I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Rare Cancers Research Program

Resource Community Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524RCRPRCDA

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), **June 17, 2024**
- **Invitation to Submit an Application: July 26, 2024**
- **Application Submission Deadline: 11:59 p.m. ET, September 23, 2024**
- **End of Application Verification Period: 5:00 p.m. ET, September 26, 2024**
- **Peer Review: November/December 2024**
- **Programmatic Review: February 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) Rare Cancers Research Program (RCRP) 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 RCRP in 2020 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the RCRP from FY20 through FY23 totaled $60 million (M). The FY24 appropriation is $17.5M.

In FY20, the Defense Appropriations Act provided $7.5M to the Department of Defense (DOD) to support rare cancers research. The rare cancers research Topic Area was first introduced under the Peer Reviewed Cancer Research Program (PRCRP) in FY19. In FY20, the rare cancers Topic Area was excluded under PRCRP by Congress and RCRP was created as an individual program. In addition to the PRCRP, the CDMRP-managed cancer-specific research programs, such as breast, melanoma, glioblastoma, and ovarian cancers have also funded rare cancer subtypes based on their site-specific origin classifications.

FY24 RCRP definition of rare cancers: Cancers affecting 6 or fewer persons per 100,000 per year in the United States. Applicants will be required to provide a justification statement explaining the relevance of the investigated cancer type(s)/subtype(s) that fall under the RCRP's definition of rare cancers.

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

II.A.1. FY24 RCRP Resource Community Development Award Focus Area

To meet the intent of the funding opportunity applications to the FY24 RCRP Resource and Community Development Award (RCDA) must address the following Research Platform Development Focus Area.

Research Platform Development: Develop platforms (such as tumor tissue repositories with clinical annotation, centralized databanks, patient registries with common data structure, research models, "Omics" databases and longitudinal studies of natural history and treatment response) for **type(s) or sub-type(s) of rare cancers** to allow sharing of data, bio-specimens and resources.

II.A.2. Award History

The RCRP RCDA mechanism was first offered in FY20. Since then, 79 RCDA applications have been received, and 12 have been recommended for funding.

II.B. Award Information

The FY24 RCRP RCDA supports the development of clinical or preclinical data sets and research resources that advance the field of rare cancers research and ultimately improve outcomes for individuals with rare cancers. Major gaps in patient care of rare cancers include lack of communication and dissemination strategies for rare cancers research and clinical findings within communities; lack of therapeutics and mechanistic studies to inform treatment development; lack of research and clinical resources, including patient tissues, cell, and tumor models; and lack of infrastructure for sharing data and other resources.

The intent of this funding opportunity is to develop research platforms that can share resources and knowledge pertaining to available preclinical or clinical research models, molecular pathways, and therapeutic approaches to facilitate collaboration and information sharing among stakeholders such as researchers, patients, caregivers, clinicians, and other members of the rare cancers community.

Clinical or preclinical datasets should strive to integrate or develop the following research resources. This list is not all-inclusive:

- Building and sharing rare tumor biospecimen repository with clinical annotation
- Databases/banks for centralizing and sharing data for patient registries that can be accessed globally
- Centralizing and sharing research models and molecular data related to genomics/ transcriptomics/immune profiling/proteomics/metabolomics/methylomics/bioinformatics
- Generating a data/reagent/model exchange program where researchers can list resources that they are willing to share and are tagged with indications that may be relevant
- Platform to enable or leverage longitudinal studies of disease natural history and treatment response
- Development of novel methods and systems for collection, sharing, and analysis of data or biospecimens

Applicants should include a well-formulated project design based on a strong scientific rationale and clearly articulate how the proposed resource platform or community development addresses an unmet need in rare cancers research. Applicants should explain the advantage of their approach to developing resources or community versus standard methodologies, techniques, or scopes. A clear plan for collaboration and data sharing needs to be demonstrated. It is critical to demonstrate how the outcome of the proposed project can benefit type(s) or sub-type(s) of rare cancers. ***It is encouraged for the research platform/resource to have an effect on multiple types or sub-types of rare cancers.***

Key Elements of the Resource and Community Development Award are as follows:

- **Impact:** Outcomes of the RCDA must have potential for major impact on an unmet need in rare cancers research. A resource, as developed in the proposed research, should aim for

long-term anticipated advantages toward greatly improving outcomes for people with rare cancers.

- **Patient Advocate Partnership:** Applications to the RCDA funding opportunity are required to include patient advocates who are involved with patient advocacy organization(s). The research team must include **at least two rare cancers patient advocates who will be early and integral partners** throughout the planning and implementation of the research project. ***Patient advocates should be involved in the development of the research question, project design, oversight, and evaluation, as well as other significant aspects of the proposed project.*** Interactions with other team members should be well integrated and ongoing, and not limited to attending seminars and semi-annual meetings. *The patient advocates must be individuals who have been directly impacted by a rare cancer either by being diagnosed themselves or as a caretaker/family member of a patient, and they should be active in a cancer advocacy organization or within a support group focused on their rare cancer. Their role should be focused on providing objective input on the research and its potential impact for individuals* with or at risk for a rare cancer. The patient advocates should have a high level of understanding of current rare cancers research.

- **Preliminary Data:** Due to the developmental nature of this award, preliminary data are not required but may be included, if available, to address the feasibility of the resource to be developed. Whether or not preliminary data are included, applications must apply solid scientific rationale and logical reasoning based on existing knowledge to the development of the proposed product.

- **Clinical Research:** Research involving human subject use is permitted under this mechanism but is restricted to studies without clinical trials. ***Clinical trials will not be supported***. Applications focused on clinical research should demonstrate how the study will leverage clinical information to address knowledge gaps in the development of platforms that can be utilized for sharing data and tissue, the development of clinical annotation datasets, process development, and/or infrastructure development.

- **Applied Research:** Preclinical studies utilizing or creating animal models to further research into rare cancers may be supported by this funding opportunity. The RCDA is intended to support projects that will have the potential to move beyond the realm of basic research, with results that may impact clinical research or patient outcomes.

- **Community Building:** A plan describing how the rare cancers stakeholder community will be built/enhanced and the community's involvement with developing the resource platform is required. It is also important to justify how the community is essential for the development and sustainment of the resource platform.

- **Dissemination:** A Dissemination Plan is required. The plan should describe the means by which the fully developed resource platform will be made easily available to the scientific and/or clinical community. Dissemination of resource platform will play a major role by not only educating the rare cancer community about the recent progress, but also help to develop an informational network.

- **Sustainment:** A plan that outlines the sustainability of the resource in the future is required. The plan should detail the types of rare cancers that are less studied in the collaborations and the resources to be gathered, annotated, and sustained. Additional expansion and feasibility plans should be included. It is important to demonstrate how the outcomes of the current award will be continued and eventually will help the rare care cancer community, beyond the award period.

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 RCRP priorities.

Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military Families, and the American public.

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

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.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, Nature 490:187-191 (https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the

proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

Clinical trials are not allowed. A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

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

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

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

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 RCRP RCDA should not exceed **$800,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $6.40M to fund approximately five RCDA ***applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the***

government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to be named as Principal Investigator (PI) of an RCRP RCDA application.

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

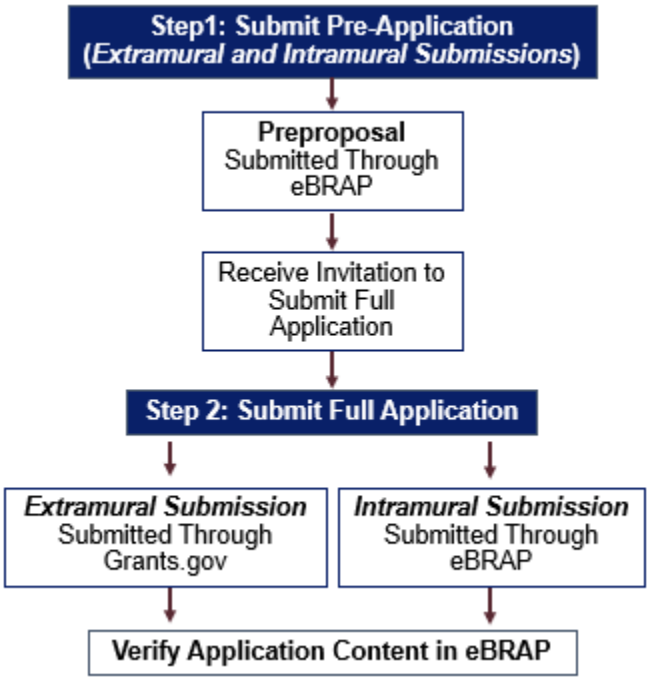
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.

- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

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 HT942524RCRPRCDA 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 HT942524RCRPRCDA 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 RCRP 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/).

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

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

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

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

- **Preproposal Narrative (two-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 (uniform resource locators) 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:

  - Describe the project's hypothesis, objective, rationale, and specific aims. Describe the project design and how that will support the hypothesis and/or objectives of the project. Also describe how the outcome of the project may affect type(s) or sub-type(s) of rare cancers. Preliminary data are not required.

  - Describe how the study will have a major impact on the outcomes of people with rare cancers and the understanding of rare cancers.

  - Briefly describe how the key personnel/collaborators and patient advocates will be integrated into the planning, design, and implementation of the community development process.

- Explain how the study is focused on rare cancers research and how the cancer type(s) or sub-types(s), in the proposed study, falls under the RCRP rare cancers definition.

- **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 RCRP, pre-applications will be screened based on the following criteria:

- How well the project's hypothesis, objectives, rationale, and specific aims are described. To what extent the study design is shown to support the hypothesis and/or objectives of the project. How the outcomes of the proposed study may impact type(s) or sub-type(s) of rare cancers.

- What potential impact the study will have on the outcomes of people with rare cancers, and/or the understanding of rare cancers.

- How well the key personnel/collaborators (including patient advocates) are integrated into the planning, design, and implementation of the community development process.

- To what degree the cancer type in the proposed study meets the definition of the RCRP rare cancers definition.

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.

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

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

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

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

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

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

(b) Attachments:

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

- **Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs 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. Preliminary data are not required but may be included, if available, to address the feasibility of the clinical resource to be developed. Preliminary data, if included, do not necessarily need to be derived from studies of the proposed rare cancer type(s)/subtype(s) under study. Whether or not preliminary data are included, applications must apply solid scientific rational and logical reasoning based on existing knowledge to the development of the proposed product. Applicants should explain the advantage of their approach to developing resources or community versus standard methodologies, techniques, or scopes**. Describe how the outcome of the study may affect type(s) or sub-type(s) of rare cancers.**

- **Background:** Clearly demonstrate a comprehensive understanding of critical barriers and gaps in rare cancers knowledge and communication to be addressed in the project. Present the scientific rationale behind the proposed resource and community, including a critical review and analysis of the literature, relevant preliminary data (if applicable), and the logical reasoning that led to the development of the proposed study.

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

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

- **Clinical Data and Resource Platform Description:** Describe the patient-based data and how outcomes will contribute to a resource platform to be developed and provide a rationale that supports the need for this resource. Describe how the resource platform will be capable of overcoming the obstacles in the care of patients with rare cancers.

- **Community Description:** Describe how the rare cancers stakeholder community will be built/enhanced and how the community's involvement will contribute to developing the resource platform. Also justify how the community is essential for the development and sustainment of the resource platform.

- **Project Design:** Describe the design, methods, and analyses of the technical and organizational platforms in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches, and potential pitfalls. Articulate the type(s) or subtype(s) of rare cancers that will be the focus of the resource. Describe how the data will be collected and analyzed in a manner that is consistent with the study objectives. Describe the methodology to produce Standard Operating Procedures (SOPs) for the community.

    - If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines 2.0 (Animal Research: Reporting of In Vivo Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

- **Data Collection and Statistical Analysis Plan:** Detail a statistical analysis plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the Food and Drug Administration or international regulatory agency, if applicable.

- If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. 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. This award cannot be used to conduct clinical trials.

- **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 (**3-**page limit per letter):** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as

those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)* (3-page limit per letter):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

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

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

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

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

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

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

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

- **Inclusion Enrollment Plan *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service 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:** Present the scientific rationale behind the proposed research project.

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

  - **Resource and Community Description:** Describe the resource platform and community to be developed and provide a rationale that supports the need for this resource community. Describe how the resource platform will be capable of overcoming the obstacles in the care of patients with rare cancers.

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

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

- **Impact:** Summarize the potential impact of the proposed resource platform toward the goal of greatly improving outcomes for people with rare cancers.

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

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

  - Describe the scientific objective and rational for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.

  - Describe the ultimate applicability of the research.

    - What types of patients will it help and how will it help them?

    - What high-impact opportunity or unmet need is addressed?

    - What is the advantage of the proposed resource over existing resources, methodologies, or techniques?

  - What are the likely contributions of this study to advancing rare cancer research?

  - What role will the rare cancer stakeholder community play in the proposed study to develop the resource platform?

  - What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life?

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

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

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** The Impact Statement should be written in plain language for lay persons. Explain in detail why the proposed research project is important, using the following headings:

State explicitly how the proposed work addresses any of the components of the FY24 RCRP's Platform Development Focus Area. Also describe how the outcome of the study may impact **type(s) or sub-type(s) of rare cancers**.

- Describe how the proposed resource platform will address a high-impact opportunity or an unmet need in rare cancers research and/or help to realize improvements in outcomes for people with rare cancers.

- Describe the anticipated long-term gains from the proposed research, including the long-term anticipated advantages toward moving the rare cancers research field forward and/or improving patient outcomes.

- **Attachment 7: Dissemination Plan (one-page limit): Upload as "Dissemination.pdf". ** A robust dissemination plan is required as part of the application. Describe the type of data and/or research resource to be made available to the community as a result of the proposed work. This includes cases where pre-existing data or research resources will be utilized and/or modified during 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 Resources Sharing Plan.

  Articulate the plans to ensure the data and/or research resource(s) is/are accessible after the period of performance expires. Provide a milestone plan for data dissemination.

- **Attachment 8: Sustainment Plan (two-page limit): Upload as "Sustainment.pdf".** Outline potential resources and plans for long-term sustained operations and improvements:

  - Describe processes, partnerships, or agreements for obtaining support for maintenance and sustainment of the dissemination effort beyond the award period.

  - Provide plans for sustainable operations including continual accrual and curation of resources for the state-of-the-science understanding of rare cancers research.

- **Attachment 9: Justification Statement (one-page limit): Upload as "Justification.pdf" (for programmatic review only).**

  - Describe how the cancer type(s) or subtype(s) are defined as rare under the definition of the **RCRP (incidence rate of 6 or fewer persons per 100,000 per year**, including citations on incidence rates, mortality, and status of disease research.

- **Attachment 10: Patient Advocate Engagement Statement (no page limit): Start each component on a new page. Combine into one document and upload as "Advocate.pdf".**

The Patient Advocate Engagement attachment should include the two components listed below.

- **Patient Advocate Involvement Statement:** The Patient Advocate Involvement Statement should be written by the PI. Provide the names of at least two patient advocates participating on the research team and describe their active involvement in a rare cancer advocacy organization(s). Describe the integral roles that the patient advocates will play in the planning, design, implementation, and evaluation of the research from the early stage of the project development. Describe how the collaborative endeavor is critical for the success of the project.

- **Patient Advocate Support Letter(s):** The Patient Advocate Support Letter(s) should be written by the patient advocates participating on the research team. One combined letter written jointly by the patient advocates or individual letters written by each individual patient advocate may be submitted. Clearly describe the proposed collaboration and your support for the proposed project. Describe how your knowledge of current rare cancer issues and how your background will contribute to the project. Describe how your interactions with the PI or other team members will be well integrated and ongoing, and not limited to attending seminars and semi-annual meetings.

- **Attachment 11: Community Organizational Structure (two-page limit): Upload as "CommOrg.pdf".** Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all key personnel and organizations participating in the community. Describe the roles, responsibilities, and intellectual contribution of key stakeholders of the community. Describe how the proposed collaboration involves a substantial contribution by different sites coordinating with each other. Describe the method for instituting SOPs and the handling of intellectual property.

- **Attachment 12: Regulatory Statement (two-page limit), if applicable (for applications recruiting human subjects): Upload as "RegState.pdf".** Outline the processes that will govern legal, ethical, and human subject issues and the use of human biospecimens in research. Describe the appropriate plans for the coordination of regulatory submissions and approvals at participating sites. Discuss the plans for obtaining patient informed consent.

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

- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the

eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

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

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

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

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

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

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

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

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

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 15.

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

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

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

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for three investigators to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the RCRP RCDA.

Must not be requested for:

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

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Impact**
    - How clearly the application articulates the extent to which the proposed research resource platform addresses a high-impact opportunity or an unmet need in rare cancers research, and the underlining importance of realizing improvements in outcomes for people with rare cancers.
    - To what degree the anticipated long-term gains from the proposed research, including the long-term anticipated advantages, will move the rare cancers research field forward and/or improve patient outcome.
    - How explicitly the application states how the proposed work addresses any of the components of the FY24 RCRP's Platform Development Focus Area in Section II.A.1.
    - How the outcome of the proposed study may impact type(s) or sub-type(s) of rare cancers.

- **Project Design**
    - How well the research resource platform/community to be developed is described. How well the scientific rationale supports the objective and the need for the research resource platform and community to be developed or advanced, as well as its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if applicable), and logical reasoning.
    - How well the objectives, aims, experimental design, methods, and analyses, and the data collection and statistical analysis plan (and if applicable a power analysis) are developed and how well they support completion of the aims.
    - Whether the type(s) or subtype(s) of rare cancers that will be the focus of the research resource are identified and appropriate.
    - To what degree the standardization of resource development will serve the community.
    - If animal studies are included, how well they are designed in accordance with the ARRIVE guidelines 2.0 to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
    - If applicable, how well the plan for the recruitment of subjects or the acquisition of samples is justified and appropriate to accomplish the proposed work.
    - How well the application acknowledges potential problems and addresses alternative approaches and potential pitfalls.
    - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- **Personnel**
    - Based on the budget and budget justification, the degree to which the levels of effort by the PI and other key personnel are appropriate to ensure the success of this research effort.
    - Based on the biographical sketch, how well the PI's record of accomplishment demonstrates their potential/ability to accomplish the proposed work.
- **Patient Advocacy Partnership**
    - Whether there is an adequate number of patient advocates involved from the early stage of the project development.
    - How well patient advocates will play an integral role in the planning, design, implementation, and evaluation of the research.

- How well the project utilizes patient advocate partnership to increase its chance for success and maximize impact.

- How well the patient advocates' understanding/knowledge of current rare cancers issues and their background will contribute to the project.

- **Community Organizational Structure**

  - Whether plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all key stakeholders and organizations participating in the community are appropriate.

  - Whether the roles, responsibilities, and contribution of key stakeholders of the community are appropriate.

  - To what extent the method for instituting SOPs is described. Whether the methodology to produce SOPs for the community is appropriate.

- **Dissemination Plan**

  - How well the data and Research Resources Sharing Plan is detailed and effective, including but not limited to:

    - The description of the type of data and/or research resource(s) to be made publicly available.

    - How well the plan for access to data or research resources is detailed.

    - The appropriateness of plans to ensure the data and/or research resource(s) is/are accessible after the period of performance expires.

- **Sustainment Plan**

  - To what extent the application demonstrates commitment to continue the effort following the award period through processes, partnerships, or agreements.

  - To what extent the plan for long-term sustained operations is feasible, including the strategies for continual accrual and curation of resources and research findings that will contribute to a state-of-the-science understanding of rare cancers research.

- **Regulatory Process (if applicable)**

  - How well the application outlines a process that will govern legal, ethical, and human subject issues and the use of human biospecimens in research.

  - Whether there are appropriate plans for the coordination of regulatory submissions and approvals at participating sites.

  - Whether the plans for obtaining patient informed consent are sufficiently developed.

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

- **Budget**
    - Whether the direct costs exceed the allowable direct costs as published in the program announcement.
    - Whether the budget is appropriate for the proposed research.
- **Environment**
    - If applicable, to what degree the intellectual and material property plan is appropriate.
    - To what degree the quality and extent of organizational support are appropriate.
    - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY24 RCRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact
    - Relevance of the study to the FY24 RCRP definition of rare cancers.

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 RCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

Refer to full text of the latest 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 IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

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

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

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.

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

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

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

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

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 RCRP 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 F***Y24 RCRP ***Programmatic Panel members can be found at https://cdmrp.health.mil/rcrp/panels/panels24***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.

- The invited application proposes a different research project than that described in the pre-application.
- The pre-application or application did not address the FY24 RCRP Focus Area of Research Platform Development.
- The cancer or cancer sub-type proposed in the application does not meet the FY24 RCRP definition of rare cancers.
- A clinical trial is proposed.
- At least two patient advocates are not included.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1**,** upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3**,** upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4**,** upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5**,** upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Dissemination Plan – Attachment 7, upload as "Dissemination.pdf"	☐
Sustainment Plan – Attachment 8, upload as "Sustainment.pdf"	☐
Justification Statement – Attachment 9, upload as "Justification.pdf"	☐
Patient Advocate Engagement Statement – Attachment 10, upload as "Advocate.pdf".	☐
Community Organizational Structure – Attachment 11, upload as CommOrg.pdf".	☐
Regulatory Statement, if applicable – Attachment 12, upload as RegState.pdf".	☐
Representations *(Extramural submissions only)* – Attachment 13**,** upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural 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) 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	☐

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

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting of In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PI	Principal Investigator
PRCRP	Peer Review Cancer Research Program
RCRP	Rare Cancers Research Program
SAM	System for Award Management
SOP	Standard Operating Procedures
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