I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Reconstructive Transplant Research Program

Idea Discovery Award

Announcement Type: Initial

Funding Opportunity Number: HT942524RTRPIDA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Prepropposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), August 7, 2024

- **Invitation to Submit an Application:** September 2024

- **Application Submission Deadline:** 11:59 p.m. ET, October 23, 2024

- **End of Application Verification Period:** 5:00 p.m. ET, October 28, 2024

- **Peer Review:** December 2024

- **Programmatic Review:** February 2025

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

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Reconstructive Transplant Research Program (RTRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. The RTRP was initiated in 2012 (FY12) to provide support for research of exceptional scientific merit to refine approaches for, and increase access to, reconstructive transplants and state-of-the-art immunotherapy. Appropriations for the RTRP from FY12 through FY23 totaled $141.0 million (M). The FY24 appropriation is $12.0M.

The RTRP challenges the scientific community to design innovative research that will advance science and standardized clinical practice of vascularized composite allotransplantation (VCA) to improve access, safety, and quality of life for catastrophically injured Service Members, Veterans, and American public. VCA refers to the transplantation of multiple tissues such as muscle, bone, nerve, and skin as a functional unit (e.g., a hand or face) from a deceased donor to a recipient with a severe injury. The ultimate goal is to return injured Service Members to duty and restore their quality of life.

Applications from investigators within the military services and applications involving multi-institutional and multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged.

II.A.1. FY24 RTRP Focus Areas

To meet the intent of the funding opportunity, of the FY24 RTRP Idea Discovery Award mechanism, applicants must address at least one of the FY24 RTRP Idea Discovery Award Focus Areas listed below (select both a bolded Focus Area and the appropriate subtopic):

Improve or optimize VCA immunosuppression.

- Define the unique targets and/or mechanisms of VCA immunogenicity.

- Develop novel tolerogenic agents or approaches for VCA immunosuppression.

- Develop less toxic and/or personalized regimens for maintenance immunosuppression.

Identify and/or validate reliable noninvasive prognostic or diagnostic biomarkers, methods, or tools for monitoring VCA immunosuppression or rejection, including applications that would be suitable for point-of-care testing or home monitoring.

- Identify and/or validate reliable noninvasive biomarkers for monitoring acute and chronic VCA graft rejection in the clinic (i.e., human clinical samples).

- Develop assays, devices, or technology for clinical graft monitoring utilizing biomarkers; proposed devices should take into account human use factors unique to VCA recipients.

- Identify and/or validate reliable noninvasive approaches to measuring/monitoring in vivo/clinical immunosuppression levels.

Advance tissue preservation strategies.

- Develop promising static preservation strategies, active perfusion modalities, or other preservation technologies for translation to the clinic.

- Develop mitigation strategies of preservation-mediated injury, including immune activation or ischemia reperfusion injury in VCA.

II.A.2. Award History

The RTRP Idea Discovery Award mechanism was first offered in FY15. Since then, 71 Idea Discovery Award applications have been received, and 21 have been recommended for funding.

II.B. Award Information

The FY24 RTRP Idea Discovery Award is intended to support *innovative, untested, high-risk/ potentially high-reward concepts, theories, paradigms, and/or methods* relevant to reconstructive transplant. The outcome of research supported by this award should be the generation of robust data that can be used as a foundation for new avenues of scientific investigation.

Important aspects of this award mechanism include:

- **Innovation:** The proposed project should be novel and innovative. Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. If the proposed project is building upon established research performed in solid tissue organs, there must be justification for how the proposed theory is novel. Research that is an incremental advance upon published data or a logical progression of an already established research project is not considered innovative and will not be considered for funding under this award mechanism.

  Important Note: Leveraging novel findings from solid organ transplant research for testing in a VCA setting is acceptable if the rationale and benefits for doing so are appropriately explained and justified. For example, it should be clear why the anticipated result might be different in VCA, or why it's important to confirm the result is the same in VCA, or why repeating the study in a VCA setting could lead to new mechanistic insights or a better understanding of unique aspects of VCA.

- **Hypothesis and Rationale:** The proposed research project should include a well-formulated testable hypothesis based on strong scientific rationale and study design. If a model system is included in the research, it should be appropriate for the study and applicable to VCA.

- **Preliminary Data:** Inclusion of *preliminary and/or published data that support the scientific rationale or evidence that the proposed work can be completed are required;* however, the proposed work should be innovative and untested.

- **Impact:** Applications **must** address at least one of the [FY24 RTRP IDA Focus Areas](). The anticipated outcome(s)/product(s), including material and/or knowledge products, should be clearly articulated, as should the anticipated long-term gains from this research trajectory.

- **Military Relevance:** All projects should be responsive to the health care needs of military Service Members and/or Veterans recovering from traumatic injury, and/or their Family members, caregivers, or clinicians, as well as the general public. Collaboration with military researchers and clinicians is encouraged.

Advancing Women's Health Research and Innovation: The 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. The RTRP therefore encourages research that addresses how various aspects of reconstructive transplant affect women uniquely, disproportionately, or differently from men.

Rigor of Experimental Design: 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 (http://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.

Use of Department of Defense (DOD) or VA Resources: Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

For research involving animals, human subjects, human anatomical substances, or human cadavers, please see to the General Application Instructions, Appendix 6, for more information.

Because the FY24 RTRP Idea Discovery Award is designed for preliminary investigations, *projects involving human subjects or anatomical substances will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 104(d) (32 CFR 219.104[d]) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110.* Studies that do not qualify for exempt status or expedited review will be administratively withdrawn and will not be funded. Therefore, *clinical trials are <u>not</u> allowed under this funding opportunity. 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 is allowed under this funding opportunity. 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.

In-Progress Review: The RTRP holds annual In-Progress Review meetings in a virtual setting as a forum for award performers to present progress updates to the Programmatic Panel and RTRP staff. Award recipients may receive an invitation to present their project at one of these meetings during the period of performance of their award.

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

The anticipated total costs budgeted for the entire period of performance for an FY24 RTRP Idea Discovery Award should not exceed **$500,000**. 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 $2.5M to fund approximately five Idea Discovery 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-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 non-academic equivalent) are eligible to be named as the Principal Investigator (PI) on an application.

There are no limitations on the number of applications for which an investigator may be named as a PI; however, the RTRP strongly encourages PIs to focus on the quality of their applications rather than quantity.

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
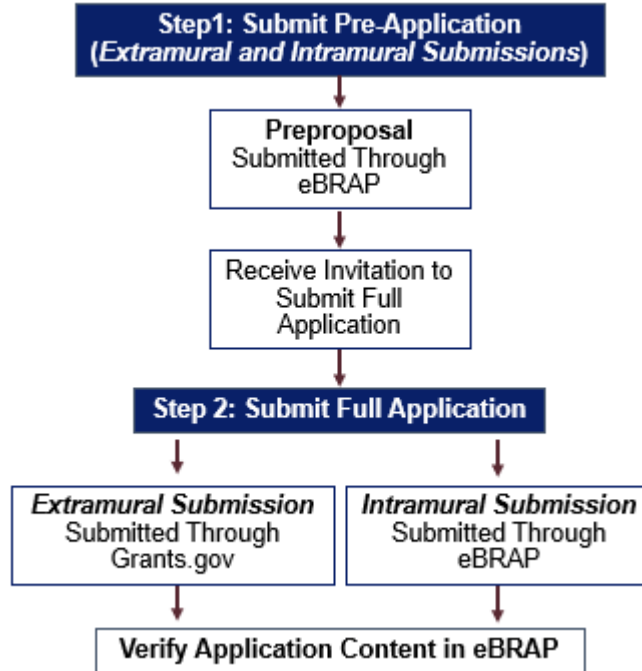
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524RTRPIDA 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 HT942524RTRPIDA 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 the 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 RTRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/).

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

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

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

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

- **Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs 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:

- ○ **Hypothesis/Background:** State the hypothesis to be tested and concisely describe the new concept, theory, paradigm, and/or method that addresses an important problem in reconstructive transplantation.

- ○ **Rationale:** Concisely state the rationale for the proposed research and explain how it supports the hypothesis. If leveraging findings from solid organ transplant research for testing in a VCA setting, briefly explain the rationale and benefits of doing so.

- ○ **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the scientific approach and how it will accomplish the study aims. Include a description of controls, as appropriate. Include any relevant literature citations that support this approach. If utilizing a model system, explain how the model is appropriate for the study and applicable to VCA. If addressing women's health research, describe how the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently from men.

- ○ **Innovation:** Describe how the proposed research is innovative (e.g., proposes new concepts, theories, or paradigms; challenges existing paradigms; looks at existing problems from new perspectives and/or methods; etc.) and has the potential to reveal new avenues for investigation in reconstructive transplantation.

- ○ **Impact and Focus Area(s):** Describe how the proposed research addresses at least one of the FY24 RTRP Idea Discovery Award Focus Areas. Describe the anticipated outcomes(s)/products(s) (including materiel and knowledge products) from this research (short-term impact), as well as the anticipated long-term gains from this research trajectory (long-term impact). Articulate how this research is part of the path toward practical applications in individuals recovering from traumatic injury.

- ○ **Military Relevance:** Describe how the proposed research project would impact health care needs of military Service Members and/or Veterans recovering from traumatic injury, and/or their Family members, caregivers, or clinicians, as well as the general public.

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

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

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

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

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

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

- **Hypothesis/Rationale:** How well the background and scientific rationale supports the hypothesis for the proposed research project. Whether there is an appropriate explanation for leveraging findings from solid organ transplant research for testing in a VCA setting (if applicable).

- **Specific Aims and Study Design:** How well the specific aims are stated and the approach is supported through scientific rationale and referenced literature, and how well the proposed research project's approach will address these aims. If a model system is proposed, whether it is appropriate for the study and applicable to VCA. If addressing women's health research, how well the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently from men.

- **Innovation:** To what extent the proposed research is innovative (e.g., proposes new concepts, theories, or paradigms; challenges existing paradigms; looks at existing problems from new perspectives and/or methods; etc.) and has the potential to reveal new avenues of investigation in reconstructive transplant research.

- **Impact and Focus Area(s):** How well the proposed research addresses at least one of the FY24 RTRP Idea Discovery Award Focus Areas and will lead to practical applications in individuals recovering from traumatic injury.

- **Military Relevance:** How well the proposed research would benefit the health care needs of military Service Members and/or Veterans recovering from traumatic injury, and/or their Family members, caregivers, or clinicians, as well as the general public.

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

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

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

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

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

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

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

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

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

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

(b) Attachments:

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

○ **Attachment 1: Project Narrative (five-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.

- **Hypothesis/Background:** State the hypothesis to be tested, and concisely describe the new concept, theory, paradigm, and/or method that addresses at least one of the FY24 RTRP Idea Discovery Award Focus Areas.

- **Rationale:** Concisely state the rationale for the proposed research and explain how it supports the hypothesis. If leveraging findings from solid organ transplant research for testing in a VCA setting, briefly explain the rationale and benefits of doing so. Inclusion of preliminary and/or published data to support the rationale or evidence that the proposed work can be completed is required (however, the proposed work should be innovative and untested). If utilizing a model system, explain how the model is appropriate for the study and applicable to VCA. If addressing women's health research, describe how the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently from men.

- **Specific Aims/Study Design:** State the project's specific aims and describe the study design and how it will accomplish the study aims. If the proposed work is part of a larger study, then present only tasks that would be funded under this FY24 RTRP award.

  - Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of appropriateness and feasibility.

  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints.

  - Describe the statistical plan and rationale for the statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, as applicable. Include any plans for blinding and randomization.

  - Address potential problem areas and present alternative methods and approaches.

  - If animal studies are proposed, briefly describe the key elements of the study/ studies as they relate to the overall project; detailed information is required in Attachment 9, Animal Research Plan. Describe the availability of and access to the animal model proposed.

  - If human subjects or anatomical substances are proposed, verify that the project is exempt under 32 CFR 219.104(d) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110. Provide evidence in Attachment 2: Supporting Documentation.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures,

tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

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

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

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

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

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

- **Evidence of Exempt Status (if applicable):** Provide evidence in the form of a statement, letter, or institutional policy document that the proposed research involving human subjects or anatomical substances is exempt under 32 CFR 219.104(d) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110.

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

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

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

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

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

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

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

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

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

– **Hypothesis/Background:** State the hypothesis to be tested and concisely describe the new concept, theory, paradigm, and/or method that addresses an important problem in reconstructive transplantation.

– **Rationale:** Concisely state the rationale for the proposed research and explain how it supports the hypothesis. If leveraging findings from solid organ transplant research for testing in a VCA setting, briefly explain the rationale and benefits of doing so. If utilizing a model system, explain how the model system is appropriate for the study and applicable to VCA. If addressing women's health research, describe how the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently from men.

– **Specific Aims/Study Design:** State the project's specific aims and describe the study design and how it will accomplish the study aims State the specific aims of the study.

– **Innovation:** Describe how the proposed research is innovative (e.g., proposes new concepts, theories, or paradigms; challenges existing paradigms; looks at existing problems from new perspectives and/or methods; etc.) and has the potential to reveal new avenues for investigation in reconstructive transplantation.

– **Impact:** Describe how the proposed research addresses at least one of the [FY24 RTRP Idea Discovery Award Focus Areas](#). Describe the anticipated outcome(s)/product(s) from this research as well as the long-term gains from this research trajectory, including how this research is part of the path toward practical applications in individuals recovering from traumatic injury.

– **Military Relevance:** Describe how the proposed research project would impact health care needs of military Service Members and/or Veterans recovering from traumatic injury, and/or their Family members, caregivers, or clinicians, as well as the general public.

○ **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.***

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. Minimize the use of acronyms and abbreviations, where appropriate. Lay abstracts should be written using the outline below.

- Clearly describe the objectives and rationale for the application in a manner readily understood by readers without a background in science or medicine.

- Identify the FY24 RTRP Idea Discovery Award Focus Area(s) to be addressed.

- Describe the innovative aspects of the proposed research.

- Describe the ultimate impact of the proposed research. The following questions may be helpful in generating your description:

  - What types of patients will the research help, and how will it help them? Include the current available statistics to the related injury/condition.

  - What are the potential clinical applications, benefits, and risks?

  - What is the projected time it may take to achieve a patient-related outcome?

- Briefly describe how the proposed project will benefit Service Members and/or Veterans recovering from traumatic injury, and/or their Family members, caregivers, or clinicians, as well as the general public.

- What are the likely contributions of the proposed research to advancing the field of reconstructive transplant research

○ **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 Statement of Work (SOW) format and recommended strategies for assembling the SOW.

  For the Idea Discovery Award mechanism, refer to the "Suggested SOW Strategy Generic Research" document for guidance on preparing the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

○ **Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf".** Describe how the proposed research is innovative in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways. Explain how exploring the concept may lead to new areas of research. Describe how the proposed research represents more than an incremental advance beyond ongoing research and published data and will move rare cancers research in a new direction. If leveraging findings from solid organ transplant research for testing in a VCA setting, briefly explain the rationale and benefits of doing so.

o **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf".**
Describe how the proposed research is relevant to at least one of the [FY24 RTRP Idea Discovery Award Focus Areas](). Detail the anticipated outcome(s)/product(s), including material and/or knowledge products, which will be directly attributed to the results of the proposed research project (short-term impact). Compare the anticipated outcomes from the proposed project to material and/or knowledge products already available, if applicable. Describe the anticipated long-term gains from this research trajectory. Articulate how this research is part of the path toward practical applications in individuals recovering from traumatic injury.

o **Attachment 8: Military Relevance Statement (one-page limit): Upload as "MilRel.pdf".** Demonstrate how the proposed research is responsive to the health care needs and quality of life of military Service Members and/or Veterans recovering from traumatic injury, and/or their Family members, caregivers, or clinicians, as well as the general public. If the active-duty military, Veteran, or military Family member or caregiver population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population is relevant to a military population. If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest.

o **Attachment 9: Animal Research Plan, if applicable (five-page limit): Upload as "AnimalResPlan.pdf".** 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 https://arriveguidelines.org/arrive-guidelines. 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.

– Describe and confirm the availability of and access to the animal model proposed. Include alternate strategies should access to the animal model become restricted or limited.

– 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 10: 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 11: Suggested Intragovernmental/Intramural Budget Form** *(if applicable)***: Upload as "IGBudget.pdf".** If an [intramural DOD organization](https://ebrap.org/eBRAP/public/Program.htm) 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 (six-page limit):** Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

○ **Key Personnel Biographical Sketches (six-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.

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

o **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 11.

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 total costs budgeted for the entire period of performance should not exceed **$500,000**. 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:

- Travel costs for the PI to present project information or disseminate project results at a DOD-sponsored meeting (e.g., Military Health System Research Symposium) during the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.

- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the RTRP Idea Discovery Award.

Must not be requested for:

- Clinical trial costs

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Innovation**

  - To what extent the proposed research is innovative (e.g., proposes new concepts, theories, or paradigms; challenges existing paradigms; looks at existing problems from new perspectives and/or methods; etc.) and has the potential to reveal new avenues of investigation in reconstructive transplant research.

  - How the proposed research represents more than an incremental advance on previous work (either the applicant's work or published data).

- **Hypothesis and Rationale]**

  - How well the background and scientific rationale supports the hypothesis for the proposed research.

  - Whether there is an appropriate explanation for leveraging findings from solid organ transplant research for testing in a VCA setting (if applicable).

  - How well preliminary data support the scientific rationale for the proposed research.

  - If a model system is proposed, whether it is appropriate for the study and applicable to VCA.

  - If addressing women's health research, how well the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently from men.

- **Study Design**

  ○ How well the specific aims are stated and supported through scientific rationale and referenced literature, and how well the proposed research project's study design will address these aims.

  ○ To what degree the statistical plan and power analysis are appropriate for the proposed project, as applicable.

  ○ How well the application acknowledges potential problems and addresses alternative approaches.

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

  For applications involving animal research:

  ○ How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.

  ○ How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

  ○ Whether the application has described the availability and accessibility of the proposed animal model.

  For applications involving human subjects or human anatomical substances:

  ○ Whether the proposed research protocol is exempt under 32 CFR 219.104(d) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110, as evidenced by supporting documentation.

  ○ The degree to which the plan to study human subjects and/or human anatomical substances is designed to achieve the objectives and is appropriate and feasible, including demonstrated access to the selected population(s) or resource(s).

  For applications involving military or Veteran populations:

  ○ The degree to which the plan to study military or Veteran populations is appropriate and feasible, including demonstrated access to the selected population.

- **Impact**

  ○ How well the proposed research addresses at least one of the [FY24 RTRP Idea Discovery Award Focus Areas](#).

  ○ How the anticipated outcome(s)/product(s) from this research will impact the reconstructive transplant community in the short-term.

- ○ How the long-term gains from this research trajectory will lead to toward practical applications in individuals recovering from traumatic injury.

- **Personnel**

  - ○ How the background and expertise of the PI and key personnel demonstrate their ability to perform the proposed work.

  - ○ How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed research project.

  - ○ Whether the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Budget**

  - ○ Whether the **total** costs exceed the allowable total costs as published in the program announcement.

  - ○ Whether the budget is appropriate for the proposed research.

- **Environment**

  - ○ Whether the scientific environment is appropriate for the proposed research project.

  - ○ Whether the research requirements are supported by the availability and accessibility to facilities and resources (including collaborative arrangements).

  - ○ Whether the quality and extent of organizational support are appropriate for the proposed research project

- **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 DHP and FY24 RTRP, as evidenced by the following:

  ○ Adherence to the intent of the award mechanism

  ○ Program portfolio composition

  ○ Programmatic relevance to FY24 RTRP Idea Discovery Award Focus Areas.

  ○ Relative innovation, impact and military relevance

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's

integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

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

II.F.4. Reporting

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

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

Award Expiration Transition Plan: 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 $10.0M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

> Phone: 301-682-5507

> Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

> Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.

- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY24 RTRP 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 RTRP Programmatic Panel members can be found at https://cdmrp.health.mil/rtrp/panels/panels24.***

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The invited application proposes a different research project than that described in the pre-application.

- Inclusion of projects involving human subjects or anatomical substances that do not qualify for exempt status under 32 CFR 219.104(d) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110.

- A clinical trial is proposed.

- The PI does not meet the eligibility criteria.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Innovation Statement – Attachment 6, upload as "Innovation.pdf"	
Impact Statement – Attachment 7, upload as "Impact.pdf"	
Military Relevance Statement – Attachment 8, upload as "MilRel.pdf"	☐
Animal Research Plan– Attachment 9, upload as "AnimalResPlan.pdf"	
Representations *(Extramural submissions only)* – Attachment 10, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 11, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDA	Idea Discovery Award
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PI	Principal Investigator
RPPR	Research Performance Progress Report
RTRP	Reconstructive Transplant Research Program
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs
VCA	Vascularized Composite Allotransplantation