP topic area(s) and at least one of the FY25 PRCRP strategic goals.
- Describe how the Pl'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>FY25 PRCRP Topic areas</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 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 (two-page limit):

- Clearly describe how the one-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 <u>FY25 PRCRP Topic Areas</u>. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY25 PRCRP topic area(s) and at least one of the FY25 PRCRP strategic goals.
- 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.
- Describe the Career Guide's track record for training early-career investigators.
 Articulate the Career Guide's experience as an independent, established researcher

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

in cancer research (including their record of publications, patents, and/or funding history).

Resident Option – Research Level 2 (two-page limit):

- Clearly describe and outline the individualized career development plan that focuses on at least one of the <u>FY25 PRCRP Topic Areas</u>. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY25 PRCRP topic area(s) and at least one of the FY25 PRCRP strategic goals.
- 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>FY25 PRCRP Topic Areas</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 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. The letter should verify that the PI is no more than seven years from their terminal degree. Include the organizational commitment for independent laboratory space and protection of the PI's time for cancer research (Refer to Section 2. Eligibility Information).
- Attachment 10: 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 11: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 12: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

- (c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI, as well as the Career Guide and other senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
 - Biographical Sketch: Upload as "Biosketch_LastName.pdf".
 - The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.
 - Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in Science Experts Network Curriculum Vitae (SciENcv) for the NIH or the U.S. National Science Foundation (NSF).
 - Current/Pending Support: Upload as "Support LastName.pdf".
 - Current and pending (other) support information are used to assess the capacity or any <u>conflicts of commitment</u> that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.
 - Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.
- (e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).
 - Budget Justification (no page limit): For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.
- (f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.
 - Extramural Subaward: Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Intramural DOD Subaward: Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.4. Other Application Elements

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

- 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 8, 2025. 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. The PI will not be able to view the letters.
 - Confidential letter(s) of recommendation from the Career Guide: The Pl's Career Guide must submit a letter describing the Career Guide's commitment to the Pl'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
 <u>FY25 PRCRP Topic Areas</u>. The relevance of the proposed research project to the
 PI's development as a researcher in at least one of the <u>FY25 PRCRP Topic Areas</u>.
 - 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 <u>FY25 PRCRP Topic Areas</u>. 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 FY25 PRCRP Topic Areas.
- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

Basic Information | Eligibility | Program Description | Application Contents and Format | <u>Submission Requirements</u> Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525PRCRPCDAFRO from <u>Grants.gov</u> or <u>eBRAP</u>, depending on which submission portal will be used.

5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), <u>SAM.gov</u>, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

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

Step1: Submit Pre-Application Letter of Intent Submitted Through eBRAP Step 2: Submit Full Application Grants.gov Extramural Organizations Verify Application Content in eBRAP

Application Submission Workflow

5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP.

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 preapplication 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

Basic Information | Eligibility | Program Description | Application Contents and Format | <u>Submission Requirements</u> Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

Application Includes:	Select Option:
PI considered a Fellow per eligibility criteria	Fellow Option
PI considered a Resident per eligibility criteria AND proposes research focused on early hypotheses or conceptual ideas	Resident Option – Research Level 1
PI considered a Resident per eligibility criteria AND proposes research focused on more developed ideas and hypotheses	Resident Option – Research Level 2

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. 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 the 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 through the appropriate portal prior to the full application submission deadline. Other application components, including subaward budget(s) and subaward budget iustification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

Basic Information | Eligibility | Program Description | Application Contents and Format | <u>Submission Requirements</u> Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in 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.*

All submission dates and times are indicated in Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements **Application Review Information** | Federal Award Notices | Post-Award Requirements | Other Information

6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the <u>CDMRP's full position on research duplication</u>.

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.

Members of the FY25 PRCRP Programmatic Panel should not be involved in any preapplication or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members *may* provide <u>letters</u> to confirm <u>PI eligibility</u> and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). *A list of the* <u>FY25 PRCRP Programmatic Panel members</u> can be found on the <u>CDMRP website</u>.

Additional restrictions and associated administrative responses are outlined in <u>Section 9.2</u>, <u>Administrative Actions</u>.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

Pre-applications submitted to this funding opportunity are used for program planning purposes only (e.g., reviewer recruitment) and will not be screened.

6.2.2. Peer Review Criteria

Fellow Option:

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.
- To what degree the PI's qualifications and achievements (e.g., awards, honors, firstauthor publications, publications in high-impact journals, presentations/speaking engagements, committees) make the PI an ideal candidate for this award.
- To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research in at least one of the FY25 PRCRP topic areas.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements <u>Application Review Information</u> | Federal Award Notices | Post-Award Requirements | Other Information

Career Development Plan, Environment, and Career Guide

- 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 cancer researcher in at least one of the FY25 PRCRP Topic Areas.
- o 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 FY25 PRCRP topic area(s).
- 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.
- Whether the Career Guide's track record in training early-career investigators indicates the potential for successful mentorship.
- 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.
- 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.

Research Strategy and Feasibility

- To what extent the ideas and scientific rationale behind the proposed research (laboratory or clinical) demonstrate strong scientific reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- Whether and how well the project's specific aims, the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, support the investigation into the hypothesis and/or objectives.
- 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.
- o 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, 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 FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- Whether the Pl's described pathway toward making an impact on cancer research and/or patient care, including the Pl'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 criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

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.

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.

Resident Option – Research Level 1:

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.
- To what degree the PI's qualifications and achievements (e.g., awards, honors, firstauthor publications, publications in high-impact journals, presentations/speaking engagements, committees) make the PI an ideal candidate for this award.
- To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career as a physician-scientist at the forefront of cancer research in at least one of the FY25 PRCRP topic areas.
- 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 one-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 in at least one of the FY25 PRCRP Topic Areas.
- 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements | Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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.

Research Strategy and Feasibility:

- To what extent the ideas and scientific rationale behind the proposed research (laboratory or clinical) demonstrate strong scientific reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- Whether and how well the project's specific aims, the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, support the investigation into the hypothesis and/or objectives.
- 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, 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 FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals.
- 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 criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements <u>Application Review Information</u> | Federal Award Notices | Post-Award Requirements | Other Information

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.

Resident Option - Research Level 2:

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.
- To what degree the PI's qualifications and achievements (e.g., awards, honors, firstauthor publications, publications in high-impact journals, presentations/speaking engagements, committees) make the PI an ideal candidate for this award.
- To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career as a physician-scientist at the forefront of cancer research in at least one of the FY25 PRCRP topic areas.
- 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 two-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 in at least one of the FY25 PRCRP Topic Areas.
- 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.
- o 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.

Research Strategy and Feasibility:

- To what extent the ideas and scientific rationale behind the proposed research (laboratory or clinical) demonstrate strong scientific reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- Whether and how well the project's specific aims, the experimental design, methods and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, support the investigation into the hypothesis and/or objectives.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements | Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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.
- o 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.
- o 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, 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 FY25 PRCRP topic areas and at least one of the FY25 PRCRP strategic goals.
- Whether the Pl's described pathway toward making an impact on cancer research and/or patient care, including the Pl'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 criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

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.

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.

6.2.3. 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 FY25 PRCRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- Program portfolio composition.
- Relative impact.
- o Programmatic relevance to the <u>FY25 PRCRP Military Health Focus Areas.</u>
- Programmatic relevance to the <u>FY25 PRCRP Strategic Goals</u> as outlined in the FY25 PRCRP portfolio categories.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

There is no review and selection process for pre-applications submitted to this funding opportunity. *CDMRP will NOT provide an invitation to submit a full application after pre-application 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.

6.3.2. Full Application

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 6.2.3</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found on the <u>CDMRP website</u>.*

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.

6.4. Risk, 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements **Application Review Information** | Federal Award Notices | Post-Award Requirements | Other Information

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt 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 additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

8. Post-Award Requirements

8.1. 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.

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.

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

8.2. 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 (RPPR).

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

PHS Inclusion Enrollment Reporting (required for research proposing clinical research and/or clinical trials): Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report.

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).

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | <u>Post-Award Requirements</u> | Other Information

8.3. Additional Requirements

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

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 H, for general information on organization or PI changes.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

9. Other Information

9.1. 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 CD25_01d. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

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

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

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY25 PRCRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the preapplication or application processes.
- Applications that include names of personnel from either of the CDMRP peer or
 programmatic review companies for which conflicts cannot be adequately mitigated. For
 FY25, the identities of the peer review contractor and the programmatic review contractor
 may be found on the <u>CDMRP website</u>.
- 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) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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.
- 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.
- The named Career Guide does not meet the eligibility criteria.
- The application does not address at least one of the <u>FY25 PRCRP Topic Areas</u>.
- The application does not address at least one of the <u>FY25 PRCRP Military Health Focus</u> Areas.
- The application does not address at least one of the <u>FY25 PRCRP Strategic Goals</u>.
- The application addresses an FY25 strategic goal from a portfolio that does not include the FY25 topic area being addressed.
- The pre-application or application does not adhere to congressional language and includes a cancer that originates in the breast, prostate, or ovary, or rare cancers (excluding relevant subtypes of the FY25 PRCRP topic areas), or melanoma as part of the research study.
- A clinical trial is proposed.

9.2.4. 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance (Grants.gov submissions only)	
Summary (Tab 1) and Application Contacts (Tab 2) (eBRAP 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"	
<u>Letter of Eligibility</u> (Grants.gov submissions only) – Attachment 9, upload as "Eligibility.pdf"	
Letters Confirming Access to Target Military or VA Patient Population(s) or Resources – Attachment 10, upload as "Access.pdf"	
Representations - Attachment 11, upload as "RequiredReps.pdf"	
<u>Suggested Intragovernmental/Intramural Budget Form</u> (if applicable) – Attachment 12, upload as "IGBudget.pdf"	
Research & Related Personal Data	
Research & Related Senior/Key Person Profile (Expanded)	
Attach Biographical Sketch for PI and Senior/Key Persons (Biosketch_LastName.pdf)	
Attach Current and pending (other) support for PI and Senior/Key Persons (Support_LastName.pdf)	
Budget Include budget justification	
Project/Performance Site Location(s) Form	
Research & Related Subaward Budget Attachment(s) Form (if applicable)	

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Appendix 2. Acronym List

CDA-FO Career Development Award – Fellow Option

CDA-FRO Career Development Award – Fellow and Resident Option

CDA-RO Career Development Award – Resident Option
CDA-SO Career Development Award – 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

DTC Disseminated Tumor Cells

eBRAP Electronic Biomedical Research Application Portal

EC Ethics Committee
ET Eastern Time

FAD Funding Authorization Document

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

LOI Letter of Intent

M Million

MIPR Military Interdepartmental Purchase Request

NIH National Institutes of Health

NSF U.S. National Science Foundation

OHARO Office of Human and Animal Research Oversight (previously Office of

Research Protections)

OUSD R&E Office of the Under Secretary of Defense for Research and Engineering

PAYAC Pediatric Adolescent and Young Adult Cancers

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

PRCRP Peer Reviewed Cancer Research Program
RPPR Research Performance Progress Report

SAM System for Award Management

SciENcv Science Experts Network Curriculum Vitae

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

DOD FY25 Peer Reviewed Cancer Career

Development Award - Fellow and Resident Option Award

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

USC United States Code

VA U.S. Department of Veterans Affairs

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Appendix 3. DOD and VA Websites

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/

Congressionally Directed Medical Research Programs

https://cdmrp.health.mil/

Defense Advanced Research Projects Agency

https://www.darpa.mil/

Defense Health Agency

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

Defense Suicide Prevention Office

https://www.dspo.mil/

Defense Technical Information Center

https://www.dtic.mil/

Defense Threat Reduction Agency

https://www.dtra.mil/

Military Health System Research Symposium

https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program

https://midrp.health.mil/

Military Operational Medicine Research Program

https://momrp.health.mil/

Navy Bureau of Medicine and Surgery

https://www.med.navy.mil/

Naval Health Research Center

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

Research-Center/

Navy and Marine Corps Public Health Center

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

Naval Medical Research Command

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

Office of Naval Research

https://www.med.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

https://www.acq.osd.mil/

DOD FY25 Peer Reviewed Cancer Career

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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 Research and Development Command https://mrdc.health.mil/

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

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

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

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

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

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

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

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