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

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-RTRP-IIRA

Catalog of Federal Domestic Assistance 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), August 19, 2020

- **Invitation to Submit an Application:** September 2020

- **Application Submission Deadline:** 11:59 p.m. ET, November 12, 2020

- **End of Application Verification Period:** 5:00 p.m. ET, November 17, 2020

- **Peer Review:** January 2021

- **Programmatic Review:** March 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 501. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2020 (FY20) Reconstructive Transplant Research Program (RTRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). 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 FY19 totaled $93 million (M). The FY20 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.

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. FY20 RTRP Investigator-Initiated Research Award Focus Areas

To meet the intent of the FY20 RTRP Investigator-Initiated Research Award mechanism, applicants must address at least one of the FY20 RTRP Focus Areas listed below (select both a bolded Focus Area and the appropriate subtopic):

Reduce the risks of VCA-associated immunosuppression

- Define the unique mechanisms of VCA immunogenicity

- Develop novel approaches for improving VCA immune tolerance

- Identify unique immunosuppression requirements for VCA compared to other solid organ transplants

Develop reliable non-invasive methods or tools for monitoring VCA graft rejection

- Develop reliable non-invasive biomarkers for monitoring chronic VCA graft rejection in a large animal model

- Identify and/or validate new peripheral biomarkers for acute and chronic rejection

- Develop assays or devices for clinical graft monitoring utilizing validated biomarkers

Advance existing or develop innovative ex vivo tissue preservation strategies to extend the timeline between procurement and transplantation

- Develop novel approaches and models for perfused, hypothermic, high subzero and low subzero, or static preservation strategies

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

II.A.2. Award History

The RTRP Investigator-Initiated Research Award mechanism was offered for the first time in FY16. Since then, 140 applications have been received, and 24 have been recommended for funding.

II.B. Award Information

The FY20 RTRP Investigator-Initiated Research Award is intended to support studies that have the potential to make an important contribution to reconstructive transplant research, patient care, and/or quality of life. Though the RTRP Investigator-Initiated Research Award mechanism supports groundbreaking research, all projects must demonstrate solid scientific rationale with military-relevant utility. Multi-institutional collaborations among clinicians and research scientists are encouraged. Important aspects of this award mechanism include:

- **Study Design and Feasibility:** The proposed study design should be clearly described, rigorous, and support maximal reproducibility and translational feasibility. A statistical plan with appropriate power analysis should be included, as applicable.

- **Impact:** The short- and long-term impact of the proposed research should be clearly articulated. Projects must address at least one of the FY20 RTRP Focus Areas.

- **Military Relevance:** All projects should 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 researchers and clinicians is encouraged.

- **Preliminary Data:** Observations that drive a research idea may be derived from laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or

anecdotal data. ***Preliminary and/or published data that are relevant to reconstructive transplantation and that support the rationale for the proposed study <u>must</u> be included.***

Investigator-Initiated Research Award applications may focus on any phase of research from basic through translational, including preclinical studies in animal models, human subjects, human anatomical substances, as well as correlative studies associated with an existing clinical trial. ***Clinical trials are <u>not</u> 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.

Multiple PI Option: The Investigator-Initiated Research Award mechanism includes an option for up to four Principal Investigators (PIs). 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). Initiating and Partnering PIs will each have different submission requirements, as described in Section II.D.2, Content and Form of the Application Submission; however, 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. Multi-institutional collaborations are encouraged.

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 FY20 RTRP Investigator-Initiated Research Award will not exceed **$1M** for Single PI applications and **$1.5M** for applications submitted under the Multiple PI Option. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information, refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $7.5M to fund approximately six Reconstructive Transplant Investigator-Initiated Research 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 FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.

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 U.S. Army Medical Research and Development Command (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 Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes*. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource 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 is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission. 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 patient populations and/or DoD 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 submission requirements. Refer to the General Application Instructions, Appendix 1, Section C, for additional detailed 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). 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 describe how these standards will be addressed; this may be included in Attachment 8: Animal Research Plan. Refer to the application submission instructions for more information. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001.

Research Involving Animals: All DoD-funded projects 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.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including 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 organization 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: 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.*

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 PI (or Initiating or Partnering PI for 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 for Multiple PI Option).

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP 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).

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.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

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 CDMRP Help Desk at 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 CDMRP Help Desk at 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 (Multiple PI Option) 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 CDMRP Help Desk at 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.

  FY20 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 CDMRP Help Desk at 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:

    – **Background/Research Problem/Rationale:** Describe the research problem, question, or knowledge gap to be addressed by the proposed research. State the ideas and reasoning on which the proposed research is based. Clearly demonstrate that there is sufficient rationale to support the proposed research.

    – **Hypothesis and Objective(s):** State the hypothesis to be tested and the objective(s) to be reached.

    – **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the scientific approach and how it will accomplish the study aims. Include a description of controls, as appropriate. Include any relevant literature citations that support this approach.

    – **Impact and Focus Area(s):** Describe the potential impact of this study on the field of reconstructive transplant research, patient care, and/or quality of life, including the impact on at least one of the FY20 RTRP Focus Areas.

    – **Military Relevance:** Describe how the proposed research project would impact 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 (five-page limit per individual). ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and experience 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 DHP and the RTRP, pre-applications will be screened based on the following criteria:

- **Background/Research Problem/Rationale:** How well the background and scientific rationale demonstrate sufficient evidence to support the proposed research project.

- **Hypothesis and Objective(s):** Whether the hypothesis and objective(s) have been clearly stated.

- **Specific Aims and Study Design:** How well the specific aims are stated and the approach is supported through scientific rationale and referenced literature, and how well the proposed research project's approach will address these aims.

- **Impact and Focus Area(s):** How well the proposed research addresses at least one of the <u>FY20 RTRP Focus Areas</u> and will make important contributions to reconstructive transplant research, patient care, and/or quality of life.

- **Military Relevance:** How the proposed research would benefit 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 (Multiple PI Option) 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 <u>Section I, Overview of the Funding Opportunity</u>. 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 (Multiple PI Option).

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://www.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
Application Package Location	
Download application package components for W81XWH-20-RTRP-IIRA from Grants.gov (https://www.grants.gov) 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-20-RTRP-IIRA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DoD Submissions
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** 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 **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. **Note:** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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 *prior to* the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** 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. ***Do not password protect any files of the application package, including the Project Narrative.***

Extramural Submissions	Intramural DoD Submissions
Application Verification Period	
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 may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	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 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 *with the exception of the Project Narrative and Research & Related Budget Form*. 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.
Further Information	
Tracking a Grants.gov Workspace Package. 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.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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 PIs 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 MB, and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs 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.

    Describe the proposed project in detail using the outline below.

    - **Background/Rationale/Readiness:** Describe the research problem, question, or knowledge gap related to at least one of the <u>FY20 RTRP Focus Areas</u> to be addressed by the proposed research. Present the ideas and scientific rationale behind the proposed project, and clearly demonstrate that there is sufficient evidence to support the proposed stage of research. *Preliminary and/or published data that are relevant to reconstructive transplantation and support the rationale for the proposed study <u>must</u> be included.* Describe how the previous experience of the PI(s) and research team relates to the proposed research project.

    - **Hypothesis and Objective:** State the hypothesis to be tested and the objective(s) to be reached.

    - **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. If the proposed work is part of a larger study, then present only tasks that would be funded under this FY20 RTRP award.

    - **Study Design and Feasibility:**

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

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

- Describe how data will be reported and how it will be ensured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

- Describe the statistical plan and rationale for the statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, as applicable. Include any plans for blinding and randomization. Explain how this plan is appropriate for the proposed study, and how the study is designed to achieve reproducible and rigorous results.

- 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 and access to the proposed study population and past successes in recruiting similar populations. ***This award may <u>not</u> be used to conduct <u>clinical trials</u>***.

- **Partnership (for 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.

– 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 will demonstrate 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 research problem, question, or knowledge gap related to at least one of the FY20 RTRP Focus Areas to be addressed by the proposed research. Present the ideas and scientific rationale behind the proposed project.

  - **Hypothesis and Objective(s):** State the hypothesis to be tested and 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.

  - **Impact:** Briefly describe the short- and long-term impact of this study on reconstructive transplant research, patient care, and/or quality of life, including the impact on at least one of the FY20 RTRP Focus Areas.

  - **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***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Do not duplicate the technical abstract. Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. 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 FY20 RTRP Focus Area(s) to be addressed.

– Describe the ultimate applicability and impact of the research.

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

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

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

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

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

○ **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** 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). For the Investigator-Initiated Research Award mechanism, use the SOW format example titled "SOW Generic Format" for a Single PI application or "SOW for Collaborative PI Projects" for the Multiple PI Option." The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

– Include the name(s) of the key personnel and contact information for each study site/ subaward site.

– Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

– For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

– Identify cell line(s) and commercial or organizational source(s) to be used.

– If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the FDA or other Government agency.

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 how the proposed project addresses a critical problem in, and will make an important contribution (both short-term and long-term) to the field of reconstructive transplant research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed project will lead to a practical application in individuals recovering from traumatic injury. Address the impact on at least one of the FY20 RTRP Focus Areas. 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 the active duty military, Veteran, or military family member or caregiver population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, 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), if applicable: Upload as "AnimalPlan.pdf".** 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).

○ **Attachment 9: 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 10: 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 A§1681 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 (five-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".

○ Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

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

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 PIs 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 10. (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.

  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 10, 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 whether the 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 9: 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](https://ebrap.org/eBRAP/public/Program.htm)). For more information, see the General Application Instructions,
   Appendix 5, Section B, Representations.

○ **Attachment 10: 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 (five-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".

○ Key Personnel Biographical Sketches (five-page limit each): Upload as
   "Biosketch_LastName.pdf".

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

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 PIs 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 10](#). (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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 costs 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 costs in accordance with each organization's negotiated rate. The combined budgeted direct 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 Partnering 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 from the RTRP Investigator-Initiated Research Award at a DoD-sponsored meeting (e.g., the Military Health System Research Symposium) during the period of performance. For budgetary purposes, it should be assumed that this will occur in year 2. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all inclusive):

- 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 meeting(s) is to present project information or disseminate project results from the RTRP Investigator-Initiated Research Award.

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.

  ○ 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 appropriate the plans are for handing the data, 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.

  ○ How appropriate the plans are for reporting data, and ensuring that the documentation will support a regulatory filing with the FDA, if applicable.

  ○ How well the application acknowledges potential problem areas and presents alternative methods and 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 and human anatomical substances is designed to achieve the objectives, and is appropriate and feasible, including demonstrated access to the selected population(s) or resource(s).

For applications involving military or Veteran populations:

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

- **Statistical Plan**

  - ○ To what degree the statistical plan and power analysis are appropriate for the proposed project, 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 FY20 RTRP Focus Areas.

  - ○ How well the proposed project addresses a critical problem in, and will make important short-term and long-term contributions to, reconstructive transplant research, patient care, and/or quality of life.

  - ○ How likely a successful outcome of the proposed study will lead to a practical application in individuals recovering from traumatic injury.

- **Personnel**

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

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

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

  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 FY20 RTRP, as evidenced by the following:

  ○ Adherence to the intent of the award mechanism

  ○ Program portfolio composition

  ○ Programmatic relevance

  ○ Relative impact

  ○ Relative 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, on behalf of the DHA and the OASD(HA). ***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 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 200.88, 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 FY20 funds are anticipated to be made no later than September 30, 2021. 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 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 other 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.B.

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

Multiple PI Option: An organizational transfer of an award supporting the Initiating PI or Partnering PI 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 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.

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 and quad charts as well as a final progress report and quad chart 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 quarterly and 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 whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 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. 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. CDMRP 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 CDMRP 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

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 CDMRP 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

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 501f. The Program Announcement numeric version code will match the General Application Instructions version code 501.

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 FY20 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 FY20 RTRP Programmatic Panel members can be found at https://cdmrp.army.mil/rtrp/panels/panels20.*

- 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 FY20, 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.

- A clinical trial is proposed.

- The PI (Initiating or Partnering PIs, if Multiple PI Option) does not meet the eligibility criteria.

- The PI (Single PI submission) or all associated PI (Initiating and Partnering PI) applications are not submitted 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

Single PI Submissions

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	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	
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	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 **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget **(intramural submissions only)**	Suggested DoD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

Multiple PI Submissions

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	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		
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable		
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		

Application Components	Action	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 **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	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
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
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	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.wpafb.af.mil/afrl/afosr/

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

Armed Forces Institute of Regenerative Medicine
https://www.afirm.mil

Armed Forces Radiobiology Research Institute
https://www.usuhs.edu/afrri/

Center for Neuroscience and Regenerative Medicine
http://www.cnrmstudies.org/

Clinical and Rehabilitative Medicine Research Program
https://mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.crmrp.overview

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

DHA Connected Health (formerly, National Center for Telehealth and Technology)
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Clinical-Support-Division/Connected-Health

Defense Health Agency J9, Research and Development Directorate
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development

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

National Museum of Health and Medicine
https://www.medicalmuseum.mil/index.cfm

Naval Health Research Center
https://www.med.navy.mil/sites/nhrc

Naval Medical Research Center
https://www.med.navy.mil/SITES/NMRC/NMRC/Pages/NMRC.aspx

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

Office of Naval Research
https://www.onr.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
http://www.tatrc.org/

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

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

U.S. Army Aeromedical Research
Laboratory
https://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://usaisr.amedd.army.mil/

U.S. Army Medical Research Acquisition
Activity
https://www.usamraa.army.mil/

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

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

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

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

U.S. Army Sharp, Ready & Resilient
Directorate
https://readyandresilient.army.mil/

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/