Program Announcement for the Defense Health Agency

Peer Reviewed Cancer Research Program

Clinical Trial Award

Funding Opportunity Number: HT942526PRCRPCTA

Pre-Application Due: June 26, 2026

Application Due: October 5, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

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 this 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 this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

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 Support 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 the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Peer Reviewed Cancer Research Program (PRCRP) Clinical Trial Award (CTA) supports the rapid implementation of clinical trials with the potential to have a significant impact on the treatment or management of cancer within at least one of the FY26 PRCRP Topic Areas. Clinical trials proposed may evaluate promising new products, pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) that evaluate the effects of interventions or inform the design of more advanced trials to large-scale trials (up to phase III) to determine efficacy in relevant patient populations.

Distinctive Features:

- Applications to this award mechanism must include a clinical trial**.**
- Projects can range from phase 0 to phase III.
- If an Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or equivalent, is required, a regulatory application ***must be submitted to the relevant regulatory agency by the Clinical Trial Award application submission deadline*****.** The regulatory application should be specific to the product and indication to be tested in the proposed clinical trial.
- Applications are required to include patient advocates.
- Animal studies are NOT allowed under this award mechanism. All preclinical work must be completed prior to the award start date.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $45.0M to fund approximately 10 Clinical Trial Award applications with total cost caps of $4.5M per award. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2026 (FY26) funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 26, 2026
- **Invitation to Submit an Application:** August 10, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, October 5, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, October 8, 2026
- **Peer Review:** December 2026
- **Programmatic Review:** February 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526PRCRPCTA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities*.**

2.1.2. Principal Investigator

Independent investigators at all career levels affiliated with an eligible organization are eligible to be named as Principal Investigator (PI) on the application, 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 GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Peer Reviewed Cancer Research Program (PRCRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. 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 FY25 totaled $1.17 billion. The FY26 appropriation is $165 million (M).

Congressional language stipulates the FY26 PRCRP must be relevant to Service Members, and address at least one of the congressionally directed FY26 PRCRP Topic Areas listed below.

- Bladder cancer
- Blood cancers
- Brain cancer
- Colorectal cancer
- Endometrial cancer
- Esophageal cancer
- Germ cell cancers
- Glioblastoma
- Liver cancer
- Lymphoma
- Mesothelioma
- Metastatic cancers
- Myeloma
- Neuroblastoma
- Neuroendocrine Tumors
- Pediatric, adolescent, and young adult cancers[1]
- 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, kidney, lung, pancreas, prostate or ovary. In addition, FY26 PRCRP funds must not be used to study rare cancers except FY26 PRCRP Topic Area cancer types that are rare by definition.

FY26 PRCRP Portfolios and Strategic Goals

To meet the intent of the funding opportunity, ***all applications for FY26 PRCRP funding must specifically address one of the FY26 PRCRP Topic Areas as directed by the U.S. Congress and have direct relevance to military health***. Additionally, the PRCRP implements a portfolio-driven 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 FY26 PRCRP strategic goals as it relates to the portfolio-assigned FY26 PRCRP Topic Area. Some topic areas are present in more than one portfolio. Applications must align to the strategic goal of the portfolio in which a topic area is included.*** If the proposed research does not specifically address one FY26 PRCRP Topic Area and one FY26 PRCRP strategic goal from a single portfolio, then the government reserves the right to administratively withdraw the application. The government reserves the right to reassign

[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).

the application's topic area if submitted to an incorrect topic area. The table below lists the FY26 PRCRP Topic Areas and strategic goals in each PRCRP portfolio category.

Portfolio: Blood Cancers	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Blood cancers, Lymphoma, Myeloma	
Knowledge Areas:	**Strategic Goals:**
Prevention and Etiology	• Improve risk assessment of precancerous conditions • 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: Gastroenterological Cancers	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Colorectal cancer, Esophageal cancer, Liver cancer, Stomach cancer	
Knowledge Areas:	**Strategic Goals:**
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 Prognosis	• Improve methods for early detection, prognostic evaluation and/or therapeutic stratification • 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: Neurological Cancers	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Brain cancer, Glioblastoma, Pediatric Brain Tumors	
Knowledge Areas:	**Strategic Goals:**
Prevention and Etiology	• Identify biological and environmental exposures, including maternal exposures during pregnancy, that increase risk
Diagnosis and Prognosis	• Develop early detection methods that avoid diagnostic uncertainties • 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: Pediatric Adolescent and Young Adult Cancers (PAYAC)	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: PAYAC, Germ cell cancers, Neuroblastoma, Sarcoma, Thyroid cancer	
Knowledge Areas:	**Strategic Goals:**
Prevention and Etiology	• Determine the molecular basis of cancer predisposition syndromes • 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 Prognosis	• Improve methods for early detection, prognostic evaluation and/or therapeutic stratification • 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.	
Topic Areas: Bladder cancer, Endometrial cancer, Mesothelioma, Sarcoma, Germ cell cancers, Thyroid cancer, Neuroendocrine tumors	
Knowledge Areas:	**Strategic Goals:**
Prevention and Etiology	• Develop methods that mitigate or identify risk • 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 Prognosis	• Improve methods for early detection, prognostic evaluation and/or therapeutic stratification • 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

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	
Knowledge Areas:	**Strategic Goals:**
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 and Prognosis	• Improve early detection of metastasis and dormant residual disease • 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, kidney, lung, pancreas, prostate, or ovaries, or rare cancers (excluding relevant subtypes of the FY26 PRCRP Topic Areas) as part of the research study; such applications will be administratively withdrawn.

FY26 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).

In addition to addressing at least one of the required FY26 PRCRP Topic Areas and FY26 Strategic Goals, ***applications for the FY26 Clinical Trial Award must define how the research is relevant to Service Members and their Families by addressing at least one of the FY26 PRCRP Military Health Focus Areas listed below.***

FY26 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 assigned duties or 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 FY26 PRCRP Military Health Focus Areas refers to the impact of cancer on the Service Member. Decreasing the impact of cancer on 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 active-duty Service Member to return to full duty;
- Treatments to minimize a cancer patient's (either a Service Member's or their Family member's) time in the hospital, thus maximizing the time the Service Member is on duty;
- Effective ways to minimize cancer relapse for Service Members or their Families; and
- Research into improvements in cancer detection that would lead to earlier diagnosis, thus allowing for improved treatment of the Service Member and early return to duty.

For more information on military health and cancer:

- PRCRP (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/)

The PRCRP strongly encourages investigators to collaborate, integrate, and/or align their research projects with DOW and/or VA research laboratories and programs (Refer to GSI Appendix 10).

3.1. Intent of the Clinical Trial Award

The FY26 PRCRP Clinical Trial Award (CTA) mechanism supports the rapid execution and analysis of clinical trials with the potential to have a significant impact on the treatment or management of cancer within at least one of the FY26 PRCRP Topic Areas. Investigators may design a clinical trial to evaluate promising new products, pharmacologic agents (drugs, biologics or medical devices), clinical guidance and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (i.e., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations. The proposed clinical trial must begin no later than 12 months after the award date or 18 months after the award date for studies regulated by the Regulatory Agency.

Funding from this award mechanism must support a clinical trial.

3.1.1. Key Elements for the CTA

- **Impact:** The proposed intervention(s) should offer significant potential for advancing to the next stage of clinical study, transition of results to fielded science, or improve the standard of care for at least one of the FY26 PRCRP Topic Areas and address one of the FY26 PRCRP Military Health Focus Areas and one of the FY26 PRCRP Strategic Goals. The impact of the intervention should include considerations of quality of life and supportive care during the trial.
- **Applications require supportive preclinical data:** Applications must include supportive preclinical data relevant for the clinical trial. ***No proposed preclinical research to support an IND/IDE application is allowed***. ***No animal work is allowed.***
- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how the research team will achieve accrual goals. as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study. 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.
- **Intervention Availability:** The application should demonstrate the documented availability of and access to the drug/compound, device and/or other materials needed, as appropriate, for the proposed duration of the study.
- **Research Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, knowledge of U.S. Food and Drug Administration (FDA) processes (if applicable), and data management. The application should include a study coordinator(s) who will guide the clinical protocol through the local IRB of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial and coordinate participant accrual. The application should show strong institutional support and, if applicable, a commitment to serve as the FDA regulatory

sponsor, ensuring all sponsor responsibilities described in Code of Federal Regulations, Title 21, Part 312, Subpart D (21 CFR 312, Subpart D), are fulfilled.

- **Patient Advocates:** Applications are required to include patient advocate involvement. The research team must include two or more patient advocates who will be integral throughout the planning and implementation of the research project. Patient advocates should be involved in the development of research questions, project design, oversight, recruitment and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. As lay representatives t*he patient advocates must be individuals who have been directly impacted by cancer either by being diagnosed themselves or as a caretaker/family member of a patient.* Their role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. Their role should be focused on providing objective input on the research and its potential impact for individuals with or at risk of cancer. The patient advocates should have a high level of knowledge of current cancer issues and the appropriate background and/or training in cancer research to contribute to the project.

When developing applications to the PRCRP CTA mechanism, the PRCRP strongly encourages applicants to provide sufficient evidence to demonstrate the following key considerations:

- Availability of, and access to, the study population.
- Intervention access and availability.
- Appropriate study team composition.
- Statistical considerations, data management and analysis plans appropriate for the proposed research.

3.1.2. Other Important Considerations for the CTA

Funding from this award mechanism must support a clinical trial. Preclinical research is not supported in this funding opportunity.

Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY26 PRCRP funding opportunities that may be more appropriate for such research.

An informational resource for preparing an application, the Human Subject Research Resource, is available on the CDMRP website.

The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for studies regulated by the Regulatory Agency. Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any equivalent international regulatory agency.

If an IND application, IDE, or equivalent, is required, a regulatory application ***must be submitted to the relevant regulatory agency by the Clinical Trial Award application submission deadline.*** The regulatory application should be specific to the product and indication to be tested in the proposed clinical trial (this includes clinical trials requesting exception from informed consent under 21 CFR 50.24.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the VA and other federal government agencies are highly encouraged. A list of websites that may be useful in identifying additional information about ongoing DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI. 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, their Families and the American Public. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY26 PRCRP priorities.

3.2. Funding Instrument

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

3.3. Funding Details

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$4.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

Research milestones to be accomplished by the end of each year in the period of performance must be clearly defined in the project SOW and will be finalized during award negotiations. The PI(s) will be required to present an update on progress toward accomplishing research milestones and goals of the project at an annual Milestone Meeting to be held virtually at the discretion of the government. Annual Milestone Meetings will be held at the conclusion of year 1 and may be held every subsequent year in the period of performance. Milestone Meetings will be attended by members of the PRCRP Programmatic Panel, CDMRP staff and the DHACA Grants Officer.

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

May be requested for (not all-inclusive):

- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving and resources/equipment to enable participation).
- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the PRCRP CTA.

Must not be requested for:

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

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 (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW 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. Pre-Application Components

Pre-application submissions must include the following components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

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

  The Preproposal Narrative should include the following:

  - **Background:** State the FY26 PRCRP Topic Area(s) and FY26 PRCRP Strategic Goal the application will address.
  - **Research Idea and Impact:** Describe how the proposed research will have a significant impact on the treatment or management of cancer within at least one of the FY26 PRCRP Topic Areas. Describe the ideas and scientific rationale on which the proposed clinical trial is based; include relevant literature citations. State the clinical intervention, subject population(s), phase of the clinical trial proposed, regulatory status and sponsor.
  - **Project Readiness:** Briefly describe the project readiness to include the level of scientific evidence that supports the initiation of the proposed clinical trial, and the availability of, and accessibility to, the intervention and the proposed subject population. Describe a plan to submit an IND/IDE by the full application deadline or describe why the proposed research does not need one.
  - **Clinical Strategy:** Concisely state the project's hypothesis and/or objectives. Briefly describe the clinical approach, including study design, endpoints/outcome measures and statistical methods for analysis.
  - **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the clinical trial. Note any DOW- or VA-relevant collaborations.
  - **Military Relevance:** Explain how the proposed research will lead to promising outcomes for one or more of the selected FY26 PRCRP Military Health Focus Area(s).

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms and Symbols:** Provide a list of abbreviations, acronyms and symbols used in the Preproposal Narrative.
  - **Key Personnel Biographical Sketches:** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
  - **Letters of Support (if applicable):** Letters of support should be provided to demonstrate commitment of collaborators (i.e., industry partners) to proposed study.

4.3. Full Application Components

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

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

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number 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 in the GAI.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below. It should be evident that the proposed study meets the definition of a clinical trial.

  - **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of the available literature and completed/ongoing studies relevant to the proposed clinical trial.
    - Describe the preliminary studies and/or preclinical data that support the proposed clinical trial.
    - Summarize key preclinical pharmacological findings, dosage studies and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
    - Provide a summary of other relevant ongoing, planned or completed clinical trials, and describe how the proposed study differs

- Describe how the proposed project addresses a FY26 topic area and corresponding FY26 PRCRP Strategic Goal.

If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source(s) of prior funding. Identify the specific portions of the study that will be supported with funds from this award.

- **Intervention:** Identify the intervention to be tested. Include the following components, as applicable: intervention type (drug, device, behavioral, surgical, etc.), complete name and composition, source, general concept of design, administration route. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights, along with access to the intervention itself, for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation, demonstrating the study team's access to the intervention(s) for the duration of the clinical trial. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care.
- **Objectives, Specific Aims and Hypotheses:** Describe the purpose of the proposed study with detailed objectives. State the hypothesis/research question to be tested in the proposed clinical trial and detail the specific aims that will address the hypothesis/research question.
- **Study Design:** Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations of what study participants will experience. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - Describe the type of study to be performed. Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Describe the interaction with the human subject, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for a person not involved in the study to understand what the study participant will experience.
  - Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s), and follow-up procedures, including, if applicable, the biospecimen that will be collected, the collection schedule and amount. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number of study participants to be enrolled. Indicate whether subjects, clinicians, data analysts and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
  - Define all endpoints/outcome measures relevant to the objectives of the study; explain why they were chosen, and describe how, when and where they will be measured. Include all evaluations that will be made for study purposes. If questionnaires or other research data collection instruments will be used, include

a copy of them in Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected endpoints/outcome measures and evaluations, along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study (or to monitor safety of human subjects).

- Briefly describe the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. Additional details should be provided in Attachment 9: Study Population Recruitment and Safety Plan.

– **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow for a thorough evaluation of statistical calculations during review of the application.

- Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
- 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. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis on sex, race and/or ethnicity as appropriate for the scientific goals of the study. Refer to the CDMRP Directive on the Inclusion of Women and Minorities as Subjects in Clinical Research for additional information on the requirements for phase 3 studies.

– **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).

– **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized 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 (two-page limit per letter is recommended):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work for the duration of the proposed clinical trial. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Patient Advocate Letters of Commitment**: Provide a letter signed by each patient advocate confirming their commitment to participate in the proposed project.
- **Questionnaires and Other Research Data Collection Instruments:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides or other instruments. This should include any drafts that are currently in use or underdevelopment.
- **Research 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 the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

  Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.

  Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

  Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the ideas and rationale behind the proposed clinical trial. State the FY26 PRCRP Topic Area(s) and Strategic Goal the proposed research will address.
  - **Hypothesis/Objective(s):** State the objective of the proposed clinical trial and the hypothesis/research question to be addressed.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Briefly describe the study design, including appropriate controls.
  - **Clinical Impact:** Briefly describe how the proposed clinical trial will have a significant impact on the research field and/or treatment or management of a least one FY26 PRCRP Topic Area(s).
  - **Military Relevance:** Identify the FY26 PRCRP Military Health Focus Area(s) to be studied. Briefly describe how the proposed research is relevant to Service Members, Veterans and other military beneficiaries.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

  - Summarize the objectives and rationale for the proposed clinical trial.
  - State the FY26 PRCRP Topic Area(s) and FY26 PRCRP Strategic Goal the proposed research will address.
  - Describe the intervention(s).
  - What population will the research help, and how will it help them?
  - What are the expected clinical applications and potential risks of the anticipated outcomes?
  - Describe the ultimate applicability and impact of the proposed study and the anticipated outcomes to advancing research, patient care and/or quality of life?
  - State the FY26 PRCRP Military Health Focus Area(s) to be addressed by the proposed research. Describe how the proposed research is relevant to Service Members, Veterans and other military beneficiaries.

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work. Include milestones for data or research resource(s) sharing.

- **Attachment 6: Relevance to Military Health Statement (one-page limit): Upload as "MilHealth.pdf". *Evaluation of the Relevance to Military Health Statement will occur during programmatic review only by the FY26 PRCRP Programmatic Panel.***

- State the FY26 PRCRP Military Health Focus Area(s) to be addressed in the study.
- Based on published literature of the impact of cancer on military populations, articulate the relevance of the research proposed and show how it will decrease the burden of cancer on Service Members, their Families and Veterans.
- If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- Identify the environmental and/or occupational exposure risk factors associated with the FY26 PRCRP Topic Area(s) to be studied and their short- and long-term impact on the basic health, welfare and/or psychosocial wellness of 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 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 Service Members, Veterans and other military beneficiaries.

- **Attachment 7 Impact Statement (two-page limit): Upload as "Impact.pdf".** The impact statement summarizes the potential short- and long-term impact of the proposed clinical trial. The statement should address the points outlined below written ***in a manner that is readily understood by readers without a background in science or medicine.***
  - Summarize the potential benefit(s) of the intervention and/or research outcome of the proposed clinical trial as it relates to the FY26 PRCRP Topic Area(s).
  - State the FY26 PRCRP Strategic Goal(s) the proposed research will address and describe how the outcomes of the clinical trial address the challenge and decrease the burden of cancer on patients and/or caregivers.
  - Detail the anticipated research outcome(s) that will be directly attributed to the results of the proposed clinical trial and describe the anticipated benefits of these outcomes for individuals and the research field. Describe any treatment issues that will be addressed by the proposed clinical trial.
  - Explain the long-range vision for how implementation/dissemination of the intervention and/or research outcome(s) will improve patient care and/or quality of life for the target population. Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
  - Describe any potential challenges that might limit the impact of the proposed clinical trial, including barriers to implementation or acceptance by users.

- **Attachment 8: Patient Advocate Statement (one-page limit): Upload as "PatientAdvocate.pdf".** The PI should write the Patient Advocate Statement. Provide the names of at least two patient advocates and their affiliation with a cancer advocacy organization(s). Describe the integral roles that the patient advocates will play in the planning, design, implementation and evaluation of the research. Describe how the patient advocates' knowledge of current cancer issues and how their background and/or training in cancer research will contribute to the project. Explain how the patient advocates' experience and expertise will be integrated into the research project and management of the collaboration.
- **Attachment 9: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.
  - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data or other relevant considerations. List and describe any evaluations (e.g., laboratory procedures, history or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Describe how the study population represents the population anticipated to benefit from the intervention.
  - **Study Population Availability:** Demonstrate that the research team has access to the proposed study population at each site. Describe the approximate number, pertinent demographic information and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. 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 4, for additional considerations.
  - **Recruitment and Retention Process:** Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail; address who will identify potential study participants, who will recruit them, and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention.

Estimate the potential for participant loss to follow up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.

- **Women and Minorities Recruitment/Retention Strategy:** Describe the strategy for recruitment, enrollment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.
- **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from study participants; include information regarding the timing and location of the consent process. If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. Appendix 6 of the General Application Instructions contains additional considerations unique to DOW-sponsored research.
- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by the human subjects before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.
  - **Risk management and emergency response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the costs of such care.
  - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 10: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.
  - State the product/intervention name.

  For products/interventions that do not require regulation by a Regulatory Agency:

  - Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information about this attachment is required.

  For products that require regulation by a Regulatory Agency:

  - Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product

indication/label. Include, as appropriate, a description of the regulatory application submission strategy.

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States. If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication.
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY26 PRCRP Clinical Trial Award application submission deadline.*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and include an indication to be tested in the proposed clinical trial. Provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission.
- Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research; include key outcomes, action items and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- **Attachment 11: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.
  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers and/or departments, and name each person's position on the project; include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.
  - **Study Personnel Description:** Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.
  - **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than

one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 12: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Discuss the anticipated methods and strategies necessary to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization and/or delivery to the civilian or military market), assuming a positive outcome from the proposed clinical trial. Investigators are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies or investors to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should:***
  - Name the project's anticipated research outcomes including knowledge products and/or clinical products for development. A "knowledge product" is a non-materiel product that aims to transition into medical practice, training, tools or to support materiel solutions; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
  - Include a timeline with defined milestones describing the logical next steps to advance the research outcome to the next stage of clinical development/implementation/dissemination. Include steps regarding Regulatory Agency approval as appropriate.
  - Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are in place or will be established to execute the steps described above. Include a discussion of the funding strategy necessary to transition the research outcome to the next level of investigation, development and/or commercialization. The discussion should include potential opportunities for securing funding through commercial sponsorship, venture capital, federal or nonfederal funding opportunities, or other relevant resources.
  - As appropriate, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. Include a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the applicant, PI or a member of the study team, describe the planned next steps necessary to make the product available to the target population.
- **Attachment 13: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW 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 available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*

4.4. Other Application Elements

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.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526PRCRPCTA from Grants.gov or eBRAP, depending on which submission portal will be used.

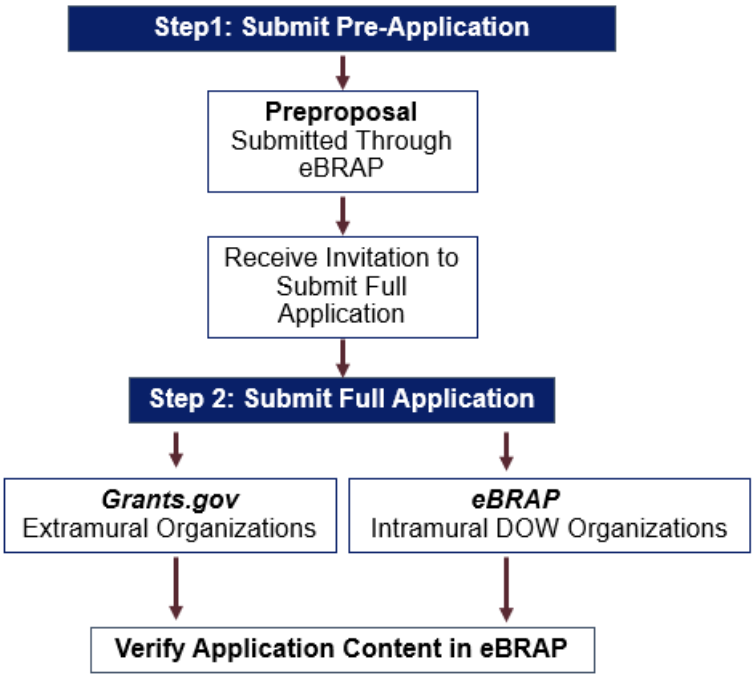
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, 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.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

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 pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify and verify the application in eBRAP. Contact the eBRAP Help Desk if any changes need to be made.

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

- Select the FY26 PRCRP portfolio the proposed research will address.
- Select the primary FY26 PRCRP Topic Area the proposed research will address.
- Select the FY26 portfolio classification and strategic goal to be studied.
- When applicable, the applicant should select a secondary FY26 PRCRP Topic Area. The secondary topic area may be any topic regardless of selected portfolio. Examples include, (not all-inclusive):
    - 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 FY26 PRCRP Military Health Focus Area to be studied.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the 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 in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

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 DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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 the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

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.

Members of the FY26 PRCRP Programmatic Panel must not be involved in any pre-application 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 letters to confirm PI eligibility 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 FY26 PRCRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the merits of the pre-application and the relevance to the mission of the PRCRP, pre-applications will be screened based on the following criteria:

- **Research Idea and Impact**
  - Whether the proposed research will have a significant impact on the treatment or management of cancer within at least one of the FY26 PRCRP Topic Areas.
  - Whether the proposed research will address at least one of the FY26 PRCRP Strategic Goal and to what degree the anticipated outcomes will impact fielded science and patient care.
- **Project Readiness**
  - To what degree the preclinical and/or clinical data supports the proposed clinical trial.
  - Whether the pre-application provides a plan to submit an IND/IDE application (if applicable) for FDA approval by the application submission deadline.
- **Clinical Strategy**
  - Whether the rationale, methodology and experimental design will test the hypothesis and support the specific aims of the project.

- Whether access to the appropriate patient population and intervention has been adequately addressed.

- **Personnel**
  - Whether the biographical sketch demonstrates competency to conduct a clinical trial.
  - Whether letters of support demonstrate commitment of collaborators (i.e., industry partners) to the proposed study, if applicable.
- **Military Relevance**
  - To what degree the proposed research may lead to promising outcomes for one or more of the selected FY26 PRCRP Military Health Focus Areas.

6.2.2. Peer Review Criteria

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

- **Clinical Impact**
  - To what degree the intervention addresses current clinical need(s), improves upon available interventions and/or standards of care, or addresses treatment issues within the field.
  - How impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to the FY26 PRCRP Topic Area(s).
  - If study sex as a biological variable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed clinical trial is supported by the review and analysis of the available literature and completed/ongoing studies.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - How well the specific aims/hypotheses/research question, study design, experimental methods, data collection procedures and evaluations are designed to address the clinical objective and purpose of the study.
  - How well studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
  - To what degree the planned route and schedule of study intervention(s), evaluations(s) and follow-up procedures are reasonable for study participants to experience.
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
  - How well potential challenges and alternative strategies are discussed.
  - If applicable, whether there is evidence indicating availability of the intervention from its source, for the duration of the proposed clinical trial.

- If applicable, whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

- **Regulatory Strategy and Transition Plan**
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight, or that the IND or IDE application (and/or international equivalent) has been submitted to the Regulatory Agency, as appropriate.
  - If applicable, how well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial.
  - If applicable, to what extent the regulatory strategy and product development plan are well described and appropriate to support the product indication or product label change.
  - To what degree the next logical steps to be taken upon successful completion of the proposed clinical trial are realistic and appropriate to bring the research outcome(s) to the next stage of clinical development/implementation/dissemination.
  - To what degree the resources (e.g., clinical practice guideline development/execution committees, training providers/resources) intended to help advance the research outcome(s) are established and/or achievable.
  - To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for.
- **Recruitment, Accrual, Retention**
  - To what degree the plan for recruiting, enrolling and retaining study participants is reasonable to meet the needs of the proposed clinical trial.
  - To what degree the number of study participants to be enrolled is reasonable based upon the proposed timeline, study procedures, available study population, inclusion/exclusion criteria and planned efforts to achieve accrual goals.
  - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
  - Whether the rationales and distribution of the proposed enrollment on the basis of age, sex, race and/or ethnicity is appropriate for the proposed research.
  - To what extent the strategy for recruitment and retention of women and minorities in the clinical trial is appropriate to the objectives of the study.
- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections are adequate to ensure proper power for the study, and as applicable, any subgroup analysis.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single sex study is sufficiently strong.
  - If a phase 3 trial is proposed, whether the plans for the valid analysis of group differences on the basis of sex, race and/or ethnicity are appropriate for the proposed research.

- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - To what degree the process of seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
  - If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.
- **Personnel and Communication**
  - To what degree the composition of the study team, including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate, clinical partners, commercial partners, manufacturing partners), is appropriate to accomplish the proposed work.
  - Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
  - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures, multi-institutional structure governing the research protocol(s) are appropriate and meet the needs of the proposed clinical trial.
  - To what degree the patient advocates' experience and expertise are integrated into the research project and management of the collaboration.
  - How well the patient advocates' knowledge of current cancer issues and how their background and/or training in cancer research will contribute to the project.

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**:

- **Environment**
  - To what degree the scientific environment, clinical setting and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
- **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 peer reviewers
- Relevance to the priorities of the FY26 PRCRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity.
    - Relative clinical care and patient impact.
    - Program portfolio composition.
    - Programmatic relevance to the FY26 PRCRP Military Health Focus Areas.
    - Programmatic relevance to the FY26 PRCRP Strategic Goals as outlined in the FY26 PRCRP portfolio categories.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information About the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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 subject to review and approval by a designated official. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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 the SAM.

An applicant organization may review the 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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW 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.

7. Federal Award Notices

For each compliant 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

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.

The GAI contain information regarding administrative requirements and national policy requirements.

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

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on ClinicalTrials.gov.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) or Ethics Committee (EC) review.

8.2. Reporting

Quarterly and annual technical progress reports, as well as a final technical progress report, will be required. Technical progress reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

Award Expiration Transition Plan: An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

Inclusion Enrollment Reporting: Enrollment reporting on the basis of sex, race and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available in eBRAP.

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

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 the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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.

8.3. Additional Requirements

The PI will be required to present their progress toward accomplishing research milestones and project goals at annual Milestone Meetings. Annual Milestone Meetings will be held at the conclusion of year 1 and may be held each subsequent year of the period of performance; meetings will be held virtually.

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

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

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

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01Td.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

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

- The Project Narrative is missing.
- The Budget is missing.
- Submission of an application for which a letter of invitation was not issued.
- The Study Population Recruitment and Safety Plan (Attachment 9) is missing.
- The Regulatory Strategy (Attachment 10) is missing.
- The Study Personnel and Organization (Attachment 11) is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing 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 FY26 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 pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.

- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The PI does not meet the eligibility criteria.
- The pre-application or application does not address at least one of the FY26 PRCRP Topic Areas.
- The pre-application or application does not address at least one of the FY26 PRCRP Military Health Focus Areas.
- The pre-application or application does not address at least one of the FY26 PRCRP Strategic Goals as outlined in the FY26 PRCRP portfolio categories.
- The application addresses a FY26 strategic goal from a portfolio that does not include the FY26 topic area being addressed.
- The pre-application or application does not adhere to congressional language and includes a cancer that originates in the breast, lung, kidney, pancreas, prostate, ovary, or rare cancers (excluding relevant subtypes of the FY26 PRCRP Topic Areas), or melanoma as part of the research study.
- The proposed research is not a clinical trial.
- The proposed project includes preclinical research.
- An IND or IDE application and/or international equivalent has not been submitted prior to the full application submission deadline for a study regulated by a relevant regulatory agency.
- An investigator may be named as a PI on a single application to this program announcement. If an investigator is named multiple times as a PI, only the first application received will be accepted; additional applications will be administratively withdrawn.

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 DHACA Grants Officer for a determination of the final disposition of the application.

9.2.5. Other Funding Opportunities

The PRCRP is committed to leveraging efforts with other funding organizations to accelerate progress in [issue] research. At the time of funding notifications, the PRCRP may inform highly rated, unfunded applicants about opportunities to provide their PRCRP applications and peer review summary statements to non-governmental and other governmental funders, who will determine the specific criteria for funding consideration.

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"	☐
Patient Advocate Statement – Attachment 8, upload as "PatientAdvocate.pdf"	☐
Study Population Recruitment and Safety Plan – Attachment 9, upload as "StudyPopPlan.pdf"	☐
Regulatory Strategy – Attachment 10, upload as "Regulatory.pdf"	☐
Study Personnel and Organization – Attachment 11, upload as "Personnel.pdf"	☐
Post-Award Transition Plan – Attachment 12, upload as "Transition.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 13, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 14, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐
Research & Related Budget	☐
Project/Performance Site Location(s)	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐

Appendix 2. Acronym List

CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTA	Clinical Trial Award
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MHS	Miliary Health System
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORRC	Office of Research and Regulatory Compliance
PAYAC	Pediatric, Adolescent and Young Adult Cancers
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRCRP	Peer Reviewed Cancer Research Program
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management

SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs