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

Clinical Network Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-RTRP-CNA

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), November 17, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, December 3, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, December 8, 2020
- **Peer Review:** January 2021
- **Programmatic Review:** March 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 503. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2020 (FY20) Reconstructive Transplant Research Program (RTRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The RTRP was initiated in 2012 to provide support for research of exceptional scientific merit to refine approaches for, and increase access to, reconstructive transplants and state-of-the art immunotherapy. Appropriations for the RTRP from FY12 through FY19 totaled $93 million (M). The FY20 appropriation is $12M.

The RTRP challenges the scientific community to design innovative research that will optimize form, function, appearance, and psychosocial health for catastrophically injured Service members, Veterans, and American civilians through the development of effective reconstructive transplantation solutions. More specifically, the RTRP seeks vascularized composite allotransplantation (VCA)-focused research, also known as composite tissue allotransplantation. VCA refers to the transplantation of multiple tissues such as muscle, bone, nerve, and skin, as a functional unit (e.g., a face or hand) from a deceased donor to a recipient with a severe injury. The ultimate goal is to return injured Service members to duty and restore their quality of life.

Applications from investigators from within the military Services and applications involving multi-institutional multidisciplinary collaborations among academia, industry, the military Services, the U.S. Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged. The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY20 RTRP Clinical Network Award Focus Areas

To meet the intent of the FY20 RTRP Clinical Network Award mechanism, applicants must address the standardization, assessment, and validation of protocols and/or standard operating procedures (SOPs) for all of the following focus areas for both face and hand transplantation.

- Patient inclusion/exclusion criteria
- Patient education
- Surgical procedures
- Immunosuppression and/or immunoregulation
- Outcome metrics
- Quality of life measures
- Rehabilitation
- Patient reporting (e.g., registry)

II.A.2. Award History

The RTRP Clinical Network Award mechanism is being offered for the first time in FY20.

II.B. Award Information

The RTRP seeks to promote a major multi-institutional network of VCA Centers and associated collaborators for the purpose of standardizing clinical protocols and SOPs for face and hand transplantation, and assessing those protocols in multi-institutional clinical trials. It is the intent of the RTRP to bring together investigators from as many VCA Centers for both face and hand transplantation as possible to establish a consensus in the field of reconstructive transplantation for these protocols and SOPs. The RTRP recognizes that such a consensus is a necessary first step to advancing face and hand transplantation from experimental status to that of a viable choice with the potential for reimbursement under health insurance policies.

This effort will be executed through a two-phased approach in the form of a single award to the Clinical Network Coordinating Center. The Coordinating Center will serve as the Clinical Network information and planning nexus, providing administrative, operational, and data management support services to implement Clinical Network activities in a timely manner. Guidance and oversight of the Clinical Network will be provided by the RTRP Clinical Network Steering Committee, composed of the RTRP Programmatic Panel, program staff, and other key U.S. Army Medical Research and Development Command (USAMRDC) personnel.

Phase I

Phase I of the award will consist of five key objectives:

- **Establish the Clinical Network:** Once awarded, the Coordinating Center must work with the RTRP Clinical Network Steering Committee to invite VCA Centers and other collaborators into the Clinical Network as subawards to serve as Network Sites. (Network Sites ***will not*** be included in the application itself.) The Clinical Network must be representative of both face and hand transplantation and include as many VCA Centers as possible, as well as other collaborators as necessary to adequately include expertise across all RTRP Clinical Network Focus Areas.

- **Develop Standardized Protocols and SOPs:** The Coordinating Center will establish a framework and collaborative environment for the Clinical Network within which the Network Sites will work as equal partners to meet the goals of standardizing protocols and SOPs for both face and hand transplantation.

- **Develop Clinical Trial Applications:** The Coordinating Center will work with the Network Sites to develop one clinical trial application for face transplantation and one clinical trial application for hand transplantation utilizing the standardized protocols and SOPs.

- **External Peer Review:** The Coordinating Center will be responsible for coordinating and funding an external scientific peer review of the two clinical trial applications developed

under Phase I of the award. Results of the peer review will then be submitted to the RTRP Clinical Network Steering Committee for assessment.

- **Regulatory Approval:** Any regulatory approvals required by the U.S. Food and Drug Administration (FDA) must be obtained during Phase I. Upon approval to proceed with the scientifically reviewed clinical trials from the RTRP Clinical Network Steering Committee, the standardized protocols and SOPs will be submitted to the single unified Institutional Review Board (IRB) of record for review and, upon approval, then submitted to the USAMRDC Human Research Protection Office (HRPO) for review and approval.

The period of performance for Phase I is 2 years, with maximum funding of $3 million (M) in total costs to the Coordinating Center. The Coordinating Center will manage funding to the Network Sites as subawards and for other key collaborators. RTRP funding for the Phase II option is contingent on successful completion of Phase I objectives and on available funding.

Phase II

The Phase II option of the award, pending availability of funds, will have one key objective:

- **Conduct Clinical Trials:** The Clinical Network will expand upon the successful development of standardized protocols and SOPs for both face and hand transplantation by assessing and validating them in multi-institutional clinical trials (one for face transplantation and one for hand transplantation). Network Sites with VCA Centers will serve as enrollment sites for at least one of the clinical trials, depending on its specialty in face and/or hand transplantation.

The period of performance for the Phase II option is 4 years, with maximum funding of $10M in total costs to the Coordinating Center. The Coordinating Center will manage funding to the Network Sites as subawards and for other key collaborators.

The clinical trial must open for enrollment within 2 months after the start of the Phase II option.

Coordinating Center Description

Key requirements for the Coordinating Center include:

- Principal Investigator (PI) with a proven track record of leadership, including clinical trials, and the scientific ability to direct and oversee a large multi-institutional VCA effort; the PI is expected to commit an appropriate level of time and effort to direct and manage a project of this magnitude.

- Experience in managing multi-institutional collaborations.

- Knowledge of the intricacies of the VCA field so that it can effectively lead the Network in achieving its objectives.

Key responsibilities of the Coordinating Center are to:

- Develop and maintain the Clinical Network organizational structure. Work with the RTRP Clinical Network Steering Committee to invite VCA Centers and other collaborators into the Clinical Network as subawards to serve as Network Sites. (Network Sites ***will not*** be included as subawards in the application itself; rather, they will be added once the Coordinating Center has been selected.)

- Under leadership of the PI, provide day-to-day management of the Clinical Network and ensure that the Clinical Network adheres to the planned timeline and milestones for overall study execution.

- Establish and manage procedures to ensure that all Network Sites receive RTRP funding for the Phase(s) in which they participate. (See special requirements for funding of clinical trials in the Phase II option.)

- Facilitate the necessary agreements (e.g., regulatory, material and intellectual property, Cooperative Research and Development Agreements [CRADAs]) between all participating Network Sites to ensure seamless collaboration so that the Clinical Network functions as a cohesive unit rather than a collection of different sites.

- Develop and manage a communications plan and real-time communications with Network Site members and other key collaborators.

- Establish and manage an intellectual and material property plan for all institutions participating in the Clinical Network.

- Manage real or potential conflicts of interest.

- Facilitate a collaborative research environment for the development of standardized protocols and SOPs for VCA, as well as for the development of clinical trial applications (one for face transplantation and one for hand transplantation), and coordinate schedules and maintain timelines for achieving objectives, etc.

    - For example, this might be done through the establishment of a multi-institutional working group for each protocol and SOP to be standardized and/or clinical trial application to be written.

    - Ensure that the appropriate expertise is included in the efforts to develop each protocol, SOP, and clinical trial (e.g., scientific, medical, human subjects protection, regulatory, etc.).

- Establish a fair and equitable process through which each protocol and SOP is reviewed and revised and ultimately finalized as standard.

- Establish and maintain procedures for ensuring compliance with FDA requirements for investigational agents, devices, and procedures, as applicable.

- Develop and manage procedures for external scientific review of the clinical trial applications (one each for both face and hand transplantation) developed during Phase I of the award.

- Provide a Clinical Research Manager, who will facilitate the regulatory approvals for each standardized protocol and will interact with the Clinical Research Coordinators at each Network Site to coordinate patient accrual and study activities across sites.

- Establish and manage procedures to obtain approval for and maintain compliance of protocols with a single unified IRB of record for the Clinical Network and with HRPO.

- Develop and manage a comprehensive data collection and data management plan that addresses the needs of all Network Sites in terms of access to data, data security, and data integrity measures.

- Develop and manage quality assurance and quality control mechanisms for clinical trial monitoring.

    - Registration, tracking, and reporting of participant accrual.

    - Timely medical review, rapid reporting, communication of adverse events, and management/coordination among all Network Sites.

    - Interim evaluation and consideration of measures of outcome.

- Ensure the standardized collection, cataloging, storage, and use of specimens, imaging products, and other data as appropriate for the clinical trials.

- Ensure that the clinical trials are initiated (i.e., open for enrollment) within 2 months of the start of the Phase II option.

- Develop and manage procedures for timely publication of major outcomes and other public dissemination of data and study results.

- During Phase I, coordinate and facilitate at least two internal Clinical Network review meetings for all Clinical Network key investigators to facilitate face-to-face discussions and evaluate progress toward objectives. These meetings should be open to and coordinated with the RTRP Clinical Network Steering Committee, and are recommended at approximately months 6 and 18 of the award.

- During the Phase II option, coordinate regularly scheduled meetings (via teleconference or other media platform) to facilitate discussion of clinical trial progress among Network Site PIs (e.g., recruitment efforts, enrollment, patient listings, transplants, rejection episodes or other adverse events, successes, challenges, etc.). These meetings should be open to the RTRP management team.

- Coordinate the preparation of briefings for and attend annual In Progress Review (IPR) meetings. IPR meetings will be hosted by the RTRP and when possible will occur in person

in the National Capital Region, but may alternatively occur via teleconference or other media platform.

- Maintain regular communications with the RTRP management team, to include the CDMRP Science Officer, Grants Officer Representative (GOR), USAMRAA Grants Officer and other USAMRDC personnel.

Network Site Description

The Network Sites are to serve as equal partners in the Clinical Network and are responsible for working collaboratively with the Coordinating Center and with the other Network Sites to meet the objectives of the Clinical Network. No single Network Site, including the Network Site associated with the Coordinating Center, if applicable, is to have authority over the other Network Sites or to have the final determination or veto power of the protocols and SOPs being developed.

Key requirements of Network Sites include one of the following:

- An established VCA Center led by a Network Site PI with expertise in face and/or hand transplantation. A Network Site with a VCA Center is expected to have an active role in both Phase I and the Phase II option of the Clinical Network.

- An institution led by a Network Site PI with a track record in VCA research that has expertise in one or more of the RTRP Clinical Network Focus Areas. A Network Site without a VCA Center is expected to have an active role in Phase I of the Clinical Network but may have a diminished role, if any, in the Phase II option.

Key responsibilities of Network Sites are to:

- Work with the Coordinating Center to complete all agreements (e.g., regulatory, material and intellectual property, CRADAs) as necessary to participate in the Clinical Network.

- Participate and work collaboratively to develop standardized protocols, SOPs, and clinical trial applications for face and/or hand transplantation.

- Comply with the Coordinating Center's communication plan (e.g., participate in scheduled meetings, etc.).

- Participate in procedures developed by the Coordinating Center for resolution of intellectual and material property issues among organizations in the Clinical Network.

- Implement procedures established by the Coordinating Center for ensuring compliance with FDA, IRB, and HRPO requirements, as applicable.

- Comply with the quality assurance and quality control procedures established by the Coordinating Center, including participation in an onsite monitoring program to be managed by the Coordinating Center.

- Implement the Coordinating Center's management plan for collection, cataloging, storage, and use of specimens, imaging products, and other clinical data.

- Share available research resources with other members of the Clinical Network.

- During the Phase II option, participate as a clinical site for enrollment in at least one clinical trial (if a VCA Center).

    - Provide a Clinical Research Coordinator, who will interact with the Clinical Research Coordinators of other Network Sites and the Coordinating Center's Clinical Research Manager to ensure regulatory approvals for the standardized clinical protocols and SOPs and to coordinate patient accrual and study activities across sites.

- Participate in procedures developed by the Coordinating Center for timely publication of Clinical Network outcomes and other public dissemination of data and study results, as applicable.

- Support the Clinical Network's collaborative effort by participating in internal Clinical Network review meetings during Phase I and regularly scheduled teleconferences during the Phase II option, as specified by the Coordinating Center. These meetings are intended to facilitate discussion across Network Sites and evaluate progress of protocol/SOP development (Phase I) and clinical trial execution (Phase II option).

- Assist with preparation of briefings for, and attend, annual IPR meetings.

Clinical Network Oversight

- **RTRP Clinical Network Steering Committee:** The RTRP Clinical Network Steering Committee will consist of the RTRP Programmatic Panel, program staff, and other key subject matter experts and USAMRDC personnel; ad hoc members may be included as needed. This committee will provide oversight of all aspects of the Clinical Network, as well as guidance for the Coordinating Center at critical junctures (e.g., establishment of the Clinical Network, scientific review of the clinical trial applications in both face and hand transplantation, etc.).

- **In Progress Reviews:** The Coordinating Center and Network Site PIs are required to present progress updates to the RTRP Clinical Network Steering Committee at annual IPR meetings, which will be hosted by the RTRP. It is anticipated that these meetings will be held in person toward the end of each performance year; however, alternate arrangements will be made (e.g., teleconference or other media platform) should in-person meetings be restricted or otherwise infeasible.

The type of award made under the Program Announcement will be an assistance agreement. An assistance agreement is appropriate when the Federal Government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of

Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated total costs budgeted for the entire period of performance for an FY20 RTRP Clinical Network Award will not exceed **$3,000,000 for Phase I and $10,000,000 for the Phase II option**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $3M in FY20 and $10M in FY22 to fund approximately one (1) Clinical Network Award application. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY20 funding opportunity will be funded with FY20 and FY22 funds, which will expire for use on September 30, 2026 and 2028, respectively.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

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

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

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Federal Government organization other than the DoD, and research institutes.

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

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent Investigators at or above the level of Assistant Professor (or equivalent) are eligible to be named PI.

Each investigator may be named on only one FY20 RTRP Clinical Network Award application as a PI.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission:

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

Intramural DoD Submission:

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

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

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

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

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

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

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

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

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

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

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

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

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

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

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at

https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

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

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

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

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

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

  FY20 RTRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the plans for serving as the Coordinating Center of the Clinical Network. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

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

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

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

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

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

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

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-20-RTRP-CNA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-20-RTRP-CNA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General	**Tab 1 – Summary:** Provide a summary of the application information.

Extramural Submissions	Intramural DoD Submissions
Application Instructions, Section III.A.1, for detailed information.	**Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. **Note:** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***

Extramural Submissions	Intramural DoD Submissions
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

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

- **Attachment 1: Project Narrative (30-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.

  Network Development Plan

  - Describe plans for building the Clinical Network in collaboration with the RTRP Clinical Network Steering Committee. Plans should demonstrate knowledge of current VCA Centers and their experience in face and/or hand transplantation, and also of other potential collaborators with VCA expertise specific to the RTRP Clinical Network Focus Areas. The intent to be inclusive of as many VCA Centers as possible should be evident in the plans described. (Network Sites ***will not*** be included as subawards in the application itself; rather, they will be added once the Coordinating Center has been awarded.)

  - Describe the projected organizational structure for the Clinical Network, including key positions and committees, and the roles they play within the Coordinating Center and/or between the Coordinating Center and Network Sites. Provide a graphical representation for the organizational structure. Explain how this structure is appropriate for achieving the objectives of the Clinical Network.

  - Describe how the Clinical Network will be representative of both face and hand transplantation and all RTRP Clinical Network Focus Areas.

  - Describe plans to acquire the necessary agreements (e.g., regulatory, material and intellectual property, CRADAs, etc.) between all participating Network Sites to ensure seamless collaboration so that the Clinical Network functions as a cohesive unit rather than a collection of different sites. This should include a plan to establish and manage an intellectual and material property plan for the Clinical Network, and to manage real or perceived conflicts of interest.

  Personnel and Resources

  - Identify key personnel and their projected roles and contributions to the Clinical Network, to include at a minimum the PI and a Clinical Research Manager. The Clinical Research Manager will facilitate the regulatory approvals for each protocol

and will interact with the Clinical Research Coordinators at each Network Site to coordinate patient accrual and study activities across sites. Explain how the level of effort proposed for the PI is appropriate to directing and managing a project of this magnitude.

- Describe the PI's previous leadership experience and accomplishments related to design, administration, and management of collaborative multi-institutional research projects, including clinical trials.

- For the PI and other key personnel, describe their breadth of understanding of, and/or experience in, VCA and related research and/or patient care, as well as the knowledge of intricacies in the VCA field (e.g., ongoing collaborative efforts, institutional policies, challenges, etc.) that could impact success of the Clinical Network's objectives.

- Describe the expertise and experience of other key personnel and how this is appropriate for their proposed role in the Clinical Network.

- Provide evidence of organizational commitment to the Coordinating Center, and describe the resources and facilities that will be available for this effort, Include leveraged activities, distinguishing between what is already established versus what would be new aspects to be supported.

- Describe the resources that the Coordinating Center will make available to Network Sites, and how they will support the Clinical Network.

Network Coordination

- Describe plans to ensure that all Network Sites and other key collaborators receive RTRP funding for the Phase(s) in which they participate.

- Describe the timeline for overall study execution and achieving the Clinical Network's objectives and milestones.

- Describe plans for day-to-day management and coordination of the Clinical Network, for facilitating a collaborative research environment, and for coordinating schedules and maintaining timelines for achieving objectives and milestones.

- Describe plans for real-time communication with and among all Network Sites and other key collaborators, including the anticipated platforms and frequencies for each communication need.

- Describe plans to coordinate and facilitate at least two internal Clinical Network review meetings during Phase I (recommended at months 6 and 18). The purpose of these meetings is to facilitate collaboration through face-to-face discussions, as well as evaluate progress toward the Clinical Network's objectives and milestones. In addition to Coordinating Center personnel, attendees should include all Network Site PIs and key collaborators, as well as the RTRP Clinical Network Steering Committee.

Describe back-up plans should in-person gatherings be restricted or otherwise infeasible.

- Describe plans to coordinate regularly scheduled meetings (via teleconference or other media platform) during the Phase II option to facilitate discussion of clinical trial progress among Network Site PIs (e.g., discuss recruitment efforts, enrollment, patient listings, transplants, rejection episodes or other adverse events, successes, challenges, etc.). These meetings should be open to the RTRP management team.

- Describe plans to coordinate the preparation of briefings for annual IPR meetings (i.e., progress reports to the RTRP Clinical Network Steering Committee), which are anticipated to be held by the RTRP toward the end of each performance year. For planning purposes, assume these will be in-person meetings in the National Capital Region that the Coordinating Center and Network PIs are required to attend; however, alternate arrangements (e.g., teleconference or other media platform) will be made should in-person gatherings be restricted or otherwise infeasible.

- Describe plans for developing and managing procedures for timely publication of major outcomes and other public dissemination of data and study results.

Protocol & SOP Development

RTRP Clinical Network Focus Areas: Applicants **must** address the standardization, assessment, and validation of protocols and/or standard operating procedures (SOPs) for **all** of the following focus areas for both face and hand transplantation.

  - Patient inclusion/exclusion criteria
  - Patient education
  - Surgical procedures
  - Rehabilitation
  - Immunosuppression and/or immunoregulation
  - Outcome metrics
  - Quality of life measures
  - Patient reporting (e.g., registry)

- Describe plans for development, review, revision, and finalization of standardized VCA protocols and SOPs for both face and hand transplantation for all RTRP Clinical Network Award Focus Areas through a fair and equitable process, utilizing the appropriate expertise (e.g., scientific, medical, human subjects protection, regulatory, etc.) for each protocol and SOP, and maintaining representation across Network Sites.

- Describe plans for mitigating and resolving conflicts that may arise during the protocol and SOP development process to ensure completion of milestones and achievement of objectives.

Clinical Trial Development

- Describe plans for preparing two clinical trial applications, one for face transplantation and one for hand transplantation, utilizing the standardized protocols and SOPs developed under Phase I.

- Describe plans for an external scientific review of the clinical trial applications, and for sharing the peer review results with the RTRP Clinical Network Steering Committee.

Clinical Trial Management

- Describe plans for ensuring compliance with FDA requirements for investigational agents, devices, and procedures during Phase I, as applicable.

- Outline plans for streamlining the process required to initiate clinical trials across Network Sites (e.g., unified IRB review and HRPO review during Phase I, site visits, training) to ensure that clinical trials are initiated (i.e., open for enrollment) within 2 months of Phase II option initiation.

- Outline plans to develop quality assurance and quality control mechanisms for clinical trial monitoring, to include:

  - Registration, tracking, and reporting of participant accrual.

  - Timely medical review, rapid reporting, communication of adverse events, and management/coordination among all Network Sites.

  - Interim evaluation and consideration of measures of outcome.

- Describe plans for developing and managing a comprehensive data collection and data management plan that addresses the needs of all Network Sites in terms of:

  - Standardized collection, cataloging, and storage of specimens, imaging products, and other data as appropriate for the clinical trials.

  - Access to specimens, imaging products, and other data.

  - Data security and data integrity measures.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures,

tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- Letters of Collaboration (if applicable): ***Do not provide letters of collaboration from potential Network Sites in this application; if provided, they will be removed prior to review. Collaborations that support the function of the Coordinating Center, however, are permitted with the application (e.g., core facilities, regulatory or statistical support, etc.).*** 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.

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

- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.

- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Attachment 3: Technical Abstract (two-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:** Briefly describe plans for developing the Clinical Network, including key personnel and any expertise and resources that will support its success. Outline the projected organizational structure for the Clinical Network and a "big picture" perspective of the planned management scheme. Briefly describe plans for facilitating a collaborative research environment to ensure that the Clinical Network functions as a cohesive unit.

- **Specific Aims:** State the Specific Aims for both Phase I and the Phase II option of the Clinical Network.

- **Protocol and SOP Development:** Briefly describe plans for standardized VCA protocol and SOP development for both face and hand transplantation for all RTRP Clinical Network Award Focus Areas through a fair and equitable process, ensuring appropriate expertise and representation across Network Sites.

- **Clinical Trial Development:** Briefly describe plans for development of two clinical trial applications (one for face transplantation and one for hand transplantation), utilizing the standardized protocols and SOPs developed in this effort. Also describe plans for an external scientific review of the clinical trial applications, and for sharing the results with the RTRP Clinical Network Steering Committee.

- **Clinical Trial Management:** Briefly describe plans for preparing the Clinical Network to initiate clinical trials in both face and hand transplantation within 2 months of the Phase II option initiation (e.g., ensuring regulatory and human subjects compliance, developing quality assurance and control mechanisms, standardized specimen and data collection and management, etc.). Briefly describe plans for managing the clinical trials during the Phase II option.

- **Impact:** Briefly describe the impact of the proposed Coordinating Center on successfully achieving the Clinical Network's objectives to standardize protocols and SOPs in both face and hand transplantation, and assess and validate them in clinical trials.

- **Military Relevance:** Briefly explain how the proposed Coordinating Center's effort will have immediate or potential long-term benefit for the healthcare needs of military Service members and/or Veterans recovering from traumatic injury, and/or their family members, caregivers, or clinicians, as well as the general public.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Do not duplicate the technical abstract. Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. Lay abstracts should be written using the outline below.

  - Describe why the PI and their organization are appropriate to lead the Clinical Network in its effort to develop standardized protocols and SOPs for both face and hand transplantation across all RTRP Clinical Network Award Focus Areas, and to assess and validate them in clinical trials.

- Describe the ultimate applicability of this research effort.
  - What types of patients will it help?
  - What are the potential applications, benefits, and risks?
  - What is the projected time to achieve a relevant outcome?
  - What are the likely contributions to advancing the field of VCA research?
- Briefly describe how the proposed Coordinating Center's effort 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.

- **Attachment 5: Statement of Work (five-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 Clinical Network Award mechanism, use the SOW format example titled, "SOW (Statement of Work) Generic Format." 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) and contact information for the key personnel. Network Site information will be added later, after award notification and once the sites have been identified.
  - ***Clearly delineate aims and tasks that fall under Phase I from those that fall under the Phase II option.***
  - Briefly state the steps that will be taken to develop the Clinical Network and integrate the Coordinating Center and each Network Site to form a cohesive unit and collaborative environment.
  - Briefly state the tasks for coordinating and managing the Clinical Network.
  - Briefly state the steps for developing and implementing a fair and equitable process for standardized VCA protocol and SOP development for both face and hand transplantation across all RTRP Clinical Network Award Focus Areas.
  - Briefly state the steps for developing clinical trial applications (one each in both face and hand transplantation), and for ensuring an external scientific review of those applications.

- Briefly state steps for preparation and management of clinical trials in both face and hand transplantation (e.g., regulatory approvals; unified IRB reviews; data and specimen collection, management, and sharing; quality assurance and quality control mechanisms, etc.).

- Include tasks for hosting and facilitating Clinical Network review meetings (Phase I) and regular meetings (via teleconference or other media platform) during the Phase II option for Network Sites to discuss clinical trial progress. Also include plans for preparing for and attending IPRs.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".**

  - Describe the potential short-term impact of the proposed Coordinating Center on the success of the Clinical Network's objectives to develop standardized protocols and SOPs for both face and hand transplantation across the RTRP Clinical Network Award Focus Areas.

  - Describe the potential long-term impact of the proposed Coordinating Center on the success of the Clinical Network's objectives to assess and validate the standardized protocols and SOPs in clinical trials, pending success of Phase I objectives and availability of funding. Describe the pathway to making an impact on the field of reconstructive transplant research, patient care, and/or quality of life.

- **Attachment 7: Military Relevance Statement (one-page limit): Upload as "MilRel.pdf".** Demonstrate how the proposed Coordinating Center's effort will have immediate or potential long-term benefit for the healthcare needs and quality of life of military Service members and/or Veterans recovering from traumatic injury, and/or their family members, caregivers, or clinicians, as well as the general public. If applicable, show how the proposed research aligns with DoD and/or VA areas of research interest.

- **Attachment 8: Clinical Strategy Statement, (no page limit): Upload as "Clinical.pdf".** If funds for a clinical trial are requested, this attachment is required. ***Since the details of a clinical trial will not be proposed until the end of Phase I, a sample statement in the FY20 Clinical Network Award application should indicate a general strategy for including women and minorities as appropriate to the objectives of the study. The clinical trial applications, when developed, must include the details below as part of the applications.***

  Describe the rationale for the proposed clinical trial. Provide a description of the intervention, and the endpoints to be measured. Provide detailed plans for initiating the clinical trial within 2 months after the initiation of the Phase II option. Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The

suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate. Describe how the clinical trial will inform the correlative clinical research, if applicable. Describe the data management plans. If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that would be supported with funds from this award. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Attachment 9: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 10: Suggested Collaborating DoD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DoD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

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

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

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

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

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

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

- **Intramural DoD Collaborator(s):** Complete the "Suggested Collaborating DoD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 10. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

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

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

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

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

II.D.5. Funding Restrictions

The maximum period of performance is 2 years for Phase I, with an option for 4 years for Phase II, pending successful completion of Phase I objectives and availability of funding.

The anticipated total costs budgeted for the entire period of performance will not exceed **$3M for Phase I** and **$10M for the Phase II option**. 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 **$3M total costs for Phase I** or **$10M total costs for the Phase II option**, or using an indirect cost rate exceeding the organization's negotiated rate.

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

A budget is required for Phase I. The Phase II option budget will be negotiated upon successful completion of Phase I, but will not exceed $10M total costs.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 2 years for Phase I, or 4 years for the Phase II option.

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

- **Clinical Network Review Meetings:** Costs to sponsor two Clinical Network review meetings during Phase I of the award, recommended at months 6 and 18.
- **In-Progress Review:** Travel costs for the Coordinating Center and Network Site PIs to attend and participate in annual IPR meetings, anticipated to occur near the end of each

performance year. For planning purposes, assume the meetings will take place in the National Capital Region.

- **DoD-Sponsored Meeting:** Travel costs for the PI to present project information or disseminate project results from the RTRP Clinical Network Award at a DoD-sponsored meeting (e.g., Military Health Services Research Symposium) once during each Phase. For planning purposes, assume that the meeting will be held in the Central Florida Region. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- **External Scientific Review:** Costs to contract for an external scientific review of two clinical trial applications (one for face transplantation and one for hand transplantation) during Phase I.

- **Network Sites:** It is the responsibility of the Coordinating Center to ensure RTRP Funding through subawards to each Network Site for their participation in Phase I and/or Phase II. For planning purposes, assume a total of 10-12 Network Sites for each Phase.

  Special Requirements:

  - Phase I (Standardized Protocol, SOP, and Clinical Trial Application Development): During Phase I, it is anticipated that costs for Network Site participation will largely be attributed to salary costs for time contributed by the PI and other key Network Site participants to draft, review, and revise protocols and SOPs, as well as for meetings and other communications with other Clinical Network participants.

  - Phase II Option (Clinical Trials):

    - A minimal budget should be provided for the Network Sites through subawards for costs such as regulatory fees and salaries for the PI and Clinical Research Coordinator.

    - Funds should be set aside within the Coordinating Center budget for the purpose of reimbursing a pre-determined flat rate amount to Network Sites for screening and transplant procedures and follow-up care (e.g., immunosuppression, rehabilitation, etc.). A separate flat rate amount may be determined for face vs. hand transplant, and unilateral vs. bilateral hand transplant, as deemed appropriate by the Coordinating Center.

May be requested for (not all inclusive):

- Travel in support of Clinical Network collaborations.

- Costs for up to three investigators to travel to one scientific/technical meeting per year (they may attend the same meeting or up to three separate meetings). The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results of the RTRP Clinical Network Award.

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

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5*.**

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are of equal importance:

Network Development Plan

- How well plans for building the Clinical Network emphasize collaboration with the RTRP Clinical Network Steering Committee and demonstrate knowledge of current VCA Centers that focus on both face and hand transplantation, as well as other potential collaborators with VCA expertise. How well the plans show evidence of being inclusive of as many VCA Centers as possible.

- How well the projected organizational structure is described (outlines key positions and committees and the roles they play within the Coordinating Center and/or between the Coordinating Center and Network Sites), and is appropriate for achieving the Clinical Network's objectives.

- How well the plans for the Clinical Network incorporate both face and hand transplantation, as well as all RTRP Clinical Network Award Focus Areas.

- How well the plans to integrate the Network Sites into the Clinical Network will ensure seamless collaboration so that it functions as a cohesive unit rather than a collection of different sites (e.g., acquisition of all necessary regulatory, collaborative, and intellectual and material property agreements; plans to manage conflicts of interest, etc.).

Personnel and Resources

- How well key personnel and their projected roles and contributions to the Clinical Network are identified and include the PI and a Clinical Research Manager, at a minimum. Whether the level of effort proposed for the PI is appropriate for directing and managing a project of this magnitude.

- The degree to which the PI has previous leadership experience and accomplishments in the design, administration, and management of collaborative multi-institutional research projects, including clinical trials.

- The degree to which the PI and other key personnel have a breadth of understanding of, and/or experience in, VCA and related research and/or patient care, as well as the knowledge of intricacies in the VCA field (e.g., ongoing collaborative efforts, institutional policies, etc.) that could impact success of the Clinical Network's objectives.

- How well the expertise and experience of key personnel are appropriate for their proposed role in the Clinical Network.

- Provision of evidence that the proposed Coordinating Center's organization is committed to the Clinical Network and will provide adequate resources and facilities.

- How well the resources to be made available to Network Sites through the Coordinating Center will support the objectives of the Clinical Network.

Network Coordination

- How well the Coordinating Center plans to ensure RTRP funding for all Network Sites and other key collaborators for the Phase(s) in which they participate.

- How well the timeline for overall study execution is described, and how strongly it supports the achievement of the Clinical Network's objectives and milestones.

- How well the plans for day-to-day management and coordination of the Clinical Network will facilitate a collaborative research environment, coordinate schedules, and maintain timelines for achieving its objectives and milestones.

- How well the plans for real-time communication with and among all Network Sites and other key collaborators describe adequate support for the communication needs of the Clinical Network.

- Whether there are plans to coordinate and facilitate at least two internal Clinical Network review meetings during Phase I, to include all Network Site PIs, key collaborators, and the RTRP Clinical Network Steering Committee.

- Whether there are plans to coordinate regularly scheduled meetings (via teleconference or other media platform) during Phase II to facilitate discussion of clinical trial progress among Network Site PIs. Whether the meetings will be open to the RTRP management team.

- Whether there are plans for the Coordinating Center to coordinate the preparation of briefings for annual IPR meetings, and whether the plans stipulate required meeting attendance by the Coordinating Center and Network Site PIs.

- Whether there are plans for developing and managing procedures for timely publication of major outcomes and other public dissemination of data and study results.

Protocol and SOP Development

- To what degree the plans for development, review, revision, and finalization of standardized VCA protocols and SOPs for both face and hand transplantation are appropriate, include all RTRP Clinical Network Award Focus Areas, utilize a fair and equitable process that incorporates appropriate expertise for each protocol and SOP, and maintain representation across Network Sites.

- How well the plans will mitigate and resolve conflicts that may arise during the protocol development process to ensure completion of milestones and achievement of objectives.

Clinical Trial Development

- Whether the plans for preparing clinical trial applications (one each for both face and hand transplantation) are appropriate and utilize the standardized protocols and SOPs developed during Phase I.

- Whether the plans for external peer review of the clinical trial applications are appropriate and include sharing the peer review results with the RTRP Clinical Network Steering Committee.

- Whether the application describes the strategy for the inclusion of women and minorities that is appropriate for the objectives of the study.

Clinical Trial Management

- How well plans are developed for ensuring compliance with FDA requirements, as applicable.

- How well plans are outlined for streamlining the process required to initiate clinical trials across Network Sites (e.g., unified IRB review and HRPO review during Phase I, site visits, training) to ensure that clinical trials are initiated (i.e., open for enrollment) within 2 months of Phase II initiation.

- How well plans are outlined for developing quality assurance and quality control mechanisms for clinical trial monitoring, to include:

    - Registration, tracking, and reporting of participant accrual.

    - Timely medical review, rapid reporting, communication of adverse events, and management/coordination among all Network Sites.

- Interim evaluation and consideration of measures of outcome.

- How well plans are outlined for developing and managing a comprehensive data collection and data management plan that addresses the needs of all Network Sites in terms of:
  - Standardized collection, cataloging, and storage of specimens, imaging products, and other data as appropriate for the clinical trials.
  - Access to specimens, imaging products, and other data.
  - Data security and data integrity measures.

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

- **Budget**
  - Whether the **total** costs exceed the allowable total costs as published in the Program Announcement.
  - Whether the budget ensures RTRP Funding for Network Sites for their participation.
  - 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 FY20 RTRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Programmatic relevance to the RTRP Clinical Network Award Focus Areas
  - Relative impact and military relevance

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.army.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the RTRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

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

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY20 and FY22 funds are anticipated to be made no later than September 30, 2021 and September 30, 2023, respectively. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.B.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. **The award document signed by the Grants Officer is the official authorizing document.**

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

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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.1.b. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Research Manager or other personnel may be requested to participate in a pre-award meeting at the Government's expense.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

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

II.F.3. Reporting

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

Annual progress reports as well as a final progress report will be required.

Quarterly progress reports and quad charts will be required.

Phase II: Inclusion Enrollment Reporting Requirement. Enrollment on the basis of sex/gender, race, and ethnicity will be required. The suggested Inclusion Enrollment Report format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

greater than $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the Program Announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 503a. The Program Announcement numeric version code will match the General Application Instructions version code 503.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY20 RTRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY20 RTRP Programmatic Panel members can be found at https://cdmrp.army.mil/rtrp/panels/panels20.***
- The application fails to conform to this Program Announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY20, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The PI does not meet the eligibility criteria.

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	Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Military Relevance Statement: Upload as Attachment 7 with file name "MilRel.pdf"	
	Clinical Strategy Statement: Upload as Attachment 8 with file name "Clinical.pdf"	
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	
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	Completed
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget **(intramural submissions only)**	Suggested DoD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRADA	Cooperative Research and Development Agreements
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RTRP	Reconstructive Transplant Research Award
SAM	System for Award Management
SOP	Standard Operating Procedure
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs
VCA	Vascularized Composite Allotransplantation