

# **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**

**Concept Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524RCRPCA**

**Assistance Listing Number: 12.420 Military Medical  
Research and Development**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 15, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 26, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 29, 2024
- **Peer Review:** October 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.”*

## TABLE OF CONTENTS

<b>I.</b>	<b>OVERVIEW OF THE FUNDING OPPORTUNITY.....</b>	<b>1</b>
<b>II.</b>	<b>DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY .....</b>	<b>3</b>
II.A.	Program Description.....	3
II.A.1.	FY24 RCRP Focus Areas .....	3
II.A.2.	Award History .....	3
II.B.	Award Information .....	4
II.C.	Eligibility Information.....	6
II.C.1.	Eligible Applicants .....	6
II.C.2.	Cost Sharing.....	6
II.C.3.	Other .....	7
II.D.	Application and Submission Information.....	7
II.D.1.	Location of Application Package .....	7
II.D.2.	Content and Form of the Application Submission .....	8
II.D.2.a.	Step 1: Pre-Application Submission .....	9
II.D.2.b.	Step 2: Full Application Submission .....	10
II.D.2.c.	Applicant Verification of Full Application Submission in eBRAP .....	15
II.D.3.	Unique Entity Identifier (UEI) and System for Award Management (SAM) .....	15
II.D.4.	Submission Dates and Times.....	15
II.D.5.	Funding Restrictions.....	15
II.D.6.	Other Submission Requirements .....	16
II.E.	Application Review Information .....	16
II.E.1.	Criteria .....	16
II.E.2.	Application Review and Selection Process.....	17
II.E.3.	Integrity and Performance Information.....	18
II.F.	Federal Award Administration Information .....	18
II.F.1.	Federal Award Notices .....	18
II.F.2.	PI Changes and Award Transfers.....	19
II.F.3.	Administrative and National Policy Requirements .....	19
II.F.4.	Reporting.....	20
II.G.	Federal Awarding Agency Contacts.....	20
II.G.1.	eBRAP Help Desk .....	20
II.G.2.	Grants.gov Contact Center .....	20
II.H.	Other Information.....	21
II.H.1.	Program Announcement and General Application Instructions Versions.....	21
II.H.2.	Administrative Actions.....	21
II.H.3.	Full Application Submission Checklist .....	24
<b>APPENDIX 1:</b>	<b>ACRONYM LIST .....</b>	<b>25</b>

## 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) is the program management agent for this funding opportunity. Congress initiated the RCRP in 2020 to provide support for research of exceptional scientific merit in the area of rare cancers research. 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 types/subtypes 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 Focus Areas

To meet the intent of the funding opportunity, applications for the FY24 RCRP Concept Award must address at least one of the three Focus Areas listed below:

- **Biology:** Identify disease-defining molecular pathways, cell context, and microenvironment.
- **Research:** Develop and validate rare tumor-specific models that can support clinical trial readiness.
- **Therapy:** Identify novel therapeutic strategies, including drug repurposing.

#### II.A.2. Award History

The RCRP Concept Award mechanism was first offered in FY20. Since then, 475 Concept Award applications have been received, and 60 have been recommended for funding.

## II.B. Award Information

The FY24 RCRP Concept Award supports highly innovative, untested, potentially groundbreaking novel concepts in rare cancers. The Concept Award is not intended to support an incremental progression of an already established research project; instead, it allows Principal Investigators (PIs) the opportunity to pursue serendipitous observations. **Preliminary data are not required.** This award mechanism supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Applications must describe how the new idea will enhance the existing knowledge of rare cancers or develop an innovative and novel course of investigation. Research completed through a Concept Award may generate sufficient preliminary data to enable the PI to prepare an application for future research.

*Reviewers will be blinded to the identity of the Principal Investigator (PI), collaborator(s), and their organization(s).* Refer to [Section II.D.2.b.i., Full Application Submission Type](#), for more information.

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

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, 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 FY24 RCRP Concept Award is designed for preliminary investigations. Research involving human subjects or specimens must be either exempt under 32 CFR 219.104(d) or eligible for expedited review (21 CFR 56.110). Exemption or expedited status is first determined by the Institutional Review Board (IRB) of record. Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt or expedited status. ***Studies that do not qualify for exempt or expedited status will be administratively withdrawn.***

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 Concept Award] should not exceed **\$100,000**. 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 \$2.88M to fund approximately 18 Concept Award 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**

Investigators at or above the level of postdoctoral fellow (or equivalent) are eligible to be named as a PI on an RCRP Concept Award 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

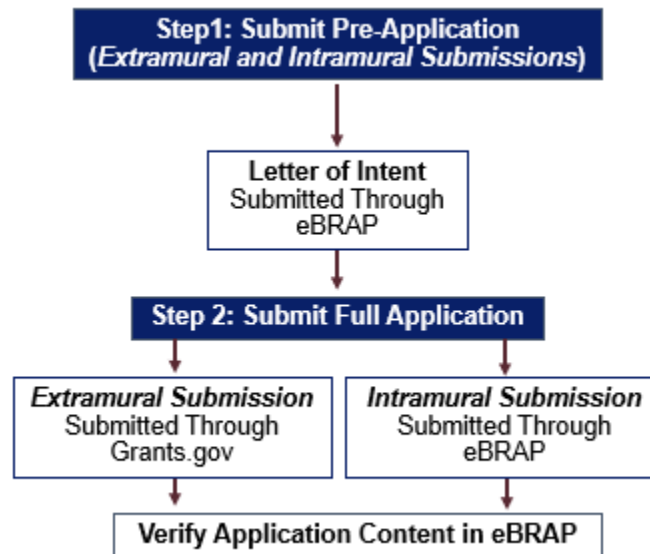
Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission 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:** 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 HT942524RCRPCA 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 HT942524RCRPCA 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](mailto:help@eBRAP.org) or 301-682-5507.

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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

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

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the Focus Area under which the application will be submitted.
- LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

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

### **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**

***Reviewers will be blinded to the identity of the PI, collaborator(s), and their organization(s).*** Due to the blinded nature of the review process, identifying or making references to the PI(s), collaborator(s), or their organization(s) in the Project Narrative, Supporting Documentations, Abstracts, Impact Statement, Intellectual Property form, Justification Statement, and Statement of Work (SOW) is prohibited and will result in administrative rejection of the application. In addition, the use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI(s), collaborator(s), or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, inclusion of URLs (uniform resource locators, or web addresses), or in any other way highlighting the names of the PI(s), collaborator(s), or their organization(s), is prohibited and will result in administrative rejection of the application and preclude invitation to submit a full application.

The following forms **are required** but will not be forwarded for peer review or programmatic review: Research & Related Budget, Research & Related Subaward Budget Attachment(s) Form (if applicable), biographical sketch, previous/current/pending support, and Project/Performance Site Location(s) Form. These documents will be used for administrative purposes only.

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 (two-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.

***Preliminary data are not required.***

Describe the proposed project in detail using the outline below.

- **Rationale:** Articulate clearly the sound scientific rationale that supports the proposed research.
- **Objectives:** State concisely the specific aims and/or study objectives.
- **Methods:** Describe the experimental design, methods, and analyses, including appropriate controls, if applicable. Address potential problem areas and present alternative methods and approaches. Details should include the specific name/genetic background of any/all model systems.
- **Outcomes:** Articulate how the study has the potential to generate preliminary data or findings that can be used as a foundation for the future research projects.

***Due to the blinded nature of the review process, identifying or making references to the PI, collaborator(s), or their organization(s) in the Project Narrative is prohibited and will result in administrative rejection of the application.***

- **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 (five-citation limit):** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full

citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). ***Do not include URLs that identify the PI(s), collaborator(s), or the organization(s) of the PI(s) or collaborator(s).***

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **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. ***Remove this element if there is a data management plan in the other attachments. Please note that data management plan instructions should alignment with the instructions outlined in the General Application Instructions.***

**Not required at time of submission**

- **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.

**Not required at time of submission**

- **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.

Not required at time of submission. Leave Attachment 3 space blank.

- **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.***

Not required at time of submission. Leave Attachment 4 blank.

- **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 Concept Award mechanism, 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.

***Identifying or making references to the PI(s), collaborator(s), or their organization(s) in the SOW is prohibited and will result in administrative rejection of the application.***

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** State how the project will have a major impact on at least one of the [FY24 RCRP Focus Area\(s\)](#). Describe how the proposed research will make an original and important contribution toward advancing basic, translational, or clinical rare cancers research or on improving outcomes for people with rare cancers. Describe how the high risk proposed research project is novel ***in the field of rare cancers***. Proposed research may apply or adapt existing methods or technologies for novel rare cancers research or clinical purposes that differ fundamentally from those originally intended. Provide a brief statement describing the short- and/or long-term impact(s) of this research on the field of rare cancers.

***Due to the blinded nature of the review process, identifying or making references to the PI, collaborator(s), or their organization(s) in the Impact Statement is prohibited and will result in administrative rejection of the application.***

- **Attachment 7: Justification Statement (one-page limit): Upload as “Justification.pdf” (for programmatic review only).** Describe how the cancer or cancer subtype is defined as rare under the definition of the [RCRP \(incidence rate 6 or fewer persons per 100,000 per year\) \(Section II.A\)](#), including citations on incidence rates, mortality, and status of disease research.

***Due to the blinded nature of the review process, identifying or making references to the PI, collaborator(s), or their organization(s) in the Justification Statement is prohibited and will result in administrative rejection of the application.***

- **Attachment 8: 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 9: 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 9.

#### **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 **2** years.

The application’s direct costs budgeted for the entire period of performance should not exceed **\$100,000**. 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 2 years.

For this award mechanism, direct costs:

Must be requested for (not all-inclusive):

- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 RCRP Concept Award.

Must not be requested for:

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

#### **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 **criteria**, which are of **equal importance**:

- **Impact**
  - How well the proposed research addresses at least one of the [FY24 RCRP Focus Areas](#).
  - How the high-risk proposed research project is novel in the field of rare cancers.
  - To what extent the proposed research will, in the short term or long term, lead to an original and important contribution toward advancing basic, translational, or clinical rare cancers research or on improving outcomes for people with rare cancers.
- **Research Strategy and Feasibility:**
  - To what degree the proposed research is supported by a sound scientific rationale.
  - To what degree the experimental design and methodology are appropriate to address the stated specific aims and/or objectives.



- Whether potential problem areas are addressed, and alternative methods and approaches are presented.
- To what extent the research has the potential to generate preliminary data or findings that can be used as a foundation for the future research projects.
- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- **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 priorities of the Defense Health Program and FY24 RCRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact in the field of rare cancers
  - 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>. For this program announcement, reviewers at both tiers of review will be blinded to the identity of the PI, collaborator(s), and their organization(s).

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 (OHARO), 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](mailto: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](mailto: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 full application:

- Pre-application was not submitted.
- 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 FY24 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.
- The PI(s), collaborator(s), or their organization(s) are identified or referenced in the Project Narrative, Supporting Documentations, Abstracts, Impact Statement, Justification Statement, and Statement of Work.
- Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI(s), collaborator(s), or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting (and therefore revealing) the names of the PI(s), collaborator(s), or their organization(s).
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not address at least one of the [FY24 RCRP Focus Areas](#).
- The cancer or cancer subtype proposed in the application does not meet the [FY24 RCRP definition of rare cancers](#).
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- Studies that do not qualify for exempt or expedited status will be administratively withdrawn.

#### **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
<b>SF424 Research &amp; Related Application for Federal Assistance</b> ( <i>Extramural submissions only</i> )	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> ( <i>Intramural submissions only</i> )	<input type="checkbox"/>
<b>Attachments</b>	
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>
Impact Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>
Justification Statement – Attachment 7, upload as “Justification.pdf”	<input type="checkbox"/>
Representations ( <i>Extramural submissions only</i> ) – Attachment 8, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form ( <i>if applicable</i> ) – Attachment 9, upload as “IGBudget.pdf”	<input type="checkbox"/>
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
<b>Research &amp; Related Budget</b> ( <i>Extramural submissions only</i> ) Include budget justification	<input type="checkbox"/>
<b>Budget</b> ( <i>Intramural submissions only</i> ) Include budget justification	<input type="checkbox"/>
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> ( <i>if applicable</i> )	<input type="checkbox"/>



## **APPENDIX 1: ACRONYM LIST**

ARRIVE	Animal Research: Reporting of In Vivo Experiments
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
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PI	Principal Investigator
RCRP	Rare Cancers Research Program
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code