

**Program Announcement for the Department of Defense Defense Health Program** 

# Rare Cancers Research Program Resource and Community Development Award

Funding Opportunity Number: HT942525RCRPRCDA

Pre-Application Due: July 1, 2025

Application Due: October 6, 2025

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# **Before You Begin**

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

# Who to Contact for Support

# eBRAP Help Desk

301-682-5507 help@eBRAP.org

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

## **Grants.gov Contact Center**

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

> Questions regarding Grants.gov registration and Workspace.

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

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# 1. Basic Information About the Funding Opportunity

**Summary:** The fiscal year 2025 (FY25) Rare Cancers Research Program (RCRP) Resource and Community Development Award (RCDA) supports the development of research resources and clinical or preclinical data sets that will advance the field of rare cancers research and ultimately improve outcomes for individuals with rare cancers. Major gaps to be filled by this funding opportunity include:

- Lack of research and clinical resources, including patient tissues, cell, and tumor models.
- Lack of communication and dissemination strategies within scientific and patient communities for sharing rare cancers research and clinical findings.
- Lack of infrastructure for sharing data and other resources.
- Lack of therapeutics and mechanistic research to inform treatment development.

#### **Distinctive Features:**

- Engagement and partnerships with Patient Advocates must be integrated into the project from development of the research question through the execution of the study.
- Community building and enhancement are key components.
- Dissemination and sustainability of the platform for scientific and/or clinical, and patient community must be described.
- Preliminary data not required but may be included to address feasibility.

**Funding Details:** (*New for FY25*) Funding limits are now listed as <u>total cost limits</u>, <u>which is</u> <u>the combination of both direct and indirect costs</u>. The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$5.60 million (M) to fund approximately five Resource and Community Development Award applications with total cost caps of \$1.12M. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

# **Submission and Review Dates and Times**

- Pre-Application (Preproposal) Submission Deadline: 5:00 p.m. Eastern Time (ET), July
   1. 2025
- Invitation to Submit an Application: August 8, 2025
- Application Submission Deadline: 11:59 p.m. ET, October 6, 2025
- End of Application Verification Period: 5:00 p.m. ET, October 9, 2025
- Peer Review: December 2025
- Programmatic Review: March 2026

**Announcement Type:** Initial

Funding Opportunity Number: HT942525RCRPRCDA

**Assistance Listing Number: 12.420** 

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# 2. Eligibility Information

# 2.1. Eligible Applicants

## 2.1.1. Organization

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

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

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

# 2.1.2. Principal Investigator

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.

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

# 2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

### 2.3. Other

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

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# 3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the RCRP. 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 FY24 totaled \$77.5 million (M). The FY25 appropriation is \$17.5M.

In FY20, the Defense Appropriations Act provided \$7.5M to the 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-manages cancer-specific research programs, such as breast, melanoma, and ovarian cancers have also funded rare cancer subtypes based on their site-specific origin classifications.

<u>FY25 RCRP definition of rare cancers: Cancers affecting six or fewer persons per 100,000 per year in the United States</u>. 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 the American public.

# 3.1. Award History

The Resource and Community Development Award mechanism was first offered in FY20. Since then, 104 Resource and Community Development Award applications were received, and 18 were recommended for funding.

### 3.2. Intent of the Resource and Community Development Award

The FY25 RCRP Resource and Community Development Award supports the development of clinical or preclinical data sets and research resources that will advance the field of rare cancers research and ultimately improve outcomes for individuals with rare cancers. Major gaps in patient care for rare cancers to be addressed by this mechanism include:

- Lack of research and clinical resources, including patient tissues, cell, and tumor models.
- Lack of communication and dissemination strategies within scientific and patient communities for sharing rare cancers research and clinical findings.
- Lack of infrastructure for sharing data and other resources.
- Lack of therapeutics and mechanistic research to inform treatment development.

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. It is expected that these platforms will facilitate collaboration and information sharing among stakeholders such as researchers, patients, caregivers, clinicians, and other members of the rare cancers community.

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

- Building and sharing rare tumor biospecimen repository with clinical annotation.
- Developing 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 which are tagged with indications that may be relevant.
- Building a platform to enable or leverage longitudinal studies of disease natural history and treatment response.
- Developing novel methods and systems for collection, sharing, and analysis of data or biospecimens.

It is encouraged for the research platform/resource to have an effect on multiple types or sub-types of rare cancers.

#### 3.2.1. Focus Area for the RCDA

To meet the intent of the funding opportunity applications to the FY25 RCRP RCDA must address the following 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.

### 3.2.2. Key Elements for the RCDA

- 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.

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- Advantage Over Standard Available Resources: Applicants should explain the advantage
  of their approach to developing resources or community versus standard methodologies,
  techniques, or scopes.
- 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 and Dissemination: The fully developed resource platform must be 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:** Sustainability of the resource in the future is an essential component of the RCDA. Plans for sustainability may include the feasibility of additional expansion.

#### 3.2.3. Other Important Considerations for the RCDA

### Clinical trials will not be supported.

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

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

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

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

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- (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.

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. 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 DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, 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.

# 3.3. CDMRP-wide Encouragements

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

VA data suggests that rare cancers are the most prevalent types or sub-types of cancers among the Veteran population. Therefore, the RCRP aims to improve the health, care, and well-being of military Service Members, Veterans, their families, and the American public.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the <u>recommendations</u> and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY25 RCRP priorities.

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

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

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# 3.4. Funding Instrument

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

# 3.5. Funding Details

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

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

**Cost Cap:** The application's total costs budgeted for the entire period of performance should not exceed **\$1.12M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for 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:

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

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# 4. Application Contents and Format

# 4.1. Application Overview

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

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

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

# 4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

• 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:

- Research: 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 subtype(s) of rare cancers. Preliminary data are not required.
- Impact: Describe how the study will have a major impact on the outcomes of people with rare cancers and the understanding of rare cancers.
- Personnel: Briefly describe how the key personnel/collaborators and patient advocates will be integrated into the planning, design, and implementation of the community development process.
- Justification: 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 <u>RCRP rare cancers</u> 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.

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 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.

# 4.3. Step 2: Full Application Components

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

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

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

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

## (b) Attachments:

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

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

Describe the proposed project in detail using the outline below.

- 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. 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.
- 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.
- Advantage: Applicants should explain the advantage of their approach to developing resources or community versus standard methodologies, techniques, or scopes.

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- Clinical Data/Preclinical and Resource Platform Description: Describe the patient-based/preclinical 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. Describe how the outcome of the study may affect type(s) or sub-type(s) of rare cancers.
- 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, 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

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published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Support (Maximum 3-page limit per letter is recommended): Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- Intellectual Property (If applicable): 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.
- Sex as a Biological Variable Strategy (two-page limit is recommended): Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the <a href="CDMRP Directive on Sex as a Biological Variable in Research">CDMRP Directive on Sex as a Biological Variable in Research</a> for additional information.
- Inclusion Enrollment Plan (only required if clinical research is proposed): Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "Public Health Service Inclusion Enrollment Report", a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, 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.

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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 eBRAP for the "Suggested SOW Format".

For the RCDA, refer to either the <u>"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work"</u> or <u>"Example: Assembling a Generic Statement of Work"</u>, whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.

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- 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, addressing the followings:
  - State explicitly how the proposed work addresses any of the components of the FY25 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. How the research could lead to improvements in the health, care and well-being of military Service Members, Veterans, and/or their families.
  - 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.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- 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 six 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".

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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: Animal Research Plan (two-page limit), If applicable: Upload as "AnimalResPlan.pdf". (Attachment 13 is only applicable and required for applications proposing animal studies.) If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting 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 <a href="https://arriveguidelines.org/arrive-guidelines">https://arriveguidelines.org/arrive-guidelines</a>. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:
  - Briefly describe the research objective(s) of the animal study. 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.

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- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- 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, statistical methods for data analysis, and identification of the primary endpoint(s).
- Attachment 14: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 15: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.
- **(c)** Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
  - Biographical Sketch: Upload as "Biosketch\_LastName.pdf".
    - The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.
    - Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in <a href="SciENcv">SciENcv</a> for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).
  - Current/Pending Support: Upload as "Support LastName.pdf".
    - Current and pending (other) support information are used to assess the capacity or any <u>conflicts of commitment</u> that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

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Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in <u>SciENcv</u> for NIH or NSF.

- (e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).
  - Budget Justification (no page limit): For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.
- **(f) Project/Performance Site Location(s) Form:** For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.
  - Extramural Subaward: Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
  - Intramural DOD Subaward: Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

## 4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, <a href="DoD Instructions 3200.12">DoD Instructions 3200.12</a> will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

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# 5. Submission Requirements

# 5.1. Location of Application Package

Download the application package components for HT942525RCRPRCDA from <u>Grants.gov</u> or <u>eBRAP</u>, depending on which submission portal will be used.

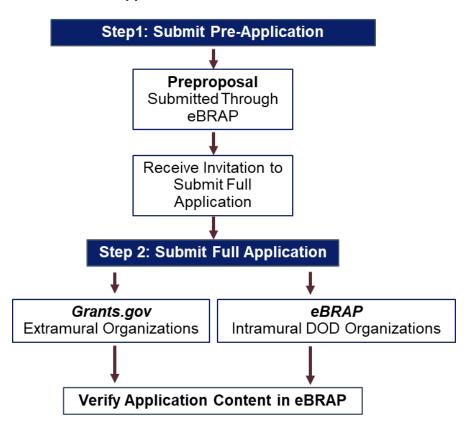
# 5.2. Unique Entity Identifier and System for Award Management

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

### 5.3. Submission Instructions

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

# Application Submission Workflow



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## 5.3.1. Pre-Application Submission

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire preapplication and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If 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, Pls should ensure that they have selected the appropriate "Cancer Type" category. After selecting one of the offered Cancer Types, a textbox will appear where the applicant should enter a specific name for the cancer that will be studied (60-character limit). Pls should also select "age groups".

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

# 5.3.2. Full Application Submission

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

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

### 5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application" Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure the proper ordering as specified in the program announcement. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline. Other application components, including subaward budget(s) and subaward budget 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.

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### 5.4. Submission Dates and Times

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

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

# 5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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# 6. Application Review Information

# 6.1. Application Compliance Review

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

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

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

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

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

#### 6.2. Review Criteria

### 6.2.1. Pre-Application Screening Criteria

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

- Research: 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.
- **Impact**: What potential impact the study will have on the outcomes of people with rare cancers, and/or the understanding of rare cancers.
- Personnel: How well the key personnel/collaborators (including patient advocates) are integrated into the planning, design, and implementation of the community development process.
- **Justification**: To what degree the cancer type in the proposed study meets the definition of the <u>RCRP rare cancers definition</u>.

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#### 6.2.2. Peer Review Criteria

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

#### Impact

- How well 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 well the proposed work addresses any of the components of the <u>FY25 RCRP's</u> Platform Development Focus Area.
- How the outcome of the proposed study may impact type(s) or sub-type(s) of rare cancers.
- If applicable, how well the anticipated outcomes of the proposed study will make an impact in understanding health differences between the sexes.

# Project Design

- How well the research resource platform will address the current challenges of specific types/sub-type of rare cancer(s). 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.
- Whether the approach to developing resources or community has advantage over standard methodologies, techniques, or scopes.
- 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.
- Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single sex study is sufficiently strong.

#### Personnel

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.

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 How well the PI's record of accomplishment demonstrates their potential/ability to accomplish the proposed work.

## Patient Advocacy Partnership

- Whether there are at least two 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 to achieve the objectives of
  the research study.
- 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.
  - The appropriateness of plans to ensure the data and/or research resource(s) is/are accessible to appropriate stakeholders 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.
- o Whether the plans for obtaining patient informed consent are sufficiently developed.

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**:

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## Budget

• Whether the budget is appropriate for the proposed research.

#### Environment

- o 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.

## 6.2.3. Programmatic Review

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

- Ratings and evaluations of the peer reviewers.
- Relevance to the priorities of the FY25 RCRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity.
  - o Program portfolio composition.
  - Relative impact.
  - Relevance of the study to the FY25 RCRP definition of rare cancers.

# 6.3. Application Review and Selection Process

## 6.3.1. Pre-Application

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

### 6.3.2. Full Application

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are 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* 

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**factors as described in Section 6.2.3, Programmatic Review.** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.

# 6.4. Risk, Integrity, and Performance Information

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

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

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## 7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the 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 additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

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# 8. Post-Award Requirements

# 8.1. Administrative and National Policy Requirements

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

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

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

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

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

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

## 8.2. Reporting

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

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

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).

## 8.3. Additional Requirements

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

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

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

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

## 9. Other Information

# 9.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code CD25\_01c. The program announcement numeric version code will match the General Application Instructions version code CD25\_01.

### 9.2. Administrative Actions

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

# 9.2.1. Rejection

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

Preproposal Narrative is missing.

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

- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

#### 9.2.2. Modification

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

#### 9.2.3. Withdrawal

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

- A member of the <u>FY25 RCRP Programmatic Panel</u> is named as being involved in the development or execution of the research proposed or is found to have assisted in the preapplication or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

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- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The invited application proposes a different research project than that described in the preapplication.
- The application does not address the FY25 RCRP Focus Area.
- The cancer or cancer sub-type proposed in the application does not meet the <u>FY25 RCRP</u> definition of rare cancers.
- A clinical trial is proposed.

### 9.2.4. Withhold

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

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

# **Appendix 1. Full Application Submission Checklist**

Grants.gov submissions only   Summary (Tab 1) and Application Contacts (Tab 2)   GeBRAP 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"   Impact 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"   Animal Research Plan (if applicable) - Attachment 13, upload as "AnimalResPlan.pdf"   Representations (Grants.gov submissions only) - Attachment 15, upload as "RequiredReps.pdf"   Suggested Intragovernmental/Intramural Budget Form (if applicable) - Attachment 15, upload as "IgBudget.pdf"   Research & Related Personal Data   Research & Related Personal Data   Research & Related Senior/Key Person Profile (Expanded)   Attach Biographical Sketch for PI and Senior/Key Persons (Biosketch_LastName.pdf)   Attach Current and pending (other) support for PI and Senior/Key Persons (Support_LastName.pdf)   Budget   Include budget justification   Project/Performance Site Location(s) Form   Project/Performance Site Loc	Full Application Components	Uploaded
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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"  Animal Research Plan (if applicable) – Attachment 13, upload as "AnimalResPlan.pdf"  Representations (Grants.gov submissions only) – Attachment 14, upload as "RequiredReps.pdf"  Suggested Intragovernmental/Intramural Budget Form (if applicable) – Attachment 15, upload as "IGBudget.pdf"  Research & Related Personal Data  Research & Related Senior/Key Person Profile (Expanded)  Attach Biographical Sketch for PI and Senior/Key Persons (Biosketch_LastName.pdf)  Attach Current and pending (other) support for PI and Senior/Key Persons (Support_LastName.pdf)  Budget Include budget justification  Project/Performance Site Location(s) Form	Summary (Tab 1) and Application Contacts (Tab 2) (eBRAP submissions only)	
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# Appendix 2. Acronym List

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations
DOD Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

EC Ethics Committee
ET Eastern Time

FAD Funding Authorization Document

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

M Million

MIPR Military Interdepartmental Purchase Request

NSF U.S. National Science Foundation

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

Research Protections)

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

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

RCDA Resource and Community Development Award

RCRP Rare Cancer Research Program

RDT&E Research, Development, Test, and Evaluation
RPPR Research Performance Progress Report

SAM System for Award Management

SciENcv Science Experts Network Curriculum Vitae

SOW Statement of Work

UEI Unique Entity Identifier

URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA U.S. Department of Veterans Affairs