

# **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**

**Advanced Technology Development Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-22-RTRP-ATDA**

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

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

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 27, 2022
- **Invitation to Submit an Application:** August 2022
- **Application Submission Deadline:** 11:59 p.m. ET, October 19, 2022
- **End of Application Verification Period:** 5:00 p.m. ET, October 24, 2022
- **Peer Review:** December 2022
- **Programmatic Review:** February 2023

*This program announcement must be read in conjunction with the General Application Instructions, version 702. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

## TABLE OF CONTENTS

<b>I. OVERVIEW OF THE FUNDING OPPORTUNITY .....</b>	<b>1</b>
<b>II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY .....</b>	<b>3</b>
II.A. Program Description .....	3
II.A.1. FY22 RTRP Advanced Technology Development Award Focus Areas .....	3
II.A.2. Award History .....	4
II.B. Award Information.....	4
II.C. Eligibility Information.....	7
II.C.1. Eligible Applicants.....	7
II.C.2. Cost Sharing.....	8
II.C.3. Other.....	8
II.D. Application and Submission Information .....	8
II.D.1. eBRAP and Grants.gov .....	9
II.D.2. Content and Form of the Application Submission .....	9
II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM).....	29
II.D.4. Submission Dates and Times .....	29
II.D.5. Funding Restrictions .....	30
II.D.6. Other Submission Requirements.....	32
II.E. Application Review Information.....	32
II.E.1. Criteria.....	32
II.E.2. Application Review and Selection Process .....	36
II.E.3. Integrity and Performance Information .....	36
II.E.4. Anticipated Announcement and Federal Award Dates .....	37
II.F. Federal Award Administration Information .....	37
II.F.1. Federal Award Notices .....	37
II.F.2. Administrative and National Policy Requirements.....	38
II.F.3. Reporting .....	38
II.G. Federal Awarding Agency Contacts .....	39
II.G.1. eBRAP Help Desk .....	39
II.G.2. Grants.gov Contact Center .....	39
II.H. Other Information .....	40
II.H.1. Program Announcement and General Application Instructions Versions.....	40
II.H.2. Administrative Actions .....	40
II.H.3. Application Submission Checklist.....	43
<b>APPENDIX 1: ACRONYM LIST.....</b>	<b>45</b>
<b>APPENDIX 2: DOD AND VA WEBSITES .....</b>	<b>47</b>

## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2022 (FY22) Reconstructive Transplant Research Program (RTRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The RTRP was initiated in 2012 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 FY21 totaled \$117 million (M). The FY22 appropriation is \$12M.

The RTRP challenges the scientific community to design innovative research that will optimize form, function, appearance, and psychosocial health for catastrophically injured Service Members, Veterans, and American civilians through the development of effective reconstructive transplantation solutions. More specifically, the RTRP seeks vascularized composite allotransplantation (VCA)-focused research, also known as composite tissue allotransplantation. 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.

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

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

#### **II.A.1. FY22 RTRP Advanced Technology Development Award Focus Areas**

To meet the intent of the FY22 RTRP Advanced Technology Development Award mechanism, applicants must address at least one of the FY22 RTRP Advanced Technology Development Award Focus Areas listed below (select both a bolded Focus Area and the appropriate subtopic):

##### **Advance existing tissue preservation strategies to extend the timeline between procurement and transplantation**

- Develop promising approaches and technologies for translation to the clinic, including, but not limited to, perfusion, hypothermic, high-subzero and low-subzero, or static preservation strategies

- Determine the extent to which VCA tissue preservation technology impacts VCA immunogenicity

**Advance reliable non-invasive prognostic/diagnostic biomarkers, methods, or tools for monitoring VCA graft rejection, including applications that would be suitable for point-of-care testing or home monitoring**

- Validate reliable non-invasive biomarkers for monitoring acute and chronic VCA graft rejection in a human model or banked human specimens and medical records
- Develop assays or devices for clinical implementation of graft monitoring utilizing validated biomarkers

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

The RTRP Advanced Technology Development Award mechanism was first offered in FY16 as the Technology Development Award. Since then, 31 applications have been received, and 6 have been recommended for funding.

## **II.B. Award Information**

The FY22 RTRP Advanced Technology Development Award is intended to support research critical for the translation of promising preclinical findings into products focused on reconstructive transplantation.

Important aspects of this award mechanism include:

- **Study Design and Feasibility:** The proposed study design should be clearly described, rigorous, well-integrated, and support maximal reproducibility and translational feasibility. A statistical plan with appropriate power analysis should be included, if applicable. It should be clear how the proposed study design of this project will position the product for the next phase of development as described in the post-award Transition Plan ([Attachment 9](#)).
- **Impact/Military Relevance:** The short- and long-term impact of the proposed research should be clearly articulated. Projects *must* address at least one of the FY22 RTRP Advanced Technology Development Award Focus Areas listed in [Section II.A.1](#) above. All products to be developed must be responsive to the healthcare 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 and VA researchers and clinicians is encouraged but not required.
- **Transition Plan:** The post-award Transition Plan ([Attachment 9](#)) should include potential funding and resources and show how the product will progress to the next level of development (e.g., clinical trials, delivery to the military or civilian market) after the successful completion of this award. A regulatory strategy as applicable to the proposed research/product should also be included.

- **Preliminary Data:** Proof of concept demonstrating potential utility of the proposed product, or a prototype/preliminary version of the proposed product, must already be established. *Preliminary and/or published data that are relevant to reconstructive transplantation, and that support the rationale for the proposed study, **must** be included (these data may be unpublished if from a member of the research team, or from the published literature).*

Proposed research and products to be developed may be materiel products such as drugs, biologic agents, or devices, or knowledge-based products such as technical reports and clinical practice guidelines that inform clinical/operational decisions and promote evidence-based changes in clinical practice and standard of care. Proposed research may include preclinical studies in animal models, human subjects, human anatomical substances, as well as correlative studies associated with an existing clinical trial.

*Clinical trials are not allowed under this funding opportunity. A clinical trial is defined* as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

*Clinical research is defined* as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. **Note:** Studies that meet the requirements for Institutional Review Board (IRB) Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

**Multiple PI Option:** The Advanced Technology Development Award includes an option for more than one PI. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). All PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Initiating and Partnering PI(s), refer to [Section II.D.2, Content and Form of the Application Submission](#).

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding

agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated total costs budgeted for the entire period of performance for an FY22 RTRP Advanced Technology Development Award will not exceed **\$1M for Single PI applications and \$1.5M for Multiple PI Option applications**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information refer to [Section II.F.1, Federal Award Notices](#).

*The CDMRP expects to allot approximately \$3.5M to fund approximately three Advanced Technology Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific 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 FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.*

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. Allow up to 3 months to complete the HRPO regulatory review and approval process following submission of *all required and complete* documents to the HRPO. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research involves more than one institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. (Note: foreign organizations and foreign public entities are exempt from this requirement). The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

**Use of DOD or VA Resources:** If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA 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. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

**Research Involving Animals:** All research funded by the FY22 RTRP Advanced Technology Development Award involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

**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 preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](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. Projects that include research on animal models are required to submit [Attachment 8](#), Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the Animal Research: Reporting In Vivo Experiments (ARRIVE) guidelines 2.0 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>.

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

**Government Agencies Within the United States:** Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

**Intramural DOD Organization:** A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

**The USAMRAA makes awards to eligible organizations, not to individuals.**

### **II.C.1.b. Principal Investigator**

Independent investigators at all academic levels (or equivalent) are eligible to be named as a PI (or Initiating or Partnering PI(s) for the Multiple PI Option).

There are no limitations on the number of applications for which an investigator may be named as a PI (or Initiating or Partnering PI(s) for the Multiple PI Option); 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.

The CDMRP strongly encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

### **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 in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

## **II.D. Application and Submission Information**

***Submission of applications that are essentially identical or 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).***



### II.D.1. eBRAP and Grants.gov

**eBRAP** (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

**Grants.gov** is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

#### ***Extramural Submission:***

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

#### ***Intramural DOD Submission:***

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

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

### II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

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

**Multiple PI Option:** The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow***

*the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, each Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.* If not previously registered, the Partnering PI(s) must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI(s). Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI(s) will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI(s)' required full application package components to eBRAP.

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

*During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.*

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an 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.

The applicant organization and associated PI(s) identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://eBRAP.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY22 RTRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

**Multiple PI Option:** The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

*Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

- **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:

- **Technology Development Product:** Describe the product (materiel or knowledge-based) that will address a need in reconstructive transplantation, and briefly compare to existing technologies or standard of care, as applicable. State the scientific rationale, the preclinical and/or clinical findings that support the need for the proposed product, and a description of how proof of concept has been demonstrated.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective(s) to be reached.
- **Specific Aims and Study Design:** Concisely state the project’s specific aims and describe the scientific approach. Explain how the study design will support the research hypothesis and/or objectives, and accomplish the study aims and the development of the product. Include a description of controls, as appropriate, and demonstrate that the work has appropriate statistical power. Include any relevant literature citations that support this approach.
- **Impact and Focus Area(s):** Describe the short- and long-term impact of the proposed research and anticipated product(s) on the field of reconstructive transplant research, patient care, and/or quality of life, including the impact on at least one of the FY22 RTRP Advanced Technology Development Award Focus Areas described in [Section II.A.1](#).
- **Military Relevance:** Describe how the proposed research project is responsive to healthcare 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.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

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

- **Technology Development Product:** How well the pre-application focuses research on a defined product (materiel or knowledge-based) that will address a need in reconstructive transplantation, and whether it is compared to existing technologies or standard of care, as applicable. Whether the product is based on promising preclinical or clinical findings, sound scientific rationale, and demonstrated proof of concept.
- **Specific Aims and Study Design:** How well the specific aims and proposed methodology support the research hypothesis and/or objectives and the development of the product. Whether the study design includes appropriate controls and statistical power.
- **Impact and Focus Area(s):** The degree to which the proposed research and anticipated product(s) (materiel or knowledge-based) will have potential short- and long-term impact on the field of reconstructive transplantation research, patient care, and/or quality of life, including the impact on one or more of the FY22 RTRP Advanced Technology Development Focus Areas described in [Section II.A.1](#).
- **Military Relevance:** How well the proposed research is responsive to the healthcare 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.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs or Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless notification of invitation has been received by the PI or Initiating PI.

*The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

**II.D.2.b.i. Full Application Guidelines**

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

*Do not password protect any files of the application package, including the Project Narrative.*

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DOD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-22-RTRP-ATDA from Grants.gov ( <a href="https://grants.gov/">https://grants.gov</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-22-RTRP-ATDA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org</a> ).
<b>Full Application Package Components</b>	
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>

Extramural Submissions	Intramural DOD Submissions
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><a href="#">Application Verification Period</a></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of</p>

Extramural Submissions	Intramural DOD Submissions
<p>application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>.</p>	<p>this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>. Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
Further Information	
<p><b>Tracking a Grants.gov Workspace Package.</b>            After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.             Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

**Multiple PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PI(s) will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Initiating PI’s and each Partnering PI’s) must be submitted by the full application submission deadline.*

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

**SF424 Research & Related Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.



- **Extramural and Intramural Applications**

**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 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (15-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 to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
  - **Background/Rationale/Readiness:** Describe the product (materiel or knowledge-based) to be developed and its proposed use. Present the ideas and scientific rationale behind the proposed research project, and clearly demonstrate that there is sufficient evidence to support the proposed stage of research. Cite relevant literature. Describe previous experience most pertinent to this project. *Preliminary data relevant to reconstructive transplant that support proof of concept of the proposed product or a prototype/preliminary version of the product must be included (these data may be unpublished if from a member of the research team, or from the published literature).*
  - **Hypothesis and/or Objective(s):** State the hypothesis to be tested and/or 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, present only tasks that would be funded under this FY22 RTRP Advanced Technology Development Award.
  - **Study Design and Feasibility:**
    - Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation.
    - Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach.

- Define the specific study outcomes, describe how they will be measured and how they will support translation of promising preclinical and/or clinical research findings into a product for clinical applications.
- 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 the 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. Explain how this plan is appropriate for the proposed study, and how the study is designed to achieve reproducible and rigorous results.
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the Food and Drug Administration (FDA) or international equivalent, if applicable.
- Describe how the proposed study design will position the product for the next phase of development as described in the post-award Transition Plan ([Attachment 9](#)).
- 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 8, Animal Research Plan](#).
- If human subjects or human anatomical substances will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. The plan should include a description of how the samples and any associated data will be stored during and after the study, including compliance with relevant laws and regulations for human subjects research. Consent Forms for all samples collected under this project should include permission for the samples to be used in future studies without the need for re-consent. Describe the availability of the proposed study population and past successes in recruiting similar populations. If an active-duty military, Veteran, or military family member or caregiver population will be used in the proposed research project, include the details in Statement 7, Military Relevance Statement. ***This award may not be used to conduct clinical trials.***
- If applicable, describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this

requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.

- **Partnership** (*only applicable and required for applications submitted under the Multiple PI Option*):
  - Describe how the proposed project incorporates the unique skills of each partner and will result in a level of productivity greater than that achievable by each PI working independently.
  - Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Provide the time commitment for each partner.
  - Demonstrate how the partnership will maximize the use of existing resources and minimize unnecessary duplication.
  - Describe the communication plan and provide evidence of institutional support for resolving potential intellectual and material property issues, and removing institutional barriers to achieving high levels of cooperation.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Clinical Research:** If applicable, provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

- **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 or not 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 or organization that demonstrates that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- **Intellectual Property:** Information can be found in the Code of Federal Regulations, Title 2, Part 200.315 (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.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP 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 from 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. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution 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. ***Do not include proprietary or confidential information.*** 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.

- **Background/Rationale/Readiness:** Describe the product to be developed and its proposed use. Present the ideas and scientific rationale behind the proposed research project.
  - **Hypothesis or Objective(s):** State the hypothesis to be tested and/or 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, including appropriate controls. Indicate how the product will be positioned for next phase of development at the end of the period of performance.
  - **Impact:** Briefly describe the short- and long-term impact of the proposed product on the field of reconstructive transplant research, patient care, and/or quality of life, including the impact on at least one of the FY22 RTRP Advanced Technology Development Focus Areas listed in [Section II.A.1](#).
  - **Military Relevance:** Briefly explain how the proposed project will have immediate or potential long-term benefit for the healthcare 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. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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 [FY22 RTRP Advanced Technology Development Award Focus Area\(s\)](#) to be addressed.
- Describe the ultimate applicability and impact of the product.
  - What types of patients will the product 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 product 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 product to advancing the field of reconstructive transplant research?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Advanced Technology Development Award, refer to either the “*Suggested SOW Strategy Clinical Research*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

**Multiple PI Option:** *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and each Partnering PI should be noted for each task.*

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”** Describe the short- and long-term impact of the proposed product on the field of reconstructive transplant research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome will lead to a practical application in individuals recovering from traumatic injury. State the relevance of the proposed product development plan to at least one of the FY22 RTRP Advanced Technology Development Award Focus Areas listed in [Section II.A.1](#), and explain the applicability of the proposed findings to improving clinical outcomes for individuals recovering from traumatic injury. Although not all-inclusive, the following are examples of ways in which research projects may have an impact, if successful:

- Has the potential to advance the field of reconstructive transplant research.
  - Has the potential to change the standard of care.
  - Contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.
- **Attachment 7: Military Relevance Statement (one-page limit): Upload as “MilRel.pdf”.** Demonstrate how the proposed research is responsive to the healthcare 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 the military population. If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest.
  - **Attachment 8: Animal Research Plan (five-page limit): Upload as “AnimalPlan.pdf”, if applicable.** When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points 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.
    - Summarize the procedures to be conducted and state the endpoints/outcome measures to be assessed. 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)/outcome measures(s).
  - **Attachment 9: Transition Plan (two-page limit): Upload as “Transition.pdf.”** Provide information on potential methods and strategies to feasibly move the product or

knowledge outcome to the next phase of development (e.g., clinical trials, partnership with DOD advanced developers, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office, or equivalent, to develop the transition plan. They are encouraged to explore the development of relationships with industry, DOD advanced developers, and/or other funding agencies to facilitate moving the product into the next phase of development. The Transition Plan should include the components listed below.

- A description of the scientific or technical requirements needed to advance the research findings.
  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication (e.g., Target Product Profile). Indicate whether there was any consideration of predicate technologies or potential pre-existing market exclusivities. Describe in detail the FDA regulatory strategy, to include considerations for compliance with Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice guidelines, if appropriate.
  - Details of the funding strategy that will be used to transition the product(s) to the next level of development and/or commercialization (e.g., specific potential industry partners, partnerships with DOD advanced developers, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
  - A description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
  - A schedule with defined milestones and deliverables for transitioning the product(s) or outcome(s) to the next phase of development (e.g., clinical trials, transition to industry, transition to DOD advanced developers, delivery to the civilian and/or military market, incorporation into clinical practice, or approval by the FDA).
  - A risk analysis for cost, schedule, manufacturability, and sustainability.
  - If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.
  - A plan to distribute the findings of the knowledge product, if applicable, to the VCA community.
- **Attachment 10: Representations, if applicable (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 5, Section B, Representations.

- **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

**Research & Related Personal Data:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **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 (NIH) 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”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- 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”.

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit): Upload as “BudgetJustification.pdf”.** The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

**Multiple PI Option: *Initiating and Partnering PI(s) must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to [Section II.D.5. Funding Restrictions](#), for detailed information.***

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 11](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

**Multiple PI Option: Suggested DOD Military Budget Format:** A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. **Note:** Applicants should complete a separate military budget using “Suggested Collaborating DOD Military Facility Budget

Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]) ([Attachment 11](#)) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

### **Multiple PI Option: Application Components for each Partnering PI**

Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

For each Partnering PI, the Initiating PI must identify if each Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in [Section II.C.1.a, Organization](#)) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). Each Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for each Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

**Attachments:**

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and each Partnering PI should be noted for each task.
- **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 5, Section B, Representations.
- **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format: Upload as “MFBudget.pdf”.** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

**Research & Related Personal Data:** For extramural submissions (via Grants.gov) refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- 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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- 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”.

**Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.

*Initiating and Partnering PI(s) must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for each Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5. Funding Restrictions](#), for detailed information.*

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form:**

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.)
- **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using Suggested Collaborating DOD Military Facility Budget Format (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]), and upload to Grants.gov attachment form as [Attachment 11](#). (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

**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/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. As published in the Federal Register, July 10, 2019, (<https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management>), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. *All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.* USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: <https://www.gsa.gov/about-us/organization/federannl-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update>.) Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. *Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see Section II.D.4, Submission Dates and Times below).* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

**II.D.4. Submission Dates and Times**

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. 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.

**Applicant Verification of Full Application Submission in eBRAP**

*For Both Extramural and Intramural Applicants:* eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with

them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***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 application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

***Extramural Submission:*** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

***Intramural DOD Submission:*** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

***For All Submissions:*** Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

#### **II.D.5. Funding Restrictions**

The maximum period of performance is **3** years.

**Single PI:** The anticipated total cost budgeted for the entire period of performance will not exceed **\$1M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$1M** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

**Multiple PI Option:** The anticipated total costs budgeted for the entire period of performance for the Initiating PI’s and each Partnering PI’s applications combined will not exceed **\$1.5M**. 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 cost in accordance with each organization's negotiated rate. The combined budgeted total costs approved by the government will not exceed **\$1.5M** or use an indirect cost rate exceeding each organization's negotiated rate. A separate award will be made to each PI's organization. The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

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

Any application that requests the higher level of funding and that does not include a collaborative PI will have its budget reduced as appropriate.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI(s) to present project information or disseminate project results at a DOD-sponsored meeting (e.g., the Military Health System Research Symposium) during the period of performance. For planning purposes, it should be assumed that the meeting 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):

- Travel in support of multidisciplinary 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 costs to scientific/technical meetings is to present project information or disseminate project results from the RTRP Advanced Technology Development Award.

Must not be requested for:

- Clinical trial costs.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations*

*collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

#### **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 4, 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 evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:

- **Study Design and Feasibility**
  - How well the preliminary and/or published data and ideas and scientific rationale support the proposed research project and demonstrate sufficient evidence to support moving into the proposed stage of research.
  - Whether preliminary data relevant to reconstructive transplant is provided and how well it supports proof-of-concept of the proposed product/prototype/preliminary version of product.
  - How well the hypothesis and objectives, specific aims, study design, methods, and analyses are developed and support the appropriateness (including controls) and feasibility of the proposed study.
  - How well the research strategy supports the translational feasibility and promise of the approach.
  - To what extent the study outcomes will be appropriately measured and will support the translation of promising preclinical and/or clinical research findings into a product for clinical applications.
  - How appropriate the plans are for handling data, including appropriate rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints.
  - Whether data will be appropriately reported and documented to support a regulatory filing with the FDA or international equivalent, as applicable.
  - How well the study design will position the product for the next phase of development as described in the post-award Transition Plan ([Attachment 9](#)).



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

***For applications involving animal research:***

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

***For applications involving human subjects:***

- The degree to which the plan to study human subjects, human anatomical substances, etc., is designed to achieve the objectives, and is appropriate and feasible, including demonstrated access to the selected population.
- Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.
- Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.

***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.

• **Statistical Plan**

- To what degree the statistical plan and power analysis are appropriate for the proposed project, as applicable.
- How well the plans for blinding and randomization are appropriate for the study, as applicable.
- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

• **Impact**

- How well the proposed research addresses at least one of the FY22 RTRP Advanced Technology Development Award Focus Areas listed in [Section II.A.1](#).
- How well the proposed product will make important short-term and long-term contributions to reconstructive transplant research, patient care, and/or quality of life.
- How the proposed product, if successful, will lead to a practical application in individuals recovering from traumatic injury in the short- or long-term.

- **Transition Plan**

- Whether a description of the scientific or technical requirements needed to advance the research findings is provided.
- How the regulatory strategy and development plan to support the proposed product label, if applicable, are appropriate and well described.
- Whether the funding strategy described to bring the product(s) to the next level of development (e.g., clinical trial, transition to industry, delivery to the market, progression toward incorporation into standard practice) is appropriate.
- To what extent the collaborations and other resources (established or planned) described are appropriate and will provide continuity of development.
- Whether the schedule and milestones for bringing the outcome(s) to the next level of development (e.g., clinical trials, transition to industry, transition to DOD advanced developers, delivery to the civilian and/or military market, progression toward incorporation into clinical practice, FDA approval) are appropriate and feasible.
- If applicable, how well the risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- How well the application identifies intellectual property plan ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.
- How well the plan supports further development and dissemination of the knowledge product to the VCA community, if applicable.

- **Personnel**

- How the background and experience/expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
- How well the PI's record of accomplishment demonstrates their ability to accomplish the proposed research project.
- How the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.

***For applications submitted under the Multiple PI Option:***

- How well the project incorporates the unique skills of each partner and will result in a level of productivity greater than that achievable by each PI working independently.

- How the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
- How well the partnership will maximize the use of existing resources and minimize unnecessary duplication.
- How well the communication plan and institutional support will facilitate high levels of cooperation and will resolve any potential intellectual and material property issues.

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

- **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**

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

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY22 RTRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism.
  - Program portfolio composition.
  - Programmatic relevance to FY22 RTRP Advanced Technology Development Award Focus Areas listed in [Section II.A.1.](#)
  - 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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the RTRP will be provided to the PI(s) and posted on the CDMRP website.

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 panel. Violations of confidentiality can result in the dissolving 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 another 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 the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## II.F. Federal Award Administration Information

### II.F.1. Federal Award Notices

Awards supported with FY22 funds are anticipated to be made no later than September 30, 2023. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

**Pre-Award Costs:** An institution of higher education, hospital, or non-profit 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. Refer to the General Application Instructions, Section III.A.5.

***Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds.*** 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.**

**Federal Government Organizations:** Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

#### II.F.1.a. PI Changes and Award Transfers

**Single PI:** Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

**Multiple PI Option:** An organizational transfer of an award supporting the Initiating PI or Partnering PI(s) is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

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 2, Section B, for general information on organization or PI changes.

### **II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#), for further information.

**New Requirement:** Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

### **II.F.3. Reporting**

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report, including quad charts, will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

If employing the **Multiple PI Option**, each PI, whether Initiating or Partnering, must submit individual annual progress reports as required by the individual award agreement, as well as a final progress report.

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 if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Public Health Service (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 FAPIIS 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 5, Section B).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. eBRAP Help Desk**

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week

(closed on U.S. federal holidays). Note that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: [support@grants.gov](mailto:support@grants.gov)

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by 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 702b. The program announcement numeric version code will match the General Application Instructions version code 702.

### **II.H.2. Administrative Actions**

After receipt of pre-applications or 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 application:

- Submission of an application for which a letter of invitation was not received.
- 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 Preproposal Narrative and Project Narrative.



- Documents not requested will be removed.

### II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY22 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. *A list of the FY22 RTRP Programmatic Panel members can be found at <https://cdmrp.army.mil/rtrp/panels/panels22>.*
- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- 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 may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- 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.
- The PI (or Initiating or Partnering PI) does not meet the eligibility criteria.
- A clinical trial is proposed.

- The application failed to address at least one of the [FY22 RTRP Advanced Technology Development Award Focus Areas](#).
- **Multiple PI Option:** Failure to submit all associated (Initiating and Partnering PI(s)) applications by the deadline.

#### **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. Application Submission Checklist

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance <b>(extramural submissions only)</b>	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) <b>(intramural submissions only)</b>	Complete tabs as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"		
	Military Relevance Statement: Upload as Attachment 7 with file name "MilRel.pdf"		
	Animal Research Plan: Upload as Attachment 8 with file name "AnimalPlan.pdf" if applicable		
	Transition Plan: Upload as Attachment 9 with file name "Transition.pdf"		
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget ( <b>extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget ( <b>intramural submissions only</b> )	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RTRP	Reconstructive Transplant Research Program
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
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

## APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with DOD and/or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DOD and VA areas of research interest, ongoing research or potential opportunities for collaboration.

Air Force Office of Scientific Research  
<https://www.afrl.af.mil/AFOSR/>

Air Force Research Laboratory  
<https://www.afrl.af.mil/>

Armed Forces Radiobiology Research  
Institute  
<https://afri.usuhs.edu/home>

Clinical and Rehabilitative Medicine  
Research Program  
<https://cdmrp.army.mil/dmrpd/jpc8crrp>

Combat Casualty Care Research Program  
<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research  
Programs  
<https://cdmrp.army.mil>

Defense Advanced Research Projects  
Agency  
<https://www.darpa.mil/>

Defense Health Agency  
<https://health.mil/dha>

Defense Technical Information Center  
<https://www.dtic.mil>

Defense Threat Reduction Agency  
<https://www.dtra.mil/>

Military Health System Research  
Symposium  
<https://mhsrs.amedd.army.mil/SitePages/Home.aspx>

Military Infectious Diseases Research  
Program  
<https://midrp.amedd.army.mil>

Military Operational Medicine Research  
Program  
<https://momrp.amedd.army.mil>

Naval Health Research Center  
<https://www.med.navy.mil/Naval-Medical-Research-Center/Naval-Health-Research-Center/>

Navy Bureau of Medicine and Surgery  
<https://www.med.navy.mil/Bureau-of-Medicine-and-Surgery/>

Naval Medical Research Center  
<https://www.med.navy.mil/Naval-Medical-Research-Center/>

Navy and Marine Corps Public Health  
Center  
<https://www.med.navy.mil/sites/nmcphc>

Office of Naval Research  
<https://www.nre.navy.mil/>

Office of the Under Secretary of Defense for  
Acquisition, Technology and Logistics  
<https://www.acq.osd.mil/>

Telemedicine and Advanced Technology  
Research Center  
<https://www.tatrc.org/www/default.html>

Uniformed Services University of the Health  
Sciences  
<https://www.usuhs.edu/research>

U.S. Air Force 59<sup>th</sup> Medical Wing  
<https://www.59mdw.af.mil/>

U.S. Army Aeromedical Research  
Laboratory  
[www.usaarl.army.mil](http://www.usaarl.army.mil)

U.S. Army Center for Environmental Health  
Research  
<https://usacehr.amedd.army.mil>

U.S. Army Institute of Surgical Research  
<https://usaistr.amedd.army.mil/>

U.S. Army Research Institute of  
Environmental Medicine  
<https://www.usariem.army.mil/>

U.S. Army Medical Research Institute of  
Infectious Diseases  
<https://www.usamriid.army.mil/>

U.S. Army Medical Research and  
Development Command  
<https://mrdc.amedd.army.mil>

U.S. Army Research Laboratory  
<https://www.arl.army.mil>

U.S. Army Research, Development and  
Engineering Command  
<https://www.arl.army.mil/>

U.S. Army Sharp, Ready and Resilient  
Directorate  
<https://www.armyresilience.army.mil/sharp/>

U.S. Department of Defense Blast Injury  
Research Program  
<https://blastinjuryresearch.amedd.army.mil/>

U.S. Department of Veterans Affairs, Office  
of Research and Development  
<https://www.research.va.gov>

U.S. Naval Research Laboratory  
<https://www.nrl.navy.mil>

Walter Reed Army Institute of Research  
<https://www.wrair.army.mil/>