I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Convergent Science Cancer Consortium Award

Announcement Type: Modified

Funding Opportunity Number: HT942524PRCRPCSCCA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 24, 2024
- **Invitation to Submit an Application:** August 29, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 15, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, Oct 22, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** January 2025
- **Invitation for Oral Presentation:** January 2025
- **Programmatic Review, Stage 2:** March 2025

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

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

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

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

II.A.1. FY24 PRCRP Topic Areas

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

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

[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).

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

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

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

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

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

FY24 PRCRP Military Health Focus Areas:

- ***Environmental exposure risk factors associated with cancer***
    - Environmental and/or occupational risk factors should be relevant to activities specific to the military, such as deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.). For more information on military-related exposures and risk factors for cancer, applicants should refer to Exposure-Related Health Concerns at https://www.publichealth.va.gov/exposures/health-concerns.asp or to the PRCRP website (https://cdmrp.health.mil/prcrp/default).
- ***Mission Readiness and Gaps in Cancer Research***
    - Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public.
    - Gaps in quality of life and/or survivorship that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public.

Mission readiness under the FY24 PRCRP Military Health Focus Areas refers to the impact of cancer on the Service Member. Decreasing the impact of cancer on Service Members and/or

their Families protects the overall military mission. Some examples of relevant research to decrease the impact on mission readiness may include, but are not limited to:

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

For more information on military health and cancer:

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

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

II.A.3. FY24 PRCRP Overarching Challenges

The PRCRP developed the Overarching Challenges as a strategy to address multiple issues in cancer research over the spectrum of different cancer topics. These Overarching Challenges are critical gaps in cancer research, care, and/or patient outcomes that, if addressed, will advance mission readiness of U.S. military members affected by cancer and improve quality of life by decreasing the burden of cancer on Service Members, their Families, Veterans, and the American public. Simply identifying an Overarching Challenge is not sufficient. Applications must address at least one of the following Overarching Challenges in a way that can lead to or make a breakthrough and have a major impact. ***The 17 FY24 PRCRP Overarching Challenges are classified in five different categories. The applicant must address at least one of the 17 FY24 PRCRP Overarching Challenges and not just select a category.***

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

- **Diagnostics/Prognostics**
    - Identify approaches to predict treatment resistance, recurrence, and the development of advanced disease.
    - Distinguish unique features driving cancer occurrence across the spectrum of ages.
    - Develop and improve minimally invasive methods for neoplasia detection, initiation, progression, and recurrence.
- **Therapeutics**
    - Transform cancer treatment, especially for advanced, recurrent, and metastatic disease.
    - Improve current therapies including systemic and local treatments.
    - Evaluate disease progression and/or treatment response over time.
    - Leverage the mechanisms of cancer development to improve treatment methods for all communities.
- **Patient Well-Being and Survivorship**
    - Study methods to address survivorship issues, including quality of life, wellness, mental health, psychological impact of recurrence, reproductive/sexual health, and/or disability.
    - Reduce short- and long-term treatment toxicities, including neurocognitive and physical effects.
    - Investigate ways to bridge gaps between treatment and survivorship, including alternative medicine, nutrition and lifestyle factors, and supportive care.
    - Understand and address the immediate and enduring burdens on caregivers, families, and communities.
- **Disparity**
    - Improve prevention strategies, diagnosis, treatment, and outcomes for patients in underserved or under recognized populations.
    - Study methods to improve accessibility to care and address survivorship.
    - Advance health equity and reduce disparities in cancer care, including telehealth.
    - Develop strategies to understand barriers to and improve communication amongst provider, patient, and care network.

II.B. Award Information

The FY24 PRCRP CSCCA supports a transdisciplinary collaboration of scientists, clinicians, and consumer advocates, working to illuminate and address urgent and complex issues of importance in cancer research. This mechanism seeks to promote novel approaches to ending cancer through convergent science cancer research. Convergent science as defined by the National Science Foundation (https://www.nsf.gov/od/oia/convergence/index.jsp) "is a means of solving vexing research problems, in particular, complex problems focusing on societal needs. It entails integrating knowledge, methods, and expertise from different disciplines and forming novel frameworks to catalyze scientific discovery and innovation." Convergent science taps into a variety of disciplines to answer the issues in cancer (i.e., prevention, diagnosis/detection, treatment, quality of life, disparities) including but not limited to biomedical sciences, data science, engineering, psychology, and chemistry. Convergent science breaks down the barriers of cancer research and builds a whole answer with tools from different areas of expertise.

The CSCCA application must identify one of the FY24 Overarching Challenges as a unifying Focal Point for the consortium, and a minimum of three research projects addressing the Focal Point. Additionally, applicants must clearly define how their application investigates at least three different FY24 PRCRP Topic Areas. For example, brain cancer, neuroblastoma, and pediatric brain tumors are three of the FY24 PRCRP Topic Areas and would be acceptable. Three different types of pediatric brain tumors (i.e., pediatric medulloblastomas, diffuse intrinsic pontine glioma, and pediatric astrocytomas) are not considered three different FY24 PRCRP Topic Areas and would not be acceptable. The proposed Convergent Science consortium should demonstrate the potential to catalyze scientific discovery and innovation, significantly advance cancer research, and have a profound positive impact on the lives of cancer patients or those at risk for cancer including Service Members, their Families, other military beneficiaries, and the American public.

Consumer advocates should be integrated into and play an active role in the leadership and decision-making for the consortium. An individual advocate can only serve as an advisor and team member at one Research Site. The advocates must be cancer patients or a caretaker of patients from the FY24 PRCRP Topic Areas, be active in a cancer advocacy organization, and possess a high level of familiarity with current issues in cancer research. The advocates' role should be independent of their employment with a participating institution.

Consortium Structure and Oversight:

The proposed consortium will be comprised of a Coordinating Center that both supports the infrastructure of the consortium and serves as a Research Site, and two additional Research Sites. The Coordinating Center and Research Sites must submit a single application for the FY24 CSCCA. The Coordinating Center Principal Investigator (PI) will submit to the CSCCA as the Initiating PI and the Research Site PIs as Partnering PIs. For individual submission requirements for the Initiating and Partnering PIs refer to Section II.D.2, Content and Form of the Application Submission. The PI and Partnering PIs should have diverse experience in different disciplines and different cancers and be located at different institutions. One of the PIs should have experience in convergent science research. The application should outline a plan for having all

regulatory, material, and intellectual property agreements in place within six months of the start of the award.

Coordinating Center: The Coordinating Center will serve as the consortium information and planning nexus, providing administrative, operational, and data management and other support services to implement consortium studies in a timely manner. It must also serve as a Research Site.

Key Aspects of the Coordinating Center:

- Previous, successful performance in multi-institutional team science.
- Facilitate consortium-wide communications to optimize and accelerate research progress.
- Coordinate the sharing of data, materials, and resources across Research Sites.
- Provide effective, coordinated plans that integrate and optimize the research and collaborations within the consortium.
- Develop standard operating procedures.
- Access to appropriate resources and facilities.
- Other responsibilities to include regulatory coordination and intellectual/material property coordination.

Director of the Coordinating Center (Consortium Director): The Initiating PI should have extensive experience in cancer research, previous experience with collaborative team science, a proven record of leadership, and scientific ability to direct and oversee a multi-institutional research effort. The Initiating PI is responsible for the management of the consortium and is expected to commit and maintain a minimum of 25% of their time to direct and manage the Coordinating Center and the Research Site at the Coordinating Center.

Research Sites: Research Sites should contribute unique research resources and different expertise to the consortium and have a proven record of accomplishment in collaborative team science.

Key Aspects of the Research Sites:

- Should demonstrate access to appropriate resources, biorepositories (if applicable), and cancer patient populations.
- Must generate data and materials as shared resources. Management plans for sharing of resources and data should be clearly explained in detail.
- Research Site PIs are expected to commit at least 10% level of effort to direct and manage the individual Research Sites.
- Each Research Site should include a consumer advocate as a project team member.

Research Projects: Each Research Site, to include the Coordinating Center, must include a proposed project in the application, therefore, a minimum of three research projects must be proposed. Research projects may include bench research, preclinical studies in animal models, translational and clinical research involving human subjects and human anatomical substances, and clinical trials. Projects must demonstrate solid scientific rationale, and applications must include published and/or preliminary data that support the feasibility of their hypotheses and/or approaches.

A portion of the total direct budget costs (no more than 5%) must be reserved to support the "seed projects," i.e., the development of new concepts that emerge during the course of the award. These seed projects should enable the research team to explore new avenues of high-risk/high-reward ideas that were not part of the original application, but that develop during the project and are within the scope of the consortium Focal Point. The Coordinating Center will be responsible for coordinating and funding an external scientific peer review of seed projects proposed for funding during the period of performance.

Steering Committee: The consortium will establish a Steering Committee, to include the Consortium Director as Chair, Research Site PIs and at least one advocate and one expert in military health as members. Military health experts may be active-duty or retired Service Members with experience in military health and cancer, or VA representatives with a deep understanding of military health and cancer. Steering Committee advocates and military health experts may be existing team members at the Research sites or consulting team members. The application should clearly explain how the Steering Committee will monitor the status of ongoing consortium studies and review research progress.

Oversight of the Convergent Science Consortium: Oversight of the consortium will be through an External Advisory Board (EAB). The DOD program office will appoint members to the EAB. The Consortium Director and Research Site PIs must present written and oral briefings to the EAB and DOD program staff at 1-day In-Progress Review (IPR) Meetings held virtually or in-person the National Capital Region. IPR meetings will be held annually or semiannually at the discretion of the government. The EAB will evaluate progress, provide feedback, and recommend actions to be taken as needed to facilitate the success of the consortium.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers:

Clinical trials are allowed under the FY24 PRCRP CSCCA mechanism.

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

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

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human

data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

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

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

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

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2, DOD and VA Websites.

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

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

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment

capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

The types of awards made under the program announcement will be cooperative agreements (31 USC 6305) based on anticipated "substantial involvement" on the part of CDMRP. Substantial involvement includes assistance, guidance, coordination, and/or participation by CDMRP staff in project activities, including but not limited to, participating in the EAB through IPRs and Milestone Meetings wherein CDMRP will evaluate progress, provide feedback, and recommend actions to be taken as needed to facilitate the success of the consortium.

The anticipated direct costs budgeted for the entire period of performance for an FY24 PRCRP CSCCA Award should not exceed **$20M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $32M to fund approximately one Convergent Science Cancer Consortium Award application. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

II.C.1.b. Principal Investigator

- **PI for the Coordinating Center (Consortium Director):**

  To be named as the (Initiating) PI for the Coordinating Center on the application, the Consortium Director must:

  - Be at or above the level of Associate Professor (or equivalent).
  - Commit at least 25% level of effort to direct and manage a project of this magnitude.
  - An investigator may be named as Consortium Director on only one pre-application or full application under this funding opportunity.

- **PIs for the Research Sites:**

  To be named as the Research Site (Partnering) PI on the application, the PI must:

  - Be at or above the level of Assistant Professor (or equivalent).
  - Commit at least 10% level of effort to direct and manage a Research Site.

The Initiating PI or one of the Partnering PIs must have experience in convergent science theory.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

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

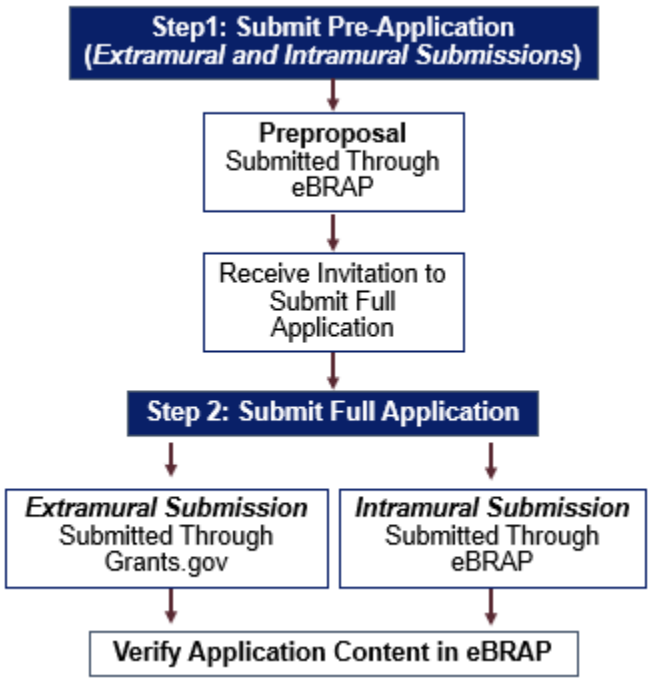
Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

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

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

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

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PRCRPCSCCA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PRCRPCSCCA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

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

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

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

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

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

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

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

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for each Partnering PI.

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 each PI, the Business Official(s), performing organization(s), and contracting organization(s) must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

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

After the Initiating PI confirms submission of the pre-application, the Partnering PIs will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PIs must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PIs must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PIs should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

- The Partnering PIs will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

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

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

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

- **Preproposal Narrative (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:

  - Identify the FY24 PRCRP Overarching Challenge that will be the Focal Point of the consortium and name the three FY24 PRCRP Topic Area(s) to be studied.

- Describe the structure of the proposed consortium including consumer advocate involvement in the consortium.

- Describe how the proposed research projects and convergent science research yield valuable knowledge that addresses the Focal Point and have a profound, positive impact on the lives of cancer patients and individuals at risk for cancer.

- Describe the Initiating and Partnering PIs' experience with cancer research, collaborative team and/or convergent science, and the Initiating PI's record of leadership in a scientific arena.

- Describe how the complementary expertise of the PIs will catalyze scientific discovery, drive innovation, and make breakthroughs that may otherwise be problematic without a convergent science approach.

- Briefly state each project's hypothesis, objectives, and rationale.

- If a clinical trial will be included, briefly describe the study including the intervention, study population, primary endpoints, and phase of the trial. (Refer to the definition of a clinical trial in Section II.B., Award Information).

- Explain how the proposed research will lead to promising outcomes for one or more of the selected FY24 PRCRP Military Health Focus Area(s).

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (five-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the PRCRP, pre-applications will be screened based on the following criteria:

- Whether the proposed consortium addresses at least three FY24 PRCRP Topic Areas and names a single FY24 PRCRP Overarching Challenge as the Focal Point of the consortium.
- To what degree the complementary expertise of the PIs will catalyze scientific discovery, drive innovation, and make breakthroughs.
- Whether PIs have a record of successful collaborative team science and at least one of the PIs has experience in convergent science.
- Whether the projects will yield valuable knowledge that addresses the consortium Focal Point.
- To what degree the proposed research will have a profound, positive impact on the lives of cancer patients and individuals at risk for cancer.
- To what degree the proposed structure of the consortium will meets the intent of the Convergent Science Cancer Consortium Award.
- To what degree the proposed research may lead to promising outcomes for one or more of the selected FY24 PRCRP Military Health Focus Areas.

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

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

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

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

The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI. Each full application package must be submitted using the unique eBRAP log number received by the Consortium Director and Research Site PIs during pre-application submission. ***All associated applications (the Initialing and Partnering PI's) must be submitted by the full application submission deadline***.

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

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

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

II.D.2.b.ii. Full Application Submission Components for the Initiating PI

The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. ***All associated applications (the Initiating PI's and each Partnering PI's) must be submitted by the full application submission deadline.***

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

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

- **Attachments:**

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

  - **Attachment 1: Project Narrative (40-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. Where appropriate, briefly describe the utility of a convergent science approach. ***Additional details on the plans for and utility of a convergent science approach can be provided in Attachment 7: Convergent Science Statement.***

Consortium Focal Point: Identify which FY24 PRCRP Overarching Challenge will be used as a unifying Focal Point for the consortium and at least three FY24 PRCRP Topic Areas to studied. Describe how the Focal Point represents a major hurdle(s) in cancer research that should be urgently addressed. Describe how the consortium's fundamental goals and expected outcomes will advance research and address the consortium's Focal Point. Describe the profound impact the consortium goals and outcomes will have on individuals living with, or at risk for, cancer. Identify the complexities of the Focal Point and briefly describe what advantages are realized using a convergent science approach, especially for problem solving across multiple cancers.

Research Projects: Describe three projects that include a minimum of three different FY24 PRCRP Topic Areas. Start an outline of each project on a separate page:

Title: Provide a title for each project.

Project Leader: Identify the project leader (either the Consortium Director or one of the Research Site PIs) and any key personnel, as appropriate.

Background: Describe in detail the rationale for the study and reasoning on which the proposed research is based. Provide sufficient preliminary data to support the feasibility of the work proposed. The application must demonstrate logical reasoning and provide a sound scientific rationale as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system.

Focal Point: Describe how the research addresses the unifying Focal Point, meets the consortium goals, and benefits from a convergent science approach.

Hypothesis/Objective: State the hypothesis to be tested and/or the objective(s) to be reached.

Specific Aims: Concisely explain the project's specific aims to be funded by this award.

Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. Explain how the project and research strategy will address the Focal Point and meet the consortium goals. Where relevant, describe the accessibility to the data, cohort(s), and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the project. If applicable, describe resources available for the development of sufficient quantities of critical reagents under Good Manufacturing Practice.

Address potential pitfalls and problem areas and present alternative methods and approaches. If proposing translational research, provide a well-developed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be supported and how it will be assured that the documentation will support a regulatory filing with the Food and Drug Administration (FDA), if applicable.

Animal Use: If animal research is proposed, describe how the study is designed to achieve reproducible and rigorous results. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives, and where appropriate, the study's relevance to human biology. Summarize the procedure to be conducted. Describe how the study will be controlled including measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. Provide a sample size estimate for each study arm and the method by which it was derived. Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints.

Human Use in Clinical Research (no intervention): If human subjects or human biological samples will be used for a clinical study, describe access to the study population or the acquisition of samples. Where applicable, describe recruitment plans, inclusion/exclusion criteria and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. Describe the strategy for the inclusion of women and minorities in the study population or biological samples in Attachment 2.

Human Use in Clinical Trials (includes an intervention): If human subjects or human biological samples will be used for a clinical trial(s), provide detailed plans for initiating and conducting the clinical trial during the course of the award using ***Attachment 10: Clinical Strategy Statement***.

Statistical Plan: Describe the statistical model and data analysis plan with respect to the study objectives. If applicable, specify the number of human subjects that will be enrolled. If multiple sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human Anatomical Substances, Databases): If the proposed research plan involves access to active-duty military and/or VA patient population(s) or resource(s), include a letter of support signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

Letters of Collaboration *(if applicable)*: Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

Commercial Entity Letters of Commitment (if applicable): If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the product for the duration of the proposed clinical trial, support for the proposed phase of research, and support for the indication to be tested.

Intellectual Property: Information can be found in the 2 CFR 200.315, "Intangible Property."

- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Commercialization Strategy *(if applicable)*:** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

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

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

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

Use of U.S. Department of Veterans Affairs (VA) Resources *(if applicable)*: Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Inclusion Enrollment Plan (only required if clinical is proposed): Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement**.**

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

  - **Background:** Describe the vision of convergent science and how it will be employed in the unification of different sciences and cancers for a more holistic approach to research.

  - **Consortium:** Describe the proposed general management and organizational structure of the consortium. Outline the management and research expertise of consortium personnel at the Coordinating Center and Research Sites.

  - **Objective:** State the objectives to be reached for each FY24 PRCRP Topic Area under a unifying consortium Focal Point.

  - **Collaboration:** Describe how the proposed collaboration can catalyze scientific discovery, drive innovation, and make breakthroughs that may otherwise be problematic without a convergent science approach.

  - **Impact:** State the FY24 PRCRP Overarching Challenge(s) to be addressed and describe how the Overarching Challenge(s) will act as a unifying focal point for at least three different FY24 PRCRP Topic Areas undertaken by the consortium.

  - **Relevance to Military Health:** Briefly describe how the proposed research is relevant to Service Members, Veterans, and their Families.

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

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

- State the FY24 PRCRP Overarching Challenge that was used as a Focal Point for the consortium and the unifying objective being studied for FY24 PRCRP Topic Areas undertaken by the consortium.
- Describe the vision of convergent science and how it will be employed by the proposed consortium to accelerate progress in cancer research.
- List the different scientific disciplines to be employed and how they will offer a synergistic and holistic approach to ending the suffering from cancer.
- What types of patients will the research help? What are the potential clinical outcomes, benefits, and risks? What is the projected time it may take to achieve a patient-related outcome? What are the likely contributions of this consortium to advancing the vision of the PRCRP to decrease the burden of cancer on Service Members, their Families, Veterans, and the American public through collaboration and discovery?
- Describe how the proposed research will benefit Service Members, Veterans, and their Families.

- **Attachment 5: Statement of Work (six-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

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

  Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and each Partnering PI should be clearly noted for each task.

- **Attachment 6: Impact Statement (two-page limit): Upload as "Impact.pdf".**

  The Impact Statement should be written in a manner that will be readily understood by readers without a background in science or medicine. Describe the importance of the unifying Focal Point, how it represents an urgent problem in cancer research, and identify which FY24 PRCRP Overarching Challenges it was based on. State how the proposed research projects will yield valuable knowledge that addresses the Focal Point. Describe the profound, positive impact the proposed research will have on the lives of cancer patients and individuals at risk for cancer in at least three FY24 PRCRP Topic Areas.

- **Attachment 7: Convergent Science Statement (two-page limit): Upload as "Convergent.pdf".** ***This attachment will be available to programmatic reviewers.***

  Articulate the PIs' vision of convergent science and what it offers toward solving the complexities of cancer research. Describe how the consortium will implement a convergent science approach to address the Focal Point and accelerate advances compared to the research being performed without collaboration. Describe how the knowledge domains of the consortium members strengthen the excellence of the research, catalyze scientific discovery, drive innovation, and accelerate outcomes. Describe the plan to overcome differing ontologies and facilitate communication and interaction among the scientifically diverse consortium members. Describe how the consortium will release information on the utility of convergent science in cancer research to the greater scientific community.

- **Attachment 8: Consortium Personnel and Organization (eight-page limit): Upload as "ConsortiumPlan.pdf".**

  Structure and Management of the Consortium: Describe how the consortium will be organized and managed and how the proposed design will help meet the consortium goals. Describe a management plan to facilitate research group collaborations, adherence to regulatory requirements, and administrative interactions. Describe procedures that maximize the use of resources and eliminate unnecessary duplication of efforts. Specify the processes and tools to be used to achieve consortium management and goals. Articulate how the consortium would prepare for additional Research Sites in the future that may cover different topic areas. Discuss the organization, oversight function, and operation of the Steering Committee and any additional committees or working groups. Include an organizational chart identifying the roles of all team members, including consumer advocates.

  Communication Plan: Describe a plan to manage communication between and among consortium team members and their institutions. Provide a strategy for how data will be shared efficiently and cooperatively among consortium members and identify a role in the Coordinating Center that will maintain the data sharing and communications technologies.

  Consortium Members: Describe how the consortium is composed of an integrated team of accomplished investigators and advocates from appropriate disciplines and institutions. Explain how the consortium brings different disciplines together to address the Focal Point. Describe the Initiating PI's background and experience as an established cancer researcher and leader in a scientific arena and their qualifications to lead the Coordinating Center. Describe the qualifications of the Research Site PIs, consumer advocates, consortium member institutions, and key institutional personnel. Identify the strengths and experiences of personnel and institutions as they pertain to the design, administration, and management of multi-institutional collaborative or convergent science research projects. Briefly describe the role of consumer advocates and how they will represent the perspective of the patient population(s) most relevant to the consortium's proposed work. Describe how the combined expertise of the Consortium Director, each Research Site PI,

and consumer advocates in the consortium will better address the research question and explain why the work should be done together rather than through separate efforts. Provide the level of effort committed by the PIs.

- **Attachment 9: Consumer Advocate Involvement Statement (two-page limit): Upload as "Advocate.pdf".** The Consumer Advocate Involvement Statement should be written by the PI. Provide the name and cancer advocacy affiliation of at least one consumer advocate for each Research Site. Describe experience of the advocate(s) and their expertise as it relates to the FY24 PRCRP Topic Areas under investigation at their respective Research Site, and how their knowledge and background will contribute to the consortium overall. Describe the integral roles that the consumer advocate(s) on the Steering Committee will play in the planning, design, implementation, and evaluation of the research.

- **Attachment 10: Clinical Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required.**

  - Describe the rationale for the proposed clinical trial. Provide a description of the endpoints to be measured. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  - Identify the intervention to be tested and how the proposed intervention compares with currently available interventions and/or standards of care. As appropriate, describe any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications. Provide preclinical and/or clinical evidence to support the safety of the intervention.

  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.

  - Provide detailed plans for initiating the clinical study, including FDA Investigational New Drug/Investigational Device Exemption application submission plans, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

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

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **Attachment 11: Data and Research Resource Sharing Plan (two-page limit): Upload as "Sharing.pdf".** Describe how data and resources generated during the performance of the proposed research projects will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed projects. Specifically describe a plan to make animal models, tissue samples, and other resources developed as a part of the proposed research projects available to the scientific community. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resource sharing plan. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 12: Relevance to Military Health Statement (two-page limit): Upload as "MilHealth.pdf".** ***The Relevance to Military Health Statement will be evaluated by the FY24 PRCRP Programmatic Panel during programmatic review only.***

  - ***Provide the name of at least one expert in military health and DOD or VA affiliations***. Describe the integral roles that the military health expert on the Steering Committee will play in the planning, design, implementation, and evaluation of the research. Describe how the military health expert's knowledge of current cancer issues in the military in the FY24 PRCRP Topic Areas and how their background will contribute to the proposed consortium.

  - State the FY24 PRCRP Military Health Focus Area(s) to be addressed in the study. Based on published literature of the impact of cancer on military populations, articulate the relevance of the research proposed to the Focus Area and show how it will decrease the burden of cancer on Service Members, their Families, and Veterans.

  - 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 their Families.

  - 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 their Families.

- **Attachment 13 Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

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

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

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

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

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

  - **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

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

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

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

  - ***Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as***

separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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

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

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

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

II.D.2.b.iii. Full Application Submission Components for each Partnering PI

The application submission process for each Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

- **Attachments:**

    - **Attachment 5: Statement of Work (six-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.

    - **Attachment 13: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**

    - **Attachment 14: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

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

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

submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".
- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.
  - **Budget Justification (no page limit):** Upload as "BudgetJustification.pdf".

  The initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for each Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions***, for detailed information.***

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

- **Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*:** Refer to the General Application Instructions, Section IV.B.(g), for detailed information.
  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
  - **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 14.

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

Oral Presentation: PIs named in Convergent Science Cancer Consortium Award applications that are selected for final consideration in Stage 2 of Programmatic Review will be required to give an oral presentation (see Section II.E.1.b, Programmatic Review) that will be held virtually and is tentatively scheduled for March 2025. ***Only the invited Initiating and Partnering PIs and one consumer advocate may attend.***

The presentation will consist of the following, with the total presentation time not to exceed 45 minutes:

- A 3- to 5-minute introductory talk by the Consortium Director consisting of no more than five slides.
- A 5- to 7-minute talk, consisting of no more than five slides, by each Research Site PI.
- A 5-minute talk by the consumer advocate consisting of no more than five slides.
- A 5-minute summary presentation by the Consortium Director consisting of no more than five slides.

Following the presentation, there will be a 30-minute question-and-answer session with the Programmatic Panel members. The questions below will be topics for discussion during the presentation and the question-and-answer session. Teams who are invited must prepare a presentation that specifically addresses the following four questions within the total presentation time of no more than 45 minutes, without addressing specific aspects of the application:

- What are the conceptual or intellectual or scientific barriers associated with the Focal Point that you consider most urgent to overcome and how will your consortium address them?
- How will the consortium's convergent science approach accelerate discoveries and advance science and technology in the FY24 PRCRP Topic Areas to be studied?
- How will the consortium make a significant, positive impact on the lives of cancer patients and those as risk of cancer?
- How will the consortium create an environment that fosters innovation?

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

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

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

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

II.D.4. Submission Dates and Times

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **4** years. ***The period of performance is not to exceed 4 years.***

The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **$20M**. 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.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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.

To support the pursuit of innovative ideas, a portion of the total direct costs (no more than 5%) must be reserved in the budget for seed projects to be developed during the project and within the scope of the overall vision of the research. Direct costs for these seed projects should be allocated into the "other direct cost" category of the budget. Funds for seed projects may not be used for equipment or travel.

Research milestones to be accomplished by the end of each year in the period of performance must be clearly defined in the consortium SOW and will be finalized during award negotiations. The Consortium Director and Research Site PIs must present written and oral briefings to the EAB and DOD program staff at 1-day In-Progress Review (IPR) Meetings held virtually or in-

person in the National Capital Region. IPR meetings will be held annually or semiannually at the discretion of the government.

In addition to IPR Meetings, the consortium must hold biannual workshops, which may be held in-person or, if necessary, virtually, to facilitate ongoing communication and exchange of information within the consortium, as well as with advisory board(s) and/or steering committee(s).

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

- Travel costs for the PIs and consumer advocates to present project information or disseminate project results at biannual consortium workshops during the period of performance in years 1, 2, 3, and 4. For planning purposes, it should be assumed that these meetings will be held at one of the PIs' institutions or virtually (if necessary). These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs for Consortium Director, Research Site PIs, and consumer advocates to attend at least one IPR Meeting during the period of performance in years 1, 2, 3, and 4. For planning purposes, it should be assumed that in-person meetings will be held virtually or in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Consortium-related meetings, teleconferences, and travel between/among participating investigators.

- Costs related to identifying and acquiring research resources.

- Computers and software required to participate in the consortium.

- Other costs associated with planning and developing the consortium collaborations, communications, and resources.

- Costs for two investigators per project to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/ technical meetings is to present project information or disseminate project results.

- For projects that include use of human subjects, 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).

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**:

- **Impact**
    - To what degree the proposed research will significantly advance cancer research and have a profound positive impact on the lives of cancer patients or those at risk for cancer.
    - To what degree the consortium demonstrates understanding of novel cancer research and the ability to conduct collaborative, convergent research efforts.
    - Whether the proposed consortium addresses at least three FY24 PRCRP Topic Areas and names a single FY24 PRCRP Overarching Challenge as the Focal Point of the consortium.
    - Whether the Focal Point represents a major hurdle(s) in cancer research that should be urgently addressed.
    - The degree to which the consortium's fundamental goals and expected outcomes will advance research and address the consortium's Focal Point.
- **Convergent Science Strategy**
    - To what degree the convergent science approach described confers an advantage to addressing the Focal Point and an urgent need in cancer research.
    - To what degree the combined knowledge domains of the consortium PIs strengthen the excellence of the research, catalyze discoveries, drive innovation, and accelerate outcomes beyond what could be achieved without collaboration.
    - Whether the application addresses potential issues with communication and interaction among scientifically diverse consortium members.
    - Whether a successful strategy to release information on the utility of convergent science in cancer research to the greater scientific community has been described.
- **Research Strategy and Feasibility**
    - Whether the research projects address at least three different FY24 PRCRP Topic Areas.
    - Whether aims for each project are included and address the Focal Point.

- To what degree the scientific rationale. experimental design, methods, and analyses, including appropriate controls, support the aims of each project.

- If applicable, whether the proposed research using animals meets the regulatory guidelines for appropriateness and robustness of experimental design.

- If applicable, to what extent the human subject population to be studied is appropriate.

- If human subject use is proposed, whether the PI, co-PIs, and/or key collaborators have experience recruiting human subjects for similar projects.

- If applicable, whether the availability of tissue, data, or human subjects for each project is demonstrated.

- To what extent potential problem areas and current alternative methods and approaches are presented for each project and are appropriate.

- Whether the application describes the strategy for the inclusion of women and minorities that is appropriate for the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.

- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity is included, as needed.

- **Consortium Structure and Management**

  - Whether the consortium includes a Coordinating Center with a Research Site and two more Research Sites with at least three different FY24 PRCRP Topic Areas.

  - To what degree the proposed Coordinating Center is capable of providing administrative, operational, and data management and other support services to implement consortium studies and serve as the consortium information and planning nexus.

  - To what degree the proposed organization, management processes, and tools will facilitate research group collaborations, adherence to regulatory requirements, and achieve consortium management and goals.

  - To what degree the plans for communication, decision-making, coordination of research progress and results, and sharing of data and resources among all organizations will achieve consortium management and goals.

  - Whether the application clearly articulates a strategy that maximizes available resources and eliminates duplication of efforts.

  - Whether the Steering Committee structure and operation will provide appropriate oversight function.

- Whether effective plans for assessing the performance of each Research Site have been described.

- Whether the application articulates an effective strategy to add Research Sites that may cover different topic areas in the future.

- **Consortium Members**

  - Whether the Initiating PI's background and experience as an established cancer researcher and leader in a scientific arena qualify them to lead the Coordinating Center.

  - Whether the Initiating PI and Partnering PIs have diverse experience in different disciplines and/or different cancers, are located at different institutions, and have a record of success in convergent and/or collaborative team science.

  - To what degree the PIs, consumer advocates, key personnel, and member institutions contribute to the consortium and the implementation of a convergent science approach to cancer research.

  - Whether Research Site PIs and institutions demonstrate access to appropriate resources, biorepositories (if applicable), and cancer patient populations.

  - Whether the time commitment for the PI and co-PIs is sufficient to build the consortium infrastructure and perform the proof-of-principle research projects.

- **Consumer Advocate Involvement**

  - Whether the application provides the name and cancer advocacy organization(s) of at least one consumer advocate at each Research Site.

  - To what degree the consumer advocates' knowledge and background in the FY24 PRCRP Topic Areas will contribute to the Research Site and the consortium.

  - To what degree the roles of consumer advocates on the Steering Committee are significant in the planning, design, implementation, and evaluation of the research.

- **Clinical Strategy**

  - How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.

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

  - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.

- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity is included.

- For phase 3 clinical trials, whether the application describes plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity that are appropriate for the scientific goals of the study.

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**:

- **Budget**

  - Whether the budget is appropriate for the proposed research.

- **Environment**

  - To what extent the scientific environment is appropriate for the proposed research project.

  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.

  - To what extent the quality and level of institutional support are appropriate for the proposed research project.

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

- **Application Presentation**

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

  - Whether the lay abstract and impact statement were written with clarity for lay persons.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the priorities of the DHP and FY24 PRCRP, as evidenced by the following:

  - **Stage 1:** During the first stage of programmatic review, applications will be selected for oral presentation at the second stage using the following criteria:

    Adherence to the intent of the funding opportunity

Programmatic relevance to the FY24 PRCRP Military Health Focus Areas

Programmatic relevance to at least three different FY24 PRCRP Topic Areas

Programmatic relevance to at least one FY24 PRCRP Overarching Challenge

Relative impact

- **Stage 2 (Oral Presentation):** During the second stage of programmatic review, the following criteria will be used:

  Articulation of how the consortium will have a profound positive impact on the lives of cancer patients or those at risk for cancer.

  Articulation of how the consortium will take a team-based, convergent science approach to research.

  Articulation of how the consortium's fundamental goals and expected outcomes will advance research and address the consortium's Focal Point.

  Articulation of the consortium's potential to foster cross-disciplinary and multi-institutional collaboration and encourage innovation.

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

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

of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

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

The organizational transfer of the Coordinating Center to another institution is not allowed. The transfer of Research Sites is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

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

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

II.F.4. Reporting

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

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

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

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

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

specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds the page limit.
- Preproposal Narrative is missing.
- More than one pre-application is received in which the same investigator is named as the Consortium Director.

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

- Submission of an application for which a letter of invitation was not issued.
- The Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 PRCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 PRCRP Programmatic Panel members can be found at https://cdmrp.health.mil/prcrp/panels/panels24***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government

organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The Initiating or a Partnering PI does not meet the eligibility criteria.
- The pre-application or application does not adhere to congressional language and addresses or includes research focused on cancers that originate in the breast, kidney, lung, pancreas, prostate, ovaries, or on melanoma, glioblastoma, or rare cancers (excluding relevant subtypes of the FY24 PRCRP Topic Areas) as part of the research study.
- The application does not address ***at least three different*** FY24 PRCRP Topic Areas.
- The application does not address at least one of the FY24 PRCRP Military Health Focus Areas.
- The application does not address one of the FY24 PRCRP Overarching Challenges.
- The invited application proposes a different consortium effort than that described in the pre-application.
- The application fails to name at least one consumer advocate per Research Site as required by this program announcement.
- All associated (Initiating and Partnering PIs) applications are not submitted by the deadline.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	Initiating PI	**Partnering PIs**
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work –Attachment 5, upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"		
Convergent Science Statement – Attachment 7, upload as "Convergent.pdf"	☐	
Consortium Personnel and Organization- Attachment 8, upload as "ConsortiumPlan.pdf"		
Consumer Advocate Involvement Statement – Attachment 9, upload as "Advocate.pdf"	☐	
Clinical Strategy Statement – Attachment 10, upload as "Clinical.pdf"		
Data and Research Resource Sharing Plan – Attachment 11, upload as "Sharing.pdf"		
Relevance to Military Health Statement – Attachment 12, upload as "MilHealth.pdf"		
Representations *(Extramural submissions only)* – Attachment 13, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 14, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf)	☐	☐

Full Application Components	Uploaded	
	Initiating PI	**Partnering PIs**
for each senior/key person		
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable)*	☐	☐
Additional Application Components		
Stage 2 Oral Presentation	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CSCCA	Convergent Science Cancer Consortium Award
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
EAB	External Advisory Board
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
IPR	In-Progress Review
IRB	Institutional Review Board
M	Million
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRCRP	Peer Reviewed Cancer Research Program
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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