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

Qualitative Research Validation and Implementation Award

Announcement Type: Initial

Funding Opportunity Number: HT942524RTRPQRVIA

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), October 9, 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 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 Qualitative Research Focus Areas

To meet the intent of the FY24 RTRP Qualitative Research Validation and Implementation Award mechanism, applicants must address one or both of the FY24 RTRP Qualitative Research Focus Areas listed below:

- **Validation of resources developed through previous qualitative studies (e.g., information materials, websites, clinical tools, etc.) related to:**
    - A patient's decision to pursue VCA
    - Optimization of patient selection for VCA
    - Increased VCA organ donation
    - Quality of life outcomes and outcome measures for VCA

- **Research of methods and best practices for effective dissemination and/or implementation of validated resources for VCA into clinical practice, health policy, or everyday use**

II.A.2. Award History

The RTRP Qualitative Research Award mechanism was first offered in FY16. Since then, 27 applications have been received, and 9 have been recommended for funding. Qualitative research applications have also been accepted and funded through other RTRP award mechanisms. This is the first time the Qualitative Research Validation and Implementation Award has been offered.

II.B. Award Information

The intent of the FY24 RTRP Qualitative Research Validation and Implementation Award mechanism is to support the continued investigation and further expansion of highly impactful resources for the VCA community that were developed through RTRP-funded qualitative research studies. These resources may benefit individuals throughout the VCA community, including those who are considering or who have already received reconstructive transplant surgery, as well as caregivers, potential donors and their families, and clinicians. The RTRP recognizes that these resources are not yet deployable products and require further research to ready them for clinical and community use. Proposed studies should expand previously funded qualitative research for the purposes of validating a VCA resource and/or investigating the most appropriate and effective methods and best practices for disseminating and/or implementing the resource. ***Important Note: This award mechanism is intended to support validation and implementation research, but not the costs of implementation itself.***

Qualitative research is a form of social inquiry that focuses on understanding how people interpret and make sense of their experiences and the world in which they live. Observations that drive a research idea may be derived from basic discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. Qualitative research is intended to be exploratory, open-ended, and unbiased. The information gathered should be meaningful and culturally appropriate to the participant, unanticipated (not hypothesis-based) by the research team, and rich and explanatory in nature.

Implementation science is defined as the scientific study of methods and strategies to adopt and integrate evidence-based health interventions, resources, etc., into clinical and community settings in order to improve patient outcomes and benefit population health. Implementation research may use a variety of qualitative and quantitative research methods to determine the most appropriate and effective way to transition interventions, resources, etc., into clinical practice, health policy, or everyday use. The research should be specific to the target population and environment and consider real-world factors and complexities, including an evolving landscape.

Important aspects of this award mechanism include:

- **Qualitative Approach:** The research approach should include primarily qualitative methods. Qualitative findings may lead the research in a more quantifiable direction, in

which case a mixed methods approach is acceptable. The specific theoretical basis (e.g., interactionism, phenomenology, critical theory) for the study should be stated and should drive the framing of the research problem.

- **Preliminary data (required):** Applications must include an Outcomes Statement (Attachment 9), which is a summary of the research previously funded, and a description of the research accomplishments, outcomes, and resource(s) developed from that award. Applications should provide an explanation of how these accomplishments, outcomes, and resource(s) provide the basis for the proposed research and how expansion of the original research ideas will address one or both of the FY24 RTRP Qualitative Research Focus Areas.

- **Study Design:** The proposed study design, sampling technique, data collection, and recording method(s) should be appropriate to yield trustworthy, credible, robust, and confirmable results. The documentation of procedures, decisions, and rationale for decisions and conclusions should support consistency, dependability, and duplicability of results and prevent biases and preconceptions. The data analysis plan should be consistent with the research problem and theoretical basis for the study, and ongoing feedback from participants should be incorporated throughout the project, especially regarding interpretation of data and study conclusions. It should be clear how the proposed study design will position the resource(s) for the next phase of development or implementation as described in the post-award Implementation Plan (Attachment 10).

- **Impact:** The short- and long-term impact of the proposed research should be clearly articulated. Projects must address one or both of the FY24 RTRP Qualitative Research Focus Areas.

- **Military Relevance:** All projects must 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, but not required.

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.

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, VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must

describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

Clinical trials are not allowed 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.

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

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

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

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

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

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

The anticipated total costs budgeted for the entire period of performance for an FY24 RTRP Qualitative Research Validation and Implementation 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 $500,000 to fund approximately one Qualitative Research Validation and Implementation Award application. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any

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

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or non-academic equivalent) are eligible to be named as a Principal Investigator (PI).

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

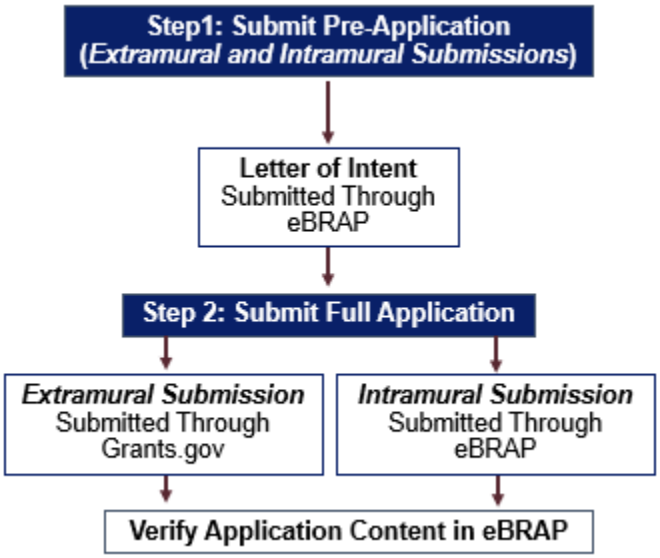
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the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

HT942524RTRPQRVIA 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 HT942524RTRPQRVIA 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

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 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

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

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

(b) Attachments:

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

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

  Describe the proposed project in detail using the outline below.

  - **Background/Research Problem/Rationale:** Identify the research problem to be addressed and discuss why it is important. Briefly describe the previous qualitative research study and the key research outcomes and resource(s) that resulted from that work (a more detailed description is to be provided in Attachment 9, Outcomes Statement). Explain how the proposed study will advance the resource(s) developed in the previous work toward validation and/or implementation into clinical practice, health policy, or everyday use. State the theoretical basis for the study; it should be clear how this drives the framing of the research problem. Explain why a qualitative approach is appropriate to address the research problem. Describe how the research team's previous experience in qualitative research will facilitate the successful completion of the project. If addressing women's health research, describe how the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently than men. ***Preliminary and/or published data relevant to the previous study's outcomes and resource(s) are required.***

  - **Objective(s):** State the objective(s) to be reached.

  - **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. If the proposed work is part of a larger study, then present only tasks that would be funded under this FY24 RTRP Qualitative Research Validation and Implementation Award.

  - **Study Design and Feasibility:** Describe the overall study design and explain how it is appropriate for either validation of previous resource(s) or for implementation research to prepare the resource(s) for advancement into clinical practice, health policy, or everyday use. It should be clear that the proposed research is exploratory and unbiased. If the methods will evolve from and be informed by the research itself, describe the method(s) used to maintain the rigor of these processes. Ensure that all interview questions and questionnaires are open-ended so that participants can respond in their own words and elaborate as needed. If a mixed-methods approach is used, clearly explain how the components interrelate and are appropriate for the

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

The following important components of qualitative research should be addressed:

- **Data Collection:** Describe the proposed methods for sampling, collection, interviewing, and recording documentation in sufficient detail for analysis. Discuss how these methods are systematic, rigorous, and appropriate to address the qualitative research questions. If methods will evolve from and be informed by the research itself, describe how the rigor of these processes will be maintained. Describe and articulate specific benchmarks to ensure the research is progressing in an efficient, timely, and thorough manner. Describe how the collected data will be stored and managed in a way that is appropriate for human subjects research, with consideration of human subjects protection, confidentiality, any data ownership and sharing issues, etc.

- **Subject Recruitment:** Include a detailed plan for the recruitment of subjects. Describe the target population, how it differs from or is similar to the population used in the previous work, and why it is appropriate for the current study. Demonstrate access to that population, provide a table of anticipated enrollment counts for each study site, and describe the efforts that will be made to achieve accrual goals. Discuss past efforts in recruiting human subjects from the target population, including any challenges encountered, mitigation strategies utilized, and ultimate enrollment success, if applicable. Address any potential barriers to accrual in the proposed study and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment. Identify other ongoing studies that may compete for the same patient population and how they may impact enrollment progress.

    - If applicable, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

    - If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- **Data Analysis:** Describe the data analysis plan for the proposed research as well as the plan for developing the rules for coding, if applicable, and discuss how these methods are appropriate to the proposed research. Describe the process for

obtaining ongoing feedback from participants, especially with respect to interpretation of data and study conclusions. Describe how the analyses are systematic, rigorous, and appropriate to address the qualitative research questions.

- **Credibility:** Describe how the plan for documenting procedures, interviewing, developing the rules for coding, making decisions and conclusions, including the rationale for the decisions and conclusions made, supports consistency, dependability, and duplicability of results. Describe the steps that will be taken to control biases and preconceptions. Explain how the project's proposed design and analyses will yield trustworthy, credible, and confirmable results.

- **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.

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

  - **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.

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

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

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

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

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities

and/or research participants. Refer to the 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 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.

  - **Background/Research Problem/Rationale:** Identify the research problem to be addressed and discuss why it is important. Briefly describe the previous qualitative research study and the key research outcomes and resource(s) that resulted from that work. Explain how the proposed study will advance the resource(s) toward validation and/or implementation into clinical practice, health policy, or everyday use. State the theoretical basis for the study; it should be clear how this drives the framing of the research problem. Explain why a qualitative approach is appropriate to address the research problem. If addressing women's health research, describe how the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently than men.

  - **Objective(s):** State the objective(s) to be reached.

  - **Specific Aims/Study Design:** State the specific aims of the proposed research project and briefly describe the study design and type(s) of analyses.

  - **Impact:** Briefly describe the short- and long-term impact of this study on reconstructive transplant research, patient care, and/or quality of life, including the impact on one or both of the FY24 Qualitative Research Focus Areas.

- **Military Relevance:** Briefly explain how the proposed project will have immediate or potential long-term benefit for 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.

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

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

  - 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 Qualitative Research Focus Area(s) to be addressed.

  - Describe the ultimate applicability and impact of the research.

    - 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 Qualitative Research Validation and Implementation Award, refer to the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe the potential short- and long-term impact of this study on the field of reconstructive transplant research, patient care, and/or quality of life. Describe how the resource(s) being advanced through this research will support the VCA community, which includes individuals who are considering or who have already received reconstructive transplant surgery, as well as their families, caregivers, clinicians, and potential donors and their families. Address the impact on one or both of the FY24 RTRP Qualitative Research Focus Areas.

- **Attachment 7: 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 an active-duty military, Veteran, or military Family Member or caregiver population will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, access to and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates or is relevant to the military population. If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest.

- **Attachment 8: Questionnaires and Other Data Collection Instruments, if applicable (no page limit): Upload as "Questionnaires.pdf".** A copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments should be included in this attachment. For each instrument, describe how the information collected is related to the objectives of the study. Describe the PI's prior experience using the proposed data collection tools and the psychometrics previously generated from their use.

- **Attachment 9: Outcomes Statement (two-page limit): Upload as "Outcomes.pdf".**

  - Provide the award identification number, fiscal year, project title, and award mechanism of the previously funded research that provides the foundation for the proposed project.

  - Describe the objectives and specific aims of the previously funded qualitative research study.

  - Describe the research accomplishments, outcomes (publications, patents, etc.), and resource(s) that resulted from the previous work.

  - Explain how the new proposed study will advance the resource(s) developed in the previous work toward validation and/or implementation into clinical practice, health policy, or everyday use.

- **Attachment 10: Implementation Plan (three-page limit): Upload as "Implement.pdf".** Provide information on the methods and strategies to deliver the resource to the VCA community. As appropriate, applicants are encouraged to work with

their organization's Technology Transfer Office (or equivalent) to develop the implementation plan. The plan should include the components listed below, as appropriate:

- Describe the next steps to implement the resource in real-world settings.
- Identify and describe potential barriers (including acceptance) to successful implementation.
- If applicable, discuss ownership rights and/or access to the intellectual property necessary for the implementation of resources supported with this award and the government's ability to access such resources in the future.
- As applicable, provide a risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 11: 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 12: 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 (six-page limit):** Upload as "Biosketch_LastName.pdf".
- **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.

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

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/ Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

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 **3** 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 **3** 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. For budgetary purposes, it should be assumed that this will occur in year 2. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Research subject compensation and reimbursement for study-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation)
- Clinical research costs
- Travel costs for one investigator to travel to one scientific/technical meeting(s) 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 FY24 RTRP Qualitative Research Validation and Implementation 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 of equal importance:

- **Research Problem**
    - Whether the research problem is identified, and its importance explained.
    - Whether the previous qualitative research study and the resulting key research outcomes and resource(s) are described and supported by preliminary data.
    - How well the proposed study will advance the resource(s) developed in the previous work toward validation and/or implementation into clinical practice, health policy, or everyday use.
    - How clearly the theoretical basis for the study is stated and is shown to drive the framing of the research problem.
    - How a qualitative approach is appropriate to address the research problem.
    - How well the research team's previous experience in qualitative research will facilitate the successful completion of the project.
    - If addressing women's health research, how well the project will investigate an aspect of reconstructive transplant that affects women uniquely, disproportionately, or differently than men.
- **Study Design and Feasibility**
    - How well the study design is appropriate for either validation of the previous resource(s) or for implementation research to prepare the resource(s) for advancement into clinical practice, health policy, or everyday use.

- Whether the proposed research is exploratory and unbiased.
- Whether the study is designed to maintain rigor of the processes.
- Whether any interview questions and questionnaires are open-ended.
- If a mixed-methods approach is proposed, how well the various components are interrelated and appropriate for the study.
- How well potential problem areas are addressed, and alternative methods and approaches are presented.
- **Data Collection**
  - How well the proposed methods for sampling, collection, interviewing, and recording documentation are systematic, rigorous, and appropriate for the study.
  - How well specific benchmarks will ensure the research is progressing in an efficient, timely, and thorough manner.
  - How appropriate the plans are for storage and management of collected data for human subjects research with consideration of human subjects protection, confidentiality, data ownership and sharing, etc.
- **Subject Recruitment**
  - The degree to which the subject recruitment plan is appropriate for the study, including the target population, access to the population, anticipated enrollment numbers, strategy for achieving accrual goals, acknowledged barriers, and mitigation plan for slow or low enrollment.
  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research, if applicable.
  - The degree to which the plan to study military or Veteran populations is appropriate and feasible, including demonstrated access to the selected population, if applicable.
- **Data Analysis**
  - The degree to which the data analysis plan is appropriate for the project, including plans for developing the rules for coding, and the process for obtaining ongoing feedback from participants, as applicable.
  - How well the proposed methods for data analysis are systematic, rigorous, and appropriate to address the research questions.

- **Credibility**
  - How well the plan for documenting procedures, interviewing, developing the rules for coding, and making decisions and conclusions (including the rationale) supports the consistency, dependability, and duplicability of results.
  - How well any biases and preconceptions are controlled.
  - How well the project's proposed design and analyses will yield trustworthy, credible, and confirmable results.

- **Implementation Plan**
  - Whether the identified next steps to implement the resource(s) are realistic and achievable.
  - How well potential barriers to successful implementation and approaches to overcome those barriers are identified and described.
  - Whether the potential risk analysis for cost, schedule, availability, and sustainability is realistic and reasonable, if applicable.
  - If applicable, how well the application identifies intellectual property ownership, and demonstrates the appropriate access to all intellectual property rights to the resource(s).
  - If applicable, how well the application describes an appropriate intellectual and material property plan among participating organizations.
  - If applicable, how well the application addresses any impact of intellectual property issues on resource implementation and the government's ability to access such resource in the future.

- **Impact**
  - How well the proposed research addresses one or both of the Qualitative Research Focus Areas, addresses a critical problem, and will make important short-term and long-term impacts to reconstructive transplant research, patient care, and/or quality of life.
  - How well the resource(s) being advanced through this research will support the VCA community, which includes individuals who are considering or who have already received reconstructive transplant surgery, as well as their families, caregivers, clinicians, and potential donors and their families.

- **Personnel**
  - How appropriate the relevant education, training, and experience of the PI and other key personnel are to accomplish the proposed project.

- How well the PI's record of accomplishment demonstrates their ability to accomplish the proposed research project.
- To what extent the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what extent the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **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 RTRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Programmatic relevance to the FY24 Qualitative Research Focus Areas
  - Relative 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 Institutional Animal Care and Use Committee, 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 (RPPR).

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than

$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

After receipt of pre-applications or 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 LOI 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 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 PI does not meet the eligibility criteria.
- A clinical trial is proposed.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact – Attachment 6, upload as "Impact.pdf"	☐
Military Relevance Statement – Attachment 7, upload as "MilRel.pdf"	
Questionnaires – Attachment 8, upload as "Questionnaires.pdf"	
Outcomes Statement – Attachment 9, upload as "Outcomes.pdf"	
Implementation Plan – Attachment 10, upload as "Implement.pdf"	
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 12, 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
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
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
QRVIA	Qualitative Research Validation and Implementation Award
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	U.S. Department of Veterans Affairs
VCA	Vascularized Composite Allotransplantation