

# **Program Announcement**

**for the**

**Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

## **Reconstructive Transplant Research Program**

### **Qualitative Research Award**

**Funding Opportunity Number: W81XWH-16-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 21, 2016
- **Invitation to Submit an Application:** October 19, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, December 14, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, December 19, 2016
- **Peer Review:** February 2017
- **Programmatic Review:** March 2017

*This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications to the Fiscal Year 2016 (FY16) Reconstructive Transplant Research Program (RTRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The RTRP was initiated in 2012 to provide support for research of exceptional scientific merit that have 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 FY15 totaled \$45 million (M). The FY16 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/CRM RP) 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/CRM RP is to return injured Service members to duty and restore their quality of life.

Applications from investigators within the military Services and applications involving 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.

### **B. FY16 RTRP Qualitative Research Award Focus Areas**

To meet the intent of the FY16 RTRP Qualitative Research Award mechanism, applicants **must** address one or more of the Focus Areas listed below.

- Psychosocial issues associated with VCA
- Development and validation of Quality of Life outcome measures for VCA

## C. Award Information

The RTRP Qualitative Research Award mechanism is being offered for the first time in FY16.

The intent of the Qualitative Research Award is to support qualitative research studies that will help researchers and clinicians better understand the experiences of individuals who are considering, or who have already received, reconstructive transplant surgery, and/or the reality of lifelong immunosuppression. This understanding will, in turn, support the ultimate goal of improving the quality of life for these individuals.

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. *Appropriate qualitative research topics include, but are not limited to, the explorative, descriptive, predictive, or explanatory study of:*

- Factors impacting a patient's decision to pursue VCA.
- Considerations and concerns for successful candidacy for reconstructive transplant surgery.
- Psychosocial factors that limit Service member and Veteran candidacy for reconstructive transplant surgery, and strategies to maximize their candidacy.
- Psychosocial factors that limit donor offers/donor authorization for VCA, and strategies for increasing 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 selection of a qualitative approach should be well justified. The specific theoretical basis for the study should be stated and should drive the framing of the research problem.
- **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/Military Relevance:** The short- and long-term impact of the proposed research should be clearly articulated. Projects should address at least one of the FY16 RTRP Qualitative Research Award Focus Areas. All projects should be responsive to the healthcare needs of military Service members and/or Veterans recovering from traumatic injury, and/or their family members, caregivers or clinicians, as well as the general public. Collaboration with military researchers and clinicians is encouraged.

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

**Multiple PI Option:** The Qualitative Research Award mechanism includes an option for up to four Principal Investigators (PIs). One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as a Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in Section II; however, all PIs should contribute significantly to the development of the proposed research project. If recommended for funding, each PI will receive his or her own award.

**Rigor of Experimental Design:** All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies.

***Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.*** Applications including a clinical trial as any part of the application will be administratively withdrawn. A clinical trial is defined as a prospective accrual of human subjects whereby an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested with a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical trials and clinical research, a Human Subject Resource Document is provided at <https://ebrap.org/eBRAP/public/Program>

**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.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

**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/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, for studies involving active duty military Service members, Veterans, military- and/or VA-controlled study materials, and military and/or VA databases. 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 [Section II.C., Full Application Submission Content, 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 – Research,  
Development, and Acquisition Directorate  
<http://www.health.mil/About-MHS/Defense-Health-Agency/Research-Development-Acquisition>

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.med.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://wrair-www.army.mil>

*The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 4, Section K.*

#### **D. Eligibility Information**

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *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.*

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## **E. Funding**

- The maximum period of performance is **3** years.
- **Application submissions with a Single PI:** The anticipated total costs budgeted for the entire period of performance will not exceed **\$1M**. 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 rate exceeding the organization's negotiated rate.
- **Application submissions with Partnering PI(s):** The combined total costs budgeted for the entire period of performance for the Initiating and the Partnering PIs' applications will not exceed **\$1.5M**. If the Initiating or Partnering PI's budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. 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 rate exceeding each organization's negotiated rate.
  - A separate award will be made to each PI's organization.
  - The PIs are expected to be partners in the research, and direct costs should be divided accordingly, unless otherwise warranted and clearly justified.
  - Any application that requests the higher level of funding and that does not include a Partnering PI will have its budget reduced as appropriate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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 (IPR) meeting. For planning purposes, it should be assumed that the meeting will take place in year 2 of the award and 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 up to one investigator to travel to one scientific/technical meeting per year, in addition to the required meeting described above. For application submissions with the Multiple PI Option, this is allowed for each Partnering PI's budget.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.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 Section II.C.4. of the General Application Instructions.***

***The CDMRP expects to allot approximately \$2.5M of the \$12M FY16 RTRP appropriation to fund approximately 2 Qualitative Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## **II. 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).***

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application

submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity.

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the application deadline.***

Application viewing, modification, and verification in eBRAP is 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.

**Multiple PI Option:** The Qualitative Research Award mechanism is structured to accommodate from one 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 Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; 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. 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 Grants.gov application package with that of the Initiating PI.*** 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.

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-RTRP-QRA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

***The pre-application process should be started early to avoid missing deadlines. There are no grace periods. 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 application process on Grants.gov.***

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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](mailto: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 either be 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 either be 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.
  - [FY16 RTRP Programmatic Panel](#) members should not be involved in any pre-application or application. For questions related to Programmatic Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
  - 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 application preparation, research, or other duties for submitted applications. For FY16, 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 conflicts of interest (COI) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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 Appendix 1, Section C, of the General Application Instructions 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.*

**Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Background/Research Problem:** Describe the research problem to be addressed and discuss why it is important. State the ideas and reasoning on which the proposed research project is based. Explain why a qualitative, rather than a quantitative, approach is more appropriate to address the research problem.
- **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the specific theoretical perspective of qualitative research upon which the study is based, as well as the overall study design, including data collection, subject recruitment, and data analyses.
- **Impact and Alignment with Focus Areas:** Describe the impact of this study on the field of reconstructive transplant research, patient care, and/or quality of life, including the impact on at least one of the FY16 RTRP Qualitative Research Award Focus Areas.
- **Military Relevance:** Describe how the proposed research project would impact healthcare needs of military Service members and/or Veterans recovering from traumatic injury, and/or their family members, caregivers or clinicians, as well as the general public.

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

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, 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 used in the Preproposal Narrative.
  - PI Biographical Sketches (six-page limit per individual). Include biographical sketches for the PI(s), including the Initiating and Partnering PIs if the application is submitted under the Multiple PI Option. *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **Tab 6 – Submit Pre-Application**
    - This tab must be completed for the pre-application to be accepted and processed.

### Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the FY16 RTRP, pre-applications will be screened based on the following criteria:

- **Background/Research Problem:** How well research problem is identified and is relevant to reconstructive transplantation. How well the selection of a qualitative approach, rather than a quantitative 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 Areas:** How well the proposed research addresses at least one of the FY16 RTRP Qualitative Research Award Focus Areas 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 and Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated

on the [title page](#) of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

### **C. Full Application Submission Content**

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

***Applications will not be accepted unless the Initiating PI 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. See Section II.C. of the General Application Instructions 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 Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

***Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.***

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline.***

The CDMRP requires separate Grants.gov 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 Grants.gov application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (Initiating PI and each Partnering PI) must be submitted by the Grants.gov deadline.***

The Grants.gov application package must be submitted using the unique eBRAP log number assigned during pre-application submission to avoid delays in application processing.

## Application Components for a Single or Initiating PI:

**Grants.gov application package components:** For the Qualitative Research Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
2. **Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names 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, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov 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, etc.) 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.

***Preliminary and/or published data relative to reconstructive transplant and the proposed research project are encouraged but not required.*** Describe the proposed project in detail using the outline below.

- **Background/Research Problem:** Identify the research problem to be addressed, and discuss why it is important. Describe the ideas and reasoning on which the proposed project is based. Explain why a qualitative, rather than a quantitative, approach is more appropriate to address the research problem. Cite relevant literature, and describe previous experience most pertinent to this project.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this application. If the proposed work is part of a larger study, present only tasks that would be funded under this FY16 RTRP award.
- **Study Design and Feasibility:** Describe the specific theoretical perspective of qualitative research upon which the study is based, as well as 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.
- **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 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 taken to control biases and preconceptions. Explain how the projects 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. Start each document on a new page. Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *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 publically 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/Funding Opportunity, 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.
- Intellectual Property
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - 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 4, Section K, for more information about the CDMRP expectations for making data and research resources publically 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 publically. ***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. Describe the ideas and reasoning on which the proposed project is based. Explain why a qualitative, rather than a quantitative, approach is more 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 at least one of the FY16 RTRP Qualitative Research Award Focus Areas.
- **Military Relevance:** Briefly explain how the proposed project will have immediate or potential long-term benefit for the healthcare needs of military Service members and/or Veterans recovering from traumatic injury, and/or their family members, caregivers or clinicians, as well as the general public.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. ***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 the ultimate applicability and impact of the research.
  - Identify the FY16 RTRP Qualitative Research Award Focus Area(s) to be addressed.

- 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, Veterans, and/or their family members.
- o What are the likely contributions of the proposed research to advancing the field of VCA 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. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating 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 6: Impact and Military Relevance Statement (two-page limit): Upload as “ImpactMilRel.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 as assessment of the likelihood that a successful outcome of the proposed project will lead to a practical application in individuals recovering from traumatic injury. Address the impact on at least one of the FY16 RTRP Qualitative Research Award Focus Areas. Although not all-inclusive, the following are examples of ways in which research projects may have an impact, if successful:
  - o Has the potential to advance the field of reconstructive transplant research.
  - o Has the potential to change the standard of care.
  - o Contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.

In addition, 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 targeted population. If applicable, show how the proposed research project aligns with DoD and/or VA areas of research interest.

- **Attachment 7: 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 8: Collaborating DoD Military Facility 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 Collaborating DoD Military Facility 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 II.C.7., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- **PI Biographical Sketch (six-page limit): Upload as “Biosketch\_LastName.pdf.”** The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.
- Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”**
  - **Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch\_LastName.pdf.”**
    - Include biographical sketches for the Initiating and Partnering PI(s), as well as other key personnel.
  - **Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”**
    - Include previous/current/pending support for the Initiating and Partnering PI(s), as well as other key personnel.

- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
  - *Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined (direct and indirect) costs budgeted for the entire period of performance for the Initiating and the Partnering PIs’ applications will not exceed \$1.5M. If the Initiating or Partnering PI’s budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. 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 rate exceeding each organization’s negotiated rate.*
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.
- Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project 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 Collaborating DoD Military Facility Budget Form (use Attachment 8, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. 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 II.C.7., for detailed information.

<b>Application Components for the Partnering PI(s):</b>
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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 Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package that includes:

**1. SF424 (R&R) Application for Federal Assistance Form**

**2. Attachments Form**

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

**3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- *Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated total (direct plus indirect) combined costs budgeted for the entire period of performance for the Initiating and the Partnering PIs’ applications will not exceed \$1.5M. If the Initiating or Partnering PI’s budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. 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 rate exceeding each organization’s negotiated rate.*

**4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

**5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.5., for detailed information.

Collaborating DoD Military Facilities Form: Refer to the General Application Instructions, Section II.C.7., for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

**D. Applicant Verification of Grants.gov 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 an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity. *If*

*either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

#### **E. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

#### **F. Other Submission Requirements**

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

All extramural applications must be submitted through Grants.gov. 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. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. 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 DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and FY16 RTRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. 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 III.B.2., 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 Title 18 United States Code 1905.

## **B. Application Review Process**

**1. 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 transplant is justified.
- How well the selection of a qualitative approach, rather than a quantitative 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 appropriate the proposed design of the study, the sampling technique, and the data collection and recording method(s) 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 PI 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 documentation of procedures, decisions, and rationale for decisions and conclusions support 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 PI acknowledges potential problems and addresses alternative approaches.



- **Impact**
  - If successful, how the study will improve our understanding of individuals who have experienced, or are facing the option of, reconstructive transplantation, and/or the reality of lifelong immunosuppression.
  - How well the proposed research project addresses a critical problem in reconstructive transplant research, patient care, and/or quality of life.
  - How well the proposed research project addresses one or more of the FY16 RTRP Qualitative Research Award Focus Areas.
- **Personnel**
  - How appropriate the relevant education, training, and experience of the key personnel are to accomplish the proposed project.
  - Whether the levels of effort are appropriate for successful conduct of the proposed work.
  - How well the PI's record of accomplishment, particularly with the use of qualitative methods, demonstrates his/her ability to accomplish the proposed research project.
  - **Partnering PI Option:** How well the evidence supports that all partners contribute substantially to the development and implementation of the research plan. How the partners' combined expertise will better address the research problem.

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 budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

- 2. 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:
- a. Ratings and evaluations of the peer reviewers**
  - b. Relevance to the mission of the DHP and FY16 RTRP, as evidenced by the following:**
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Programmatic relevance to FY16 RTRP Qualitative Research Award Focus Areas
    - Relative impact and military relevance

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **E. Notification of Application Review Results**

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.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

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

- 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.

## **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.

## **C. Withdrawal**

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

- An FY16 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 FY16 RTRP Programmatic Panel members can be found at <http://cdmrp.army.mil/rtrp/panels/panels16>.*
- The application fails to conform to this Program Announcement/Funding Opportunity 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 FY16, 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 Government. Refer to the General Application Instructions, Appendix 1, 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.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline, if applicable.
- A clinical trial is proposed.
- The PI(s) does not meet the eligibility criteria.

## **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.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

### **C. National Policy Requirements**

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

### **D. Reporting**

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Quarterly technical progress reports and quad charts, as well as in-person presentation(s), will be required.

### **E. Award Transfers**

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 4, Section L, for general information on organization or PI changes.

## **VI. VERSION CODES AND AGENCY CONTACTS**

### **A. Program Announcement/Funding Opportunity and General Application Instructions Version**

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20160210j. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code 20160210.

### **B. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application 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](mailto:help@eBRAP.org)

### **C. Grants.gov Contact Center**

Questions related to 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](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity 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.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Impact and Military Relevance Statement: Upload as Attachment 6 with file name "ImpactMilRel.pdf."		
	7	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 7 with file name "Surveys.pdf," if applicable.		
	8	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 8 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.		
Research & Related Budget		Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form		Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.		