I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Reconstructive Transplant Research Program

Qualitative Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-RTRP-QRA

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), September 20, 2017

- **Invitation to Submit an Application:** October 12, 2017

- **Application Submission Deadline:** 11:59 p.m. ET, December 6, 2017

- **End of Application Verification Period:** 5:00 p.m. ET, December 11, 2017

- **Peer Review:** February 2018

- **Programmatic Review:** March 2018

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications 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 2017 (FY17) 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 that has the potential to make a significant impact on improving the function, wellness, and overall quality of life for injured military Service members and Veterans, their caregivers and family members, and the American public. Appropriations for the RTRP from FY12 through FY16 totaled $57 million (M). The FY17 appropriation is $12M.

The RTRP challenges the scientific community to design innovative research that will foster new directions for, and address neglected issues in, the field of reconstructive transplantation, specifically 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, and as a functional unit (e.g., a hand or face) from a deceased donor to a recipient with a severe injury. The RTRP closely aligns with the Joint Program Committee 8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRMRP) mission to implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal for both the RTRP and JPC-8/CRMRP 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. Though the RTRP award mechanisms support groundbreaking research, all projects must demonstrate solid scientific rationale with military-relevant utility.

II.A.1. FY17 RTRP Focus Area

To meet the intent of the FY17 RTRP Qualitative Research Award mechanism, applicants ***must*** address the Focus Area listed below.

- Psychosocial considerations and challenges associated with VCA, including but not limited to the following examples:

  ○ Development of quality of life measures

  ○ Return to full participation in community life

  ○ Criteria for impacting successful patient selection

  ○ Factors influencing donor registration and authorization

II.B. Award Information

The RTRP Qualitative Research Award mechanism was first offered in FY16. Five Qualitative Research Award applications were received, and two were recommended for funding.

The intent of the FY17 RTRP Qualitative Research Award is to support qualitative research studies that will help researchers and clinicians better understand the experiences of individuals involved in the reconstructive transplant process. This includes those who are considering, or who have already received, reconstructive transplant surgery and/or the reality of lifelong immunosuppression, as well as caregivers, potential donors and their families, and even the clinicians themselves. This understanding will, in turn, support the ultimate goal of improving transplant outcomes and the quality of life for individuals who receive these life-changing procedures.

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

- Factors impacting a patient's decision to pursue VCA.

- Considerations and concerns for successful candidacy for reconstructive transplant surgery.

- Criteria for defining quality of life after VCA from a patient's perspective.

- Impact of patient and donor/authorized party education, as well as public awareness, on the patient and their family members as they deal with functional expectations, deformities, disabilities, and aesthetic expectations.

- Psychosocial factors that limit Service member and Veteran candidacy for reconstructive transplant surgery, and strategies to maximize their candidacy.

- Concerns, fears, and barriers that limit donor offers/donor authorization for VCA, and strategies for overcoming them.

- Innovative ways to prevent and mitigate psychological rejection, including persistent volitional noncompliance.

- Unique psychosocial concerns of Service members, pre- and post-transplant.

- Impact of various systems (family, friends, primary medical team, transplant team, etc.) on patient compliance, psychological adjustment, quality of life, and health outcomes after amputation, severe facial injury, and/or reconstructive transplant surgery.

- Development of methods to maximize psychological adjustment to severe facial injury.

- Methods to optimize long-term psychological adjustment after reconstructive transplantation.

Important aspects of this award mechanism include:

- **Qualitative Approach:** The research approach *must* be predominantly qualitative and well-justified. Qualitative findings may lead the research in a more quantifiable direction, in which case a mixed methods approach is acceptable. The specific theoretical basis (e.g., interactionism, phenomenology, critical theory) for the study should be stated and should drive the framing of the research problem.

- **Qualitative Research Expertise:** The study team must include someone with a demonstrated track record in qualitative research, to include publication and/or funding history. It should be evident in the application that qualitative expertise was involved in the development of the study design.

- **Study Design:** The proposed study design, sampling technique, data collection, and recording method(s) should be appropriate to yield trustworthy, credible, robust, and confirmable results. The documentation of procedures, decisions, and rationale for decisions and conclusions should support consistency, dependability, and duplicability of results, and prevent biases and preconceptions. The data analysis plan should be consistent with the research problem and theoretical basis for the study, and ongoing feedback from participants should be incorporated throughout the project, especially regarding interpretation of data and study conclusions.

- **Impact:** The short- and long-term impact of the proposed research should be clearly articulated. Projects must address the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA."

- **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 and VA researchers and clinicians is encouraged.

Preliminary and/or published data relevant to reconstructive transplant and the proposed research project are encouraged, but not required.

The anticipated total costs budgeted for the entire period of performance for an FY17 RTRP Qualitative Research Award will not exceed **$1M** for Single Principal Investigator (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.

Multiple PI Option: The Qualitative Research Award mechanism includes an option for up to four 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 a Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in Section II, Detailed Information About the Funding Opportunity; however, all PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work, and other required components. If recommended for funding, each PI will receive his or her own award. ***Multi-institutional collaborations are encouraged.***

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (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 Materiel Command (USAMRMC) 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. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. 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.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

Use of Military and VA Populations or Resources: If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the PI is responsible for establishing such access. If possible, access to target active duty military and/or VA patient populations and/or resources should be confirmed at the time of application submission by inclusion of a letter of support, signed by the lowest ranking person with approval authority. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources. Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator, where the VA investigator has a substantial role in the research, or by advertising to the general public. Use Attachment 2 to provide this documentation (see Attachment 2, Supporting Documentation).

DoD and VA Collaboration and Alignment Encouraged: Relevance to the healthcare needs of the Armed Forces and Veterans, as well as their family members, caregivers, or clinicians is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DoD and VA areas of research interest:

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

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

Center for Neuroscience and Regenerative Medicine
http://www.usuhs.mil/cnrm/

Clinical and Rehabilitative Medicine Research Program
https://crmrp.amedd.army.mil

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

Congressionally Directed Medical Research Programs
http://cdmrp.army.mil

Defense Advanced Research Projects Agency
http://www.darpa.mil

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

Defense Technical Information Center
http://www.dtic.mil

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

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

National Center for Telehealth and Technology
http://t2health.org/

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

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

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

Office of Naval Research
http://www.onr.navy.mil

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

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

U.S. Army Medical Research and Materiel
Command
https://mrmc.amedd.army.mil

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

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

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

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

Walter Reed Army Institute of Research
http://www.wrair.army.mil/

The CDMRP intends that information, data, and research resources generated under awards
funded by this Program Announcement be made available to the research community (which
includes both scientific and consumer advocacy communities) and to the public at large. For
additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to
Section II.F.1, Federal Award Notices.

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 academia, biotechnology companies, foundations, Government, and
research institutes. *Extramural Submission: Application submitted by a non-DoD organization
to Grants.gov.*

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 who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.*

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

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

II.C.1.b. Principal Investigator:

Independent investigators at all academic levels (or equivalent) are eligible to submit applications**.**

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 http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

All 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 is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submitted by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (https://eBRAP.org).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

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* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

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.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. 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. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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 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 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 this email in order to associate his/her full application package with that of the Initiating PI. After following the link, each Partnering PI must verify his/her contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Do not delay completing these steps. If they are not completed, the Partnering PI(s) will not be able to view and modify his/her application during the verification period in eBRAP.

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed 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 may result in delays in 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.

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.

PIs and organizations 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 PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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**

- **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 (R&R) 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 (R&R) 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.

    FY17 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.

    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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage

conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **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.

  ○ **Prepreposal Narrative (two-page limit):** The Prepreposal 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 Prepreposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

    The Prepreposal Narrative should include the following:

    – **Background/Research Problem:** Describe the research problem to be addressed and discuss why it is important. State the theoretical basis for the study; it should be clear how this drives the framing of the research problem. Explain why a qualitative approach is appropriate to address the research problem.

    – **Specific Aims and Study Design:** Concisely state the project's specific aims and overall study design, including data collection, subject recruitment, and data analyses.

    – **Impact and Alignment with Focus Area:** Describe the impact of this study on the field of reconstructive transplant research, patient care, and/or quality of life, including the impact on the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA."

    – **Military Relevance:** Describe how the proposed research project would impact 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.

  ○ **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 Prepreposal 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 expertise through education, positions, publications, and previous work accomplished. The scope and extent of qualitative research expertise should be evident in these documents.

- **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 FY17 RTRP, pre-applications will be screened based on the following criteria:

- **Background/Research Problem:** How well the research problem is identified and is relevant to reconstructive transplantation. Whether the theoretical basis for the study is stated, and how clearly it drives the framing of the research problem. How well the selection of a qualitative approach is justified.

- **Specific Aims and Study Design:** How well the specific aims and proposed methodology will address the research problem to be explored. How well the project meets the definition of qualitative research.

- **Impact and Alignment with Focus Area:** How well the proposed research addresses the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA," and will make important contributions to reconstructive transplant research, patient care, and/or quality of life.

- **Military Relevance:** How the proposed work would benefit the healthcare needs of military Service members and/or Veterans recovering from traumatic injury, and/or their families, 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 time frame for notification of invitation to submit an application is indicated in Section

I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless the PI or Initiating PI (Multiple PI Option) has received notification of invitation.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

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, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-RTRP-QRA from Grants.gov (https://www.grants.gov).	Download application package components for W81XWH-17-RTRP-QRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) 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.

Full Application Package Components	
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable)	**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	
Submit package components to Grants.gov (https://www.grants.gov). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need 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.	**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 "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.
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, *with the exception of the Project Narrative and Budget Form,* may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI(s) will receive an 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, *with the exception of the Project Narrative and Budget Form,* may be modified.
Further Information	
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.

The organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Budget cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

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 (R&R) 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 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. ***Preliminary and/or published data relative to reconstructive transplant and the proposed research project are encouraged but not required.***

– **Background/Research Problem:** Identify the research problem to be addressed, and discuss why it is important. State the theoretical basis for the study; it should be clear how this drives the framing of the research problem. Explain why a qualitative approach is appropriate to address the research problem. Cite any relevant literature and describe how the research team's previous experience in qualitative research will facilitate the successful completion of the project.

– **Specific Aims:** Concisely explain the project's specific aims to be funded by this application, as well as the overall study design, including data collection, subject recruitment, and data analyses. If the proposed work is part of a larger study, present only tasks that would be funded under this FY17 RTRP award.

– **Study Design and Feasibility:** Describe the overall study design. Address potential problem areas and present alternative methods and approaches. The following important components of qualitative research should be addressed:

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

▪ **Subject Recruitment:** Include a detailed plan for recruitment of subjects or the acquisition of samples, and demonstrate access to the targeted population.

▪ **Data Analysis:** Describe the data analysis plan for the proposed research, as well as the plan for developing the rules for coding, if applicable, and discuss how these methods are appropriate to the qualitative research. Describe how the analyses are systematic, rigorous, and appropriate to address the qualitative research questions.

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

- **Partnership (for Multiple PI Option):**

  - Describe how the proposed project incorporates the unique skills of each partner. Provide the time commitment for each partner.

  - Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information.

  - 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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested 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 publications 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 Confirming Access to Military or VA Patient Populations or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

– 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 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.

○ **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/Research Problem:** Identify the research problem to be addressed, and discuss why it is important. State the theoretical basis for the study; it should be clear how this drives the framing of the research problem. Explain why a qualitative approach is appropriate to address the research problem.

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

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

- **Impact:** Briefly describe the short- and long-term impact of this study on reconstructive transplant research, patient care, and/or quality of life, including the impact on the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA."

- **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. 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.

- Describe how the proposed research addresses the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA".

- Describe the ultimate applicability and impact of the research.

  ▪ What types of patients will it 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 (SOW) (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 Qualitative Research Award mechanism, use the SOW format example titled "SOW for Clinical Research." 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.

Briefly state the methods to be used.

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 human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

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 U.S. Food and Drug Administration 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 (one-page limit): Upload as "Impact.pdf."** Describe the short- and long-term impact of this study on 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. Describe how the study will improve our understanding of individuals involved in the reconstructive transplant process, including those who are considering, or who have already received, reconstructive transplant surgery, and/or the reality of lifelong immunosuppression, as well as their families, caregivers, clinicians, and potential donors and their families. Address the impact on the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA." 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 Veterans recovering from traumatic injury, and/or their family members, caregivers, or clinicians, as well as the general public. If the active duty military, Veteran, or military family member or caregiver population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the military population. If applicable, show how the proposed research project aligns with DoD and/or VA areas of research interest.

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

○ **Attachment 9: DoD Military Budget Form(s), if applicable: Upload as "MFBudget.pdf."** If a military facility (Military Health System facility, research laboratory, 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 the DoD Military Budget Form, 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 and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  Research & Related Senior/Key Person Profile (Expanded): 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.

  ○ 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 Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) 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."

    – **Multiple PI Option:** Include biographical sketches for the Initiating and Partnering PI(s), as well as any other key personnel and collaborators.

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

    – **Multiple PI Option:** Include previous/current/pending support for the Initiating and Partnering PI(s), as well as any other key personnel and collaborators.

  Research & Related Budget: 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.

  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 each submit a budget and justification specific to his/her own portion of the efforts as part of his/her 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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

  R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

  - ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

  - ○ **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 9. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

  DoD Military Budget Form: 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. However, do not complete the Grants.gov R&R Subaward Budget Attachment Form; instead, complete the DoD Military Budget Form (Attachment 9) 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.7, for detailed information.

Application Components for the Partnering PI(s)

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 his/her full application package with that of the Initiating PI.

For each Partnering PI, the Initiating PI must identify if that Partnering PI will be submitting 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 his/her contact information and mode of submission within eBRAP to ensure proper submission of his/her application.

The application submission process for the Partnering PI(s) uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications –**

  Attachments:

  - ○ **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf."** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. **Multiple PI Option:** Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.

- ○ **Attachment 9: DoD Military Budget Form: Upload as "MFBudget.pdf."** Refer to the General Application Instructions, Section III.A.7, for detailed information. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.4, and for intramural submissions refer to the General Application Instructions, Section IV.A.3, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

Multiple PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to his/her own portion of the efforts as part of his/her separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to <u>Section II.D.5, Funding Restrictions</u>, for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

  R&R 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.6, for detailed information.)

  - ○ **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 9. (Refer to the General Application Instructions, Section IV.A.3, 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 subrecipient 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's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by 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.

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

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. 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 retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. *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 Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

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

Single PI: The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **$1M** for Single PI submissions. 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 combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating PI and all Partnering PIs' applications 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 total costs approved by the Government will not exceed **$1.5M** or use an indirect cost rate exceeding each organization's negotiated rate. A separate award will be made to each PI's organization. The PIs are expected to be balanced 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 applicants may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

- Travel costs for the PI(s) to disseminate project results at one DoD RTRP In-Progress Review meeting. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary

- Research supplies

- Research-related subject costs

- Clinical research costs (*clinical trials NOT allowed*)

- Support for multidisciplinary collaborations, including travel

- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. *The Government reserves the right to direct the selection of one of these meetings, should a relevant DoD-sponsored meeting be convened during the award period of performance.*

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). 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 fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund 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. Application packages from associated extramural partners will be funded through assistance agreements.

Refer to the General Application Instructions, Section III.A.4, 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.4.*

The CDMRP expects to allot approximately $4M of the $12M FY17 RTRP appropriation to fund approximately three Qualitative Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

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 of equal importance:

- **Research Problem**

  ○ How well the research problem is identified and the relevance of the proposed research project to reconstructive transplantation is justified.

  ○ How well the selection of a qualitative approach is justified.

  ○ How well the research questions or topics are described and appropriate to address the research problem.

  ○ How clearly the specific theoretical basis for the study is stated, and is shown to drive the framing of the research question(s).

- **Study Design**

  ○ How well the project meets the definition of qualitative research.

    – The extent to which the research is exploratory and unbiased.

    – Whether questions are open-ended, giving participants the opportunity to respond in their own words, and to elaborate on the questions.

    – If a mixed-methods approach is used, whether qualitative findings will lead to the quantitative component.

  ○ How appropriate the proposed design of the study, the sampling technique, the data collection and recording method(s), and the data storage and management plans are to address the research question and to yield trustworthy, credible, robust, and confirmable results.

  ○ If methods will evolve from and be informed by the research itself, such as the use of snowball sampling techniques, how well the PI describes the method(s) used to maintain the rigor of these processes.

  ○ How well the application demonstrates access to, and ability to recruit, the appropriate population(s) (e.g., military, Veteran, or family/caregiver), or has demonstrated access to proposed resources/databases.

- ○ How well the plan for documentation of procedures, decisions, and rationale for decisions and conclusions supports consistency, dependability, and duplicability of results, and prevents biases and preconceptions.

    - – How consistent the data analysis plan is with the research problem and theoretical basis of the study.

    - – How well the project will obtain ongoing feedback from the participants, especially regarding interpretation of data and study conclusions.

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

- **Impact**

  - ○ How well the proposed research project addresses the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA".

  - ○ How well the proposed research project addresses a critical problem in 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.

  - ○ If successful, how the study will improve our understanding of individuals involved in the reconstructive transplant process, including those who are considering or have already received reconstructive transplant surgery and/or the reality of lifelong immunosuppression, as well as their families, caregivers, clinicians, and potential donors and their families.

- **Personnel**

  - ○ How appropriate the relevant education, training, and experience of the PI(s) and other key personnel are to accomplish the proposed project.

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

  - ○ Whether someone on the research team has a demonstrated track record in qualitative research, as evidenced by publication and/or funding history.

  - ○ To what extent the levels of effort are appropriate for successful conduct of the proposed work.

  For applications submitted under the Multiple PI Option:

  - ○ How well the evidence supports the substantial contribution of all partners to the development and implementation of the research plan.

- ○ How the partners' combined expertise will better address the research problem.

- ○ How well the communication plan and institutional support will facilitate the success of the partnership.

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

- **Environment**

  - ○ To what extent the scientific environment is appropriate for the proposed research project.

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

  - ○ To what extent the quality and level of institutional support are appropriate for the proposed research project.

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

- **Budget**

  - ○ Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.

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

- **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 FY17 RTRP, as evidenced by the following:

  - ○ Adherence to the intent of the award mechanism

  - ○ Program portfolio composition

  - ○ Programmatic relevance to the FY17 RTRP Focus Area, "Psychosocial considerations and challenges associated with VCA"

○ Relative impact and military relevance

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and RTRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 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 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 (currently $150,000) 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, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself 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 (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in <u>Section I, Overview of the Funding Opportunity</u>.

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 will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative 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. 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). Substantial involvement may include 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.

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

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 documents.

Intramural Organizations: Awards 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 managers (RM).

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

II.F.1.a. Award Transfers

Single PI: 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 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 DoDGAR found in 32 CFR, Chapter 1, 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 [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) 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.

Annual progress reports as well as a final progress report will be required. In-person presentations as well as quarterly technical progress reports and quad charts will be 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.

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 Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the [July 2016 R&D General Terms and Conditions](). The applicable Terms and Conditions for for-profit organizations are available in Section 34 of the [February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations]().

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 20170516c. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

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.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

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 FY17 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 FY17 RTRP Programmatic Panel members can be found at http://cdmrp.army.mil/rtrp/panels/panels17*.

- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.

- 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 FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review 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.

- If a clinical trial is proposed, the application will be withdrawn.

- An application for which the PI does not meet the eligibility criteria will be withdrawn.

- Multiple PI Option: All associated (Initiating PI 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

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.		
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these 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."		
	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 8 with file name "Surveys.pdf," if applicable.		
	DoD Military Budget Form(s): Upload as Attachment 9 with file name "MFBudget.pdf," if applicable.		
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.		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
Research & Related Budget (**Extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Budget (**Intramural submissions only)**	Complete the DoD Military Budget Form and Justification.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R&R Subaward Budget Attachment(s) Form	Complete form as instructed.		

APPENDIX 1: ACRONYM LIST

CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRMRP	Clinical and Rehabilitative Medicine Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	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
FY	Fiscal Year
HRPO	Human Research Protection Office
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
RTRP	Reconstructive Transplant Research Program
SAM	System for Award Management
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	U.S. Department of Veterans Affairs