

RESEARCH ANNOUNCEMENT

for the Department of Defense

Congressionally Directed Medical Research Programs

Reconstructive Transplant Research Program

Clinical Network Award

Funding Opportunity Number: HT9425-23-RTRP-CNA

SUBMISSION AND REVIEW DATES AND TIMES

- **Questions to Program Office Deadline:** 8:00 a.m. Eastern time (ET), January 11, 2023
- **Pre-Application Submission Deadline:** 5:00 p.m. ET, January 18, 2023
- **Application Pre-submission Meeting:** To be scheduled upon pre-application submission
- **Application Submission Deadline:** 11:59 p.m. ET, February 1, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, February 6, 2023
- **Peer Review:** March 2023
- **Programmatic Review Stage 1:** March 2023
- **Programmatic Review Stage 2:** March 2023

This research announcement must be read in conjunction with the General Application Instructions, attached to the end of this document.

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I. FUNDING OPPORTUNITY DESCRIPTION

I.A. Program Description

Applications to the Fiscal Year 2022 (FY22) Reconstructive Transplant Research Program (RTRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4021 (10 USC 4021). The execution managing agent for this research announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The RTRP was initiated in FY12 to provide support for research of exceptional scientific merit to refine approaches for, and increase access to, reconstructive transplants and state-of-the-art immunotherapy. Appropriations for the RTRP from FY12 through FY21 totaled \$117 million (M). The FY22 appropriation is \$12.0M.

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

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 transplant solutions. More specifically, the RTRP seeks vascularized composite allotransplantation (VCA)-focused research, also known as composite tissue allotransplantation. VCA refers to the transplantation of multiple tissues such as muscle, bone, nerve, and skin, as a functional unit (e.g., a hand or a face) from a deceased donor to a recipient with a severe injury. The ultimate goal is to return injured Service Members to duty and restore their quality of life.

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

I.B. FY22 RTRP Clinical Network Award Focus Areas

To meet the intent of the FY22 RTRP Clinical Network Award mechanism, applicants must address the standardization and assessment of protocols and/or clinical practice guidelines (CPGs) for all 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)

I.C. Award Information

The RTRP Clinical Network Award mechanism was first offered in FY20, with awards to be made as grants or cooperative agreements. Three applications were received, but none were funded. This FY22 research announcement is being offered through a different type of award mechanism, a Research Other Transaction Award (rOTA) under the authority of 10 USC 4021.

Statement on the Research Other Transaction Agreement: The principal purpose of a rOTA is to carry out non-duplicative basic, applied, and advanced research projects rather than the acquisition of property or services for the direct benefit or use of the government. The anticipated deliverables to the government under a rOTA are reports on research rather than prototypes.

The rOTA requires resource sharing, with government funds not to exceed the total amount provided by other parties to the maximum extent practicable. Offerors will be required to demonstrate how resources (e.g., cash and non-cash) will be made available for this project. The rOTA is intended to promote the use of best business practices and to foster relationships among performers from different sectors.

In addition, as a matter of DOD policy, rOTAs may only be awarded when one or more for-profit firms are to be involved either in the: (1) performance of the research project(s) or (2) commercial application of the research results. A consortium should either include, collaborate with, or involve one or more for-profit firms (e.g., pharmaceutical company to provide medication, rehabilitation clinic to provide services to recipients, etc.) in addition to state or local government agencies, institutions of higher education, or other nonprofit organizations. For the FY22 Clinical Network Award, the for-profit firm may be involved in either Phase 1, Phase 2, or both phases of the award.

The government will enter into negotiations to finalize the terms and conditions of the anticipated Agreement with the presumptive awardee after applications are evaluated in accordance with [Section III.B.1](#) and [Section III.B.2](#) of this Research Announcement. A draft Agreement has been provided for informational purposes. The content of the draft Agreement reflects the government's baseline terms and conditions for an expenditure-based rOTA and is subject to negotiation upon selection of the most advantageous offeror.

General Information: The RTRP intends to allocate up to \$13M to support the RTRP Clinical Network over 6 years, subject to availability of funding. This effort will be executed through a two-phase approach in the form of a single award to the Clinical Network Coordinating Center, hereby referred to as the 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. The period of performance for Phase 1 is 2 years, with maximum funding of \$3M in RTRP funding for Coordinating Center costs. RTRP funding for the Phase 2 is contingent on successful completion of Phase 1 objectives and subject to the availability of funding. The

period of performance for Phase 2 is 4 years, with maximum funding of \$10M in RTRP funding for Coordinating Center costs and Network Site costs. The Coordinating Center will manage funding to the Network Sites through the execution of subaward agreements for Phase 1 and/or Phase 2 reimbursable activities and for other key collaborators. See [Section I.E., Funding](#), for additional 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 CPGs for face and hand transplantation and assessing those protocols in multi-institutional clinical trials (see **Figure 1, Sample Network Structure**). 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 CPGs. 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.

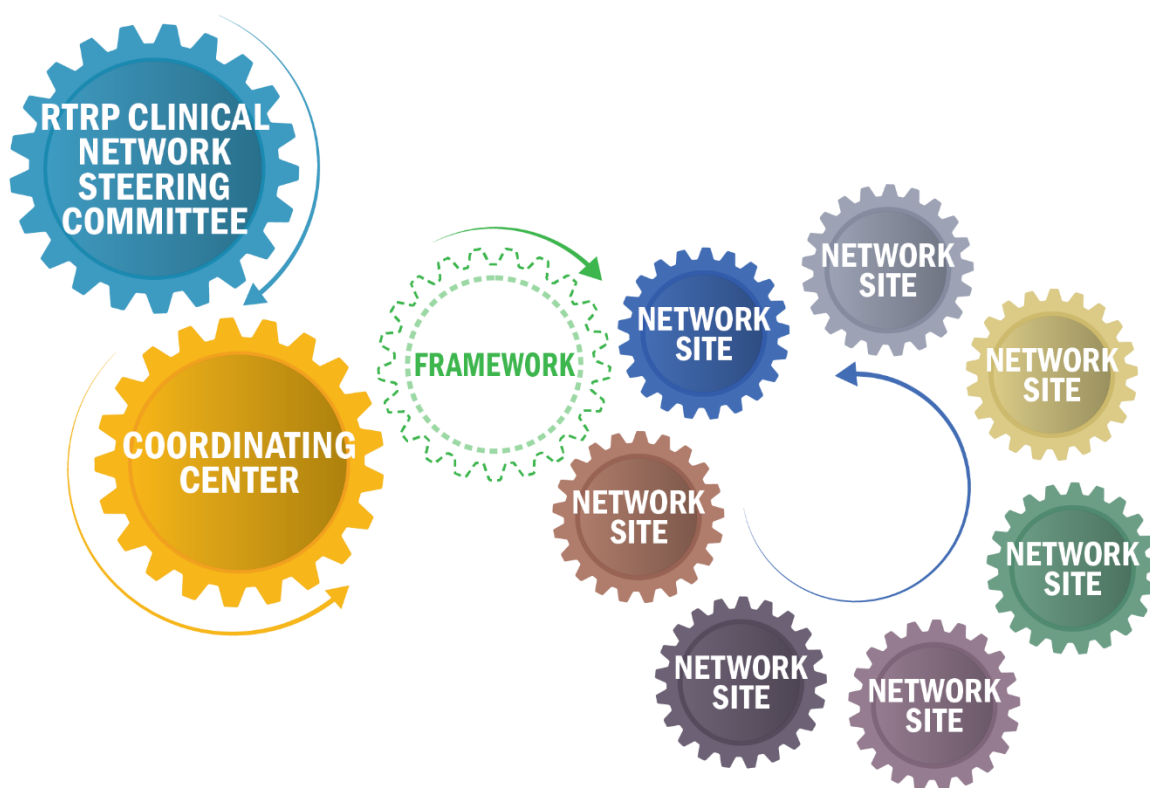


Figure 1: Sample Network Structure. This sample network structure is provided for clarity of concept and is not intended as a preferred structure. Applicants may propose a structure that differs from this sample.

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 partners. See additional details in the [Clinical Network Oversight](#) section below.

Phase 1

Phase 1 of the award will consist of four key objectives (see *Figure 2, Clinical Network 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 to participate as Network Sites. To establish a level playing field among investigators/Network Sites, *it is critical that no Network Site collaborations are established at the application stage between proposed Coordinating Centers and Network Sites*. This is because it might be perceived that pre-established collaborators have a stronger position within the Clinical Network, and/or that those pre-established collaborators have greater influence in the final determination of standards. **Thus, 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 CPGs:** 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 CPGs for both face and hand transplantation. These standards should include expected and acceptable outcomes for the subsequent clinical trials. The framework will consist of a structure conducive to accomplishing these tasks with oversight by the RTRP Clinical Network Steering Committee. This should include a set of rules and/or guidelines by which the Network Sites will work together to develop, review, revise, and finalize the protocols and CPGs in a logical, fair, and unbiased manner. It should be clear that the determination of standards lies within these rules and/or guidelines, and not with select individuals, a single Network Site, or with the Coordinating Center.
- **Develop Clinical Trials:** 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 CPGs. Plans for these clinical trials will then be submitted to CDMRP via the standard electronic Biomedical Research Application Portal (eBRAP) submission process for peer and programmatic review. Funding for clinical trials will not occur until Phase 2, after successful completion of all Phase 1 objectives.
- **Regulatory Approval:** In preparation for Phase 2, any regulatory approvals required by the U.S. Food and Drug Administration (FDA) must be obtained during Phase 1. Upon approval to proceed with the scientifically reviewed clinical trials from the RTRP Clinical Network Steering Committee, the standardized protocols and CPGs will be submitted to the single unified Institutional Review Board (IRB) of record for review and, upon approval, then submitted to the USAMRDC Office of Human Research Oversight (OHRO) for review and approval.

Phase 2

The Phase 2 option of the award, pending successful completion of Phase 1 objectives and availability of funds, will have one key objective:

- **Conduct Clinical Trials:** The Clinical Network will expand upon the successful development of standardized protocols and CPGs for both face and hand transplantation by assessing them for safety and efficacy 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 clinical trial is expected to open for enrollment within 2 months after the start of Phase 2.

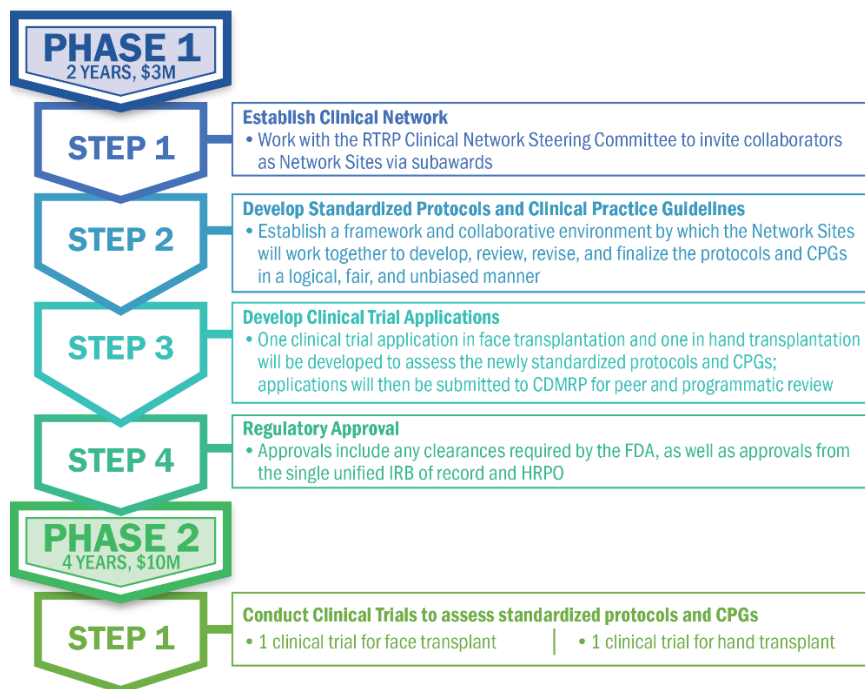


Figure 2: Clinical Network Objectives

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. Since the clinical trials developed under the Clinical Network will be assessing the safety and efficacy of the standardized protocols and CPGs developed under Phase 1, the RTRP understands that Phase 2 clinical trials may only be prospectively assigning human subjects to one intervention (i.e., hand or face transplant) using historical controls only.

Coordinating Center Description

Key requirements for the Coordinating Center include:

- A Principal Investigator (PI) with a proven track record of leadership and the scientific ability to direct and oversee a large multi-institutional VCA effort will serve as the Network Director. The Network Director is expected to commit an appropriate level of time and effort to direct and manage a project of this magnitude. A succession plan should be incorporated in the event of an unforeseen change in Director.
- Experience in managing multi-institutional collaborations. This can be demonstrated by the Network Director/PI or another member of the Coordinating Center team.
- Experience in managing clinical trials. This can be demonstrated by the Network Director/PI or another member of the Coordinating Center team.
- Knowledge of the intricacies of the VCA field so that the Coordinating Center can effectively lead the Network in achieving its objectives. This can be demonstrated by the Network Director/PI or another member of the Coordinating Center team.

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 Network Sites. ***Network Sites will not be included as subawards in the application itself. Once the government has made the primary award to the Coordinating Center, the Coordinating Center will be responsible for establishing the Clinical Network and making subawards to Network Sites for Phase 1 and/or Phase 2 reimbursable activities.***
- Under leadership of the Network Director, 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 in both Phases 1 and 2.
- 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 Phase 2.
- Facilitate the necessary agreements (e.g., Clinical Network constitution and by-laws and operating manuals) 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, the RTRP Clinical Network Steering Committee, 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 CPGs for VCA, as well as for the development of clinical trials (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 CPG to be standardized and/or clinical trial protocol to be written.
 - Ensure that the appropriate expertise is included in the efforts to develop each protocol, CPG, and clinical trial (e.g., scientific, medical, human subjects protection, regulatory).
- Establish a fair and equitable process through which each protocol and CPG is developed, reviewed, revised, and ultimately finalized as standard.
- Establish and maintain procedures for ensuring compliance with FDA requirements for investigational agents, devices, and procedures, as applicable.
- Provide a Clinical Research Manager who will facilitate the regulatory approvals for each clinical trial 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 OHRO.
- 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 Phase 2.

- Develop and manage procedures for timely publication of major outcomes and other public dissemination of data and study results.
- During Phase 1, 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 Phase 2, coordinate regularly scheduled meetings (via teleconference or other media platform) to facilitate discussion of clinical trial progress among Network Sites (e.g., recruitment efforts, enrollment, patient listings, transplants, rejection episodes or other adverse events, successes, challenges). 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, Agreements Officer Technical Representative (AOTR), USAMRAA Agreements Officer, and other USAMRDC personnel.

Network Site Description

Network Sites will be invited into the Clinical Network after the Coordinating Center is awarded. 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 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 CPGs 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 1 and Phase 2 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 FY22 RTRP Clinical Network Focus Areas. A Network Site without a VCA Center is expected to have an active role in Phase 1 of the Clinical Network but may have a diminished role, if any, in Phase 2.

Note: A Network Site may reside at the same institution as the Coordinating Center, but a plan must be in place to avoid bias and manage conflicts of interest.

Key responsibilities of Network Sites are to:

- Work with the Coordinating Center to complete all agreements (e.g., Clinical Network constitution and by-laws and operating manuals) as necessary to participate in the Clinical Network.
- Participate and work collaboratively to develop standardized protocols, CPGs, and clinical trials for face and/or hand transplantation.
- Comply with the Coordinating Center's communication plan (e.g., participate in scheduled meetings).
- 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 OHRO 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 Phase 2, 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 protocols and CPGs 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 1 and regularly scheduled teleconferences during Phase 2, as specified by the Coordinating Center. These meetings are intended to facilitate discussion across Network Sites and evaluate progress of protocol/CPG development (Phase 1) and clinical trial execution (Phase 2).
 - 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, to include establishment of the Clinical Network, scientific review of the clinical trial applications in both face and hand transplantation, etc.
- **In Progress Reviews:** The Network Director 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, alternative arrangements will be made (e.g., teleconference or other media platform) should in-person meetings be restricted or otherwise infeasible.

Research Involving Human Anatomical Substances, Human Subjects, or Human

Cadavers: All Department of Defense (DOD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow up to 3 months for OHRO regulatory review and approval processes following submission of all required and complete documents to OHRO.*** The OHRO reviews and approves the participation of each site in the clinical trial. ***For the FY22 RTRP Clinical Network Award, initial OHRO approval will take place during Phase 1 of the award.*** Refer to [Appendix 2](#) and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Women and Minorities in the Study: Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” as well as congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Applications must describe the strategy for the inclusion of women and minorities in the clinical trials appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Applications must 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 that can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout

the proposed research. Refer to [Section II.D. Application and Submission Information](#), for detailed information. Refer to [Appendix 2](#), for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this research announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to [Appendix 3, Section K, Sharing of Data and Research Resources](#).

In addition to the funding provided through the FY22 RTRP Clinical Network Award, the Network is encouraged to seek funding opportunities from additional sources including industry, the private sector, and other federal organizations.

I.D. Eligibility Information

- The Network Director at the Coordinating Center must be an independent investigator at or above the level of Associate Professor (or equivalent) with experience in developing and running large-scale initiatives such as clinical trials or consortia.
- Each investigator may be named on only one FY22 RTRP Clinical Network Award application as the PI/Network Director.
- Resource sharing/matching is a requirement, with government resources not to exceed the total amount provided by other parties to the maximum extent practicable.
 - Resource sharing in a transaction occurs when a portion of the total cost of the project is to be paid out of funds provided by sources other than the federal government. Contributions can be in cash or non-cash (i.e., in-kind) form, and costs can be either direct or indirect, so long as the contributions are allowable, allocable, reasonable, and consistently accounted for by the awardee. Generally, cash contributions are preferred over in-kind contributions as they are easier to value and often represent a higher level of commitment to the success of the program.
- **Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.
- **Government Agencies Within the United States:** Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

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

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

- **Intramural DOD Organization:** A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***
- Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective Resource Managers (RMs). ***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.***

I.E. Funding

A single award will be made to the RTRP Clinical Network Coordinating Center. The Coordinating Center, as the Network Manager, will provide funding support for the selected Network Sites.

- The maximum period of performance is 2 years for Phase 1, with an option for an additional 4 years for Phase 2, pending successful completion of Phase 1 objectives and availability of federal funds. The USAMRDC may consider extending this period of performance further to include noncompetitive follow-on work contingent upon receipt of future congressional appropriations.
- Upon award, funding from the government of proposals received in response to this research announcement is expected to be limited to approximately \$3M in total costs (direct plus indirect costs). A budget is required for Phase 1.
- If exercised, RTRP funding for Phase 2 is expected to be limited to approximately \$10M in total costs (direct plus indirect costs). A generalized budget outline should be provided for Phase 2, to include cost categories for maintaining the Coordinating Center, providing support for Network Sites and clinical trial costs, as well as other categories deemed essential. The Phase 2 budget may not be negotiated prior to issuance of the Clinical Network Award, but it is subject to negotiations prior to the beginning of Phase 2 once clinical trials are identified.
- If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's most recent federally negotiated rate. No budget will be approved by the government exceeding **\$3M** total costs (direct plus indirect costs) for Phase 1 or using an indirect cost rate exceeding the organization's negotiated rate.
- The PI may request up to \$3M in total costs (direct + indirect costs) for Phase 1 for the full proposed period of performance (up to 2 years) to cover Coordinating Center costs and Network activities. This will be funded using allocations from the FY22 RTRP congressional appropriation. A budget for the Coordinating Center should be submitted using the SF424 Research & Related (R&R) Budget Form.

- For individual clinical trials, funding will be based upon negotiated milestones and deliverables which will be negotiated once clinical trials are identified.
- All direct and indirect costs of any Phase 1 and/or Phase 2 subaward (or subcontract) must be included in the total direct costs of the primary award. Although Network Sites will not be determined at the time of application submission, the budget should provide a dollar amount to be allotted for Network Site operations.
- Resource sharing includes cash or in-kind contributions. The proposed shared resources must be necessary and reasonable, in line with cost principles, and not part of another federal award. Costs of prior research are not allowed. Sunk costs of patents or other intellectual property (IP) are not allowed.

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

- **Clinical Network Review Meetings:** Costs to sponsor two Clinical Network review meetings during Phase 1 of the award, recommended at months 6 and 18.
- **In-Progress Review:** Travel costs for the Network Director 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 these meetings will take place in the National Capital Region.
- **DOD-Sponsored Meeting:** Travel costs for the Network Director/PI or other designated investigator 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 the meeting will be held in the Central Florida Region. These travel costs are in addition to those allowed for annual scientific/technical meeting meetings.
- **Network Sites:** It is the responsibility of the Coordinating Center to ensure RTRP funding to each Network Site for their participation in Phase 1 and/or Phase 2. For planning purposes, assume a total of 10-12 Network Sites will be added to the Clinical Network. The Coordinating Center should make a subaward to each Network Site for reimbursable Phase 1 activities and a separate subaward for reimbursable Phase 2 activities.

Special Requirements:

- Phase 1 (Standardized Protocol, CPG, and Clinical Trial Development):
 - It is anticipated that costs for Network Site participation will largely be attributed to salary costs for the time contributed by the Network Director and other Network Site participants to develop, review, revise, and finalize protocols and CPGs, as well as for meetings and other communications with other Clinical Network participants.

- Phase 2 (Clinical Trials):
 - A minimal budget should be provided for the Network Sites through subawards for costs such as regulatory fees and salaries for the Network Site PIs and Clinical Research Coordinators.
 - 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, transplant procedures, and follow-up care (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.
- Regulatory Review:
 - Costs associated with conducting regulatory reviews of the standardized clinical protocols and CPGs and informed consent/assent forms.

May be requested for (not all-inclusive):

- Salary support
- Implementation of Network-developed standardization plans, data management program, real-time communications system, and administration plans for the Network.
- Support of Network-related meetings, teleconferences, and travel in support of 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.
- Research-related subjects costs (Phase 2)
- Clinical trial costs (Phase 2)
- Costs associated with face and hand transplantation follow-up care (Phase 2)
- Other costs directly associated with planning and developing the Network
- Publication costs

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award partner 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 [Appendix 1, 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 noted in that section.*

The CDMRP expects to allot approximately \$3M in FY22 and \$10M in FY24 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.

I.F. Resource Share

To the maximum extent practicable, the resources from the government do not exceed the total amount provided by the other parties. This resource-sharing requirement is intended to highlight the dual-use focus of this authority and show commitment on the part of the performing team to pursue transition of treatments to the clinic in the future. While the default position of the government is a 50/50 resource share, the final amount of the share should be based on full consideration of factors such as the partner's resources, prior investment in the research versus military relevance, unusual performance risk, and precompetitive nature of the project.

Sample Resource-Sharing Plan: *The applicant is required to provide an initial resource-sharing plan.* The government's expectation is that the resource-sharing plan is only a sample, given that the Network Sites are not identified in the application, and clinical trials will not be approved at the time of award. However, the applicant will identify potential sources of resource shares, as well as examples of resource shares on previous projects, if applicable. The applicant will also identify an approach for tracking resource shares across the life of the award.

Resource sharing may include, but is not limited to, cash and third-party contributions to the project or program made either by or through any subpartners, unrecovered indirect costs, services or property that are submitted by the applicant or any subpartners, third-party in-kind contributions. The cash contribution may be derived from the awardee's (or awardee's subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the offeror will be spent on performance of the Statement of Work (SOW). Prior IR&D funds will not be considered as part of the offeror's cash contribution.

In-kind contribution means the offeror's non-financial resources expended to provide support such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the prototype, as well as the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the rOTA.

Prior IR&D funds will not be considered part of the offeror’s cash or in-kind contributions, except when using the same procedures as those that authorize pre-award costs, nor will fees be considered on an offeror’s resource sharing portion.

II. SUBMISSION INFORMATION

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 Submission 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 application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to [Appendix 1](#) for further information regarding Grants.gov requirements.

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

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-RTRP-CNA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online	Download application package components for HT9425-23-RTRP-CNA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DOD Submissions
completion of the application components and routing of the application package through the applicant organization for review prior to submission.	
Full Application Package Components	
<p>SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Appendix 1, Section III.A.1, for detailed information.</p>	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • 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 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>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.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>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.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or needs to be</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>

Extramural Submissions	Intramural DOD Submissions
<p>modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	
Application Verification Period	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
Further Information	
<p>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.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

II.A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number HT9425-23-RTRP-CNA in Grants.gov (<https://www.grants.gov/>).

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

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

II.B. 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.

Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Agreements Officer.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the [Appendix 1](#) for additional information on pre-application submission):

- **Tab 1 – Application Information**

- Enter the application information as described in eBRAP before continuing the pre-application. Submission of application information includes assignment of primary and secondary research classification codes, which can be found at <https://ebrap.org/eBRAP/public/Program.htm>. The codes have been revised.
- Applicants are strongly encouraged to review and confirm the codes prior to making their selection. Click on “Save.”

- **Tab 2 – Application Contacts**

- Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 R&R Budget Form). Depending on screen resolution, scrolling horizontally may be necessary to locate the box to “Invite an AOR” (Authorized Organizational Representative) to register the performing and/or contracting organizations. The Business Official must

either be selected from the eBRAP list or invited in order for the pre-application to be submitted. **If the Business Official cannot be found in eBRAP, an invitation must be sent to him/her to register in eBRAP.**

- Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 R&R Budget Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
- PIs are recommended to identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

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

- Enter the name, organization, and role of all collaborators and key personnel associated with the application.
- FY22 RTRP Programmatic Panel members may not be involved in preparation of the application.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors who has any role in application preparation, research, or other duties for submitted applications. For FY22, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess.aspx>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest are provided and deemed appropriate by the government.

- **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) (two-page limit):** Provide a brief description of the plans for serving as the Coordinating Center of the Clinical Network. For program purposes in planning the Full Application Pre-submission Meeting, it is important to address the following points:
 - **Coordinating Center Team:** Identify the proposed Network Director/PI and any key personnel for the team.

- **Collaborations:** It should be clear that collaborations with Network Sites will not be included in the application; however, collaborations with other entities may be appropriate at the application stage, and could be mentioned in the LOI. For example, collaborations with the required for-profit firm, and/or collaborations with consultants that will serve the entire Clinical Network (statistics, regulatory, consumer perspective, etc.). In addition, applicants should indicate initial thoughts regarding the optimal number of Network Sites for achieving the goals of the Clinical Network.
- **Cost Share:** Identify potential sources of cost share.
- **For-Profit Firm:** Identify a potential for-profit firm that is to be involved in either the (1) performance of the research project(s) or (2) commercial application of the research results.

LOIs are used for program planning purposes only (e.g., full application pre-submission meeting with RTRP program staff, reviewer recruitment) and will not be reviewed during either peer or programmatic review sessions. Specific details are requested for administrative purposes only. Upload the document as a PDF.

eBRAP will not allow a document to be uploaded in the “Required Files” tab if the number of pages exceeds the limits specified.

- **Tab 6 – Submit Pre-Application**

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

II.C. Full Application Pre-submission Meeting

Each applicant who submits a pre-application will be required to participate in a personalized virtual question and answer session. Responses to questions specific to an applicant’s technical approach will not be shared with other applicants. However, responses to clarification questions that are raised due to confusion with any part of the research announcement may be shared with other applicants. The government will schedule these meetings following LOI submission. *The applicant is encouraged to submit the LOI as soon as possible to maximize the amount of time between the Full Application Pre-submission Meeting and the full application deadline.* This meeting is not intended as a review of the LOI, and an invitation is not required to submit a full application.

II.D. Application and Submission Information

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant’s organization’s entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the [Appendix 1](#) for additional information.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different

software versions will result in corruption of the submitted file. See [Appendix 1](#) for details on compatible Adobe software.

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

Each application submission must include the completed Grants.gov application package for this research announcement. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

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

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

Grants.gov application package components: For the Clinical Trial Consortium Award, the Grants.gov application package includes the following components (refer to the [Appendix 1](#) for additional information on application submission):

II.D.1. SF424 R&R Budget Form Application for Federal Assistance Form: Refer to the General Application Instructions, [Appendix 1](#), for detailed information.

II.D.2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in the General Application Instructions.

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

- **Attachment 1: Project Narrative (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 (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the key features of the RTRP Clinical Network 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 (Potential Network Sites should not be contacted during the proposal preparation stage). 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, and rationale for the anticipated number of Network Sites representative of both hand and face transplantation should be included. Network Sites will not be included as subawards in the application itself. Once the government has made the primary award to the Coordinating Center, the Coordinating Center will be responsible for establishing the Clinical Network and making subawards to Network Sites for Phase 1 and/or Phase 2 reimbursable activities.
- 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 the framework for the Clinical Network, including key operations, as well as relationships between various groups within the organizational structure. Describe how the framework is conducive to a collaborative environment. Describe the rules and/or guidelines by which the Network Sites will work together to achieve its goals in a logical, fair, and unbiased manner.
- Describe how the Clinical Network will be representative of both face and hand transplantation and all RTRP Clinical Network Focus Areas.
- Describe plans to execute the necessary agreements (e.g., Clinical Network constitution and by-laws and operating manuals) 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, plans for a single IRB, and plans 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 (i.e., Network Director) 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 Network Director is appropriate to directing and managing a project of this magnitude.

- Describe the previous leadership experience of the Network Director/PI and/or other named key personnel, and describe accomplishments related to design, administration, and management of collaborative multi-institutional research projects, including clinical trials and/or consortia awards.
- For the Network Director 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) 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.
- Describe a succession plan for the Network Director in the event of an unforeseen change.
- **Network Coordination**
 - Describe plans to coordinate with the RTRP Clinical Network Steering Committee.
 - Describe plans to ensure that all Network Sites and other key collaborators receive appropriate 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 how the Network will avoid/mitigate conflicts of interest between institutions and study personnel.

- Describe plans to coordinate and facilitate at least two internal Clinical Network review meetings during Phase 1 (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 and the RTRP management team. 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 Phase 2 to facilitate discussion of clinical trial progress among Network Sites (e.g., discuss recruitment efforts, enrollment, patient listings, transplants, rejection episodes or other adverse events, successes, challenges). 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 and CPG Development**
 - Describe plans for development, review, revision, and finalization of standardized VCA protocols and CPGs 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, clinical, human subjects protection, regulatory) for each protocol and CPG, and maintaining representation across Network Sites.
 - Describe plans for mitigating and resolving conflicts that may arise during the protocol and CPG development process to ensure completion of milestones and achievement of objectives.
- **Clinical Trial Development**
 - Describe plans for preparing two clinical trials, one for face transplantation and one for hand transplantation, utilizing the standardized protocols and CPGs developed during Phase 1.
 - Describe general plans for ensuring the inclusion of women and minorities in the clinical trials to be developed.

- **Clinical Trial Management**
 - Describe plans for ensuring compliance with FDA requirements during Phase 1 for investigational agents, devices, and procedures, as applicable.
 - Outline plans for streamlining the process required to initiate clinical trials across Network Sites (e.g., unified IRB review and OHRO review during Phase 1, site visits, training) to ensure that clinical trials are initiated (i.e., open for enrollment) within 2 months of Phase 2 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.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.***
 - References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not

government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the research announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that demonstrates that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement. ***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).***
- **Intellectual Property:**
 - Should the applicant intend to use, in the performance of this program, pre-existing, legally protected, and perfected IP, and for which no federal funds had been used in the development of said IP, the applicant must:
 - Clearly identify all such IP:
 - Identify the cost to the federal government for use or license of such IP, if applicable; or
 - Provide a statement that no IP meeting this definition will be used on this project.
 - It is the intent of the government to provide the government's beginning negotiation point for intellectual property and data rights in the draft agreement. After the agreement is awarded, deviations to these terms for specific clinical trials may be negotiated in individual Project Approval Letters.
- **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **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.
 - The technical abstract should be structured as follows:
 - **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.
 - **Protocol and CPG Development:** Briefly describe plans for standardized VCA protocol and CPG 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 trials (one for face transplantation and one for hand transplantation), utilizing the standardized protocols and CPGs developed in this effort.
 - **Clinical Trial Management:** Briefly describe plans for preparing the Clinical Network to initiate clinical trials in both face and hand transplantation within two months of Phase 2 initiation (e.g., ensuring regulatory and human subjects compliance, developing quality assurance and control mechanisms, standardized specimen and data collection and management). Briefly describe plans for managing the clinical trials during Phase 2.
 - **Impact:** Briefly describe the impact of the proposed Coordinating Center on successfully achieving the Clinical Network’s objectives to standardize protocols and CPGs in both face and hand transplantation, and assess 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.
 - The lay abstract should be composed using the outline below:
 - Describe why the PI/Network Director and their organization are appropriate to lead the Clinical Network in its effort to develop standardized protocols and CPGs for both face and hand transplantation across all RTRP Clinical Network Award Focus Areas, and to assess them for safety and efficacy in clinical trials.
 - Describe the ultimate applicability of the Clinical Network’s research effort.
 - What types of patients will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a clinically 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 (5-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Clinical Network Award, refer to “**Suggested SOW Strategy Clinical Research**” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Sample Cost/Resource Sharing Plan: Upload as “Cost_Resource Share.pdf”.** Provide a plan for sharing costs and resources that is expected to be available at

the Coordinating Center and potentially within eventual Network Sites. Indicate whether each cost is cash or in-kind and provide the amount, a description, and the valuation technique (quote, historical cost, labor hours, etc.).

- **Attachment 7: Data Management Plan: Upload as “DataPlan.pdf”.** Provide a data management plan that includes: (1) descriptions of the overall approach to data collection and management; (2) methods to monitor the quality and consistency of data collection and analysis; (3) a plan for real-time data transfer among Network Sites and the Coordinating Center; and (4) data security measures appropriate for protecting data confidentiality, integrity, and availability.
- **Attachment 8: Constitution and By-Laws and Operating Manuals: Upload as “Manual.pdf”.** Provide a copy of a Manual of Operations or Standard Operating Procedures (SOPs) by which the Network will operate. Also include documents that describe governance and guidelines by which the Network membership operates, including, but not limited to, the agreements of collaboration (or other partnership documents such as a constitution and by-laws) between institutions.
- **Attachment 9: Data and Research Resources Sharing Plan: Upload as “DataSharing.pdf”.** Provide a well-detailed description of the data and resources (i.e., tissues, samples, methods) that are expected to be generated during the performance period of the project and how they may be shared with the research community (if applicable). Include the type of data or research resource(s) to be made publicly available, when they are expected to become available, and how they will be made accessible both during and after the performance period of the project. *The RTRP encourages the Clinical Network to consider ways to work with the VCA research community through collaborations.* Refer to [Appendix 3, Section K](#), for more information about the CDMRP’s expectations for making data and research resources publicly available.
- **Attachment 10: 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 CPGs 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 CPGs in clinical trials, pending success of Phase 1 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 11: 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, 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 12: 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 6, Section B, Representations.
- **Attachment 13: 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 the “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 and Related Budget form under subaward costs. Refer to the General Application Instructions, [Appendix 1](#), for detailed information.

II.D.3. 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. Refer to [Appendix 1](#) for detailed information.

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

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches for site PIs, and Operations Center personnel (six-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

II.D.4. Research & Related Budget: An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year (Phase 1 and Phase 2), must be submitted on the Grants.gov SF424 R&R Budget Form. The budget for Phase 2 can be a generalized budget outline, to include cost categories for maintaining the Coordinating Center, providing support for Network Sites and clinical trial costs, as well as other categories deemed essential. Since the clinical trials have not yet been developed, detailed justifications are not expected for

Phase 2. The Phase 2 budget will be negotiated following successful completion of Phase 1, and will be dependent upon availability of federal funds. The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. ***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.*** At the time of application submission to Grants.gov, the AOR is certifying to the best of their knowledge that all costs are current, accurate, and complete.

If the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.

- **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.
- State an estimate of the amount of funds to be used by the Coordinating Center and in individual trials over the period of performance.
- Include the proposed resource sharing in the Budget Justification. Indicate whether each cost is cash or in-kind, and provide the amount, a description, and the valuation technique (quote, historical cost, labor hours, etc.).
- The government reserves the right to request a revised budget and budget justification and/or additional information.
- Budget Regulations and Restrictions:
 - Cost of Preparing Applications: The cost of preparing applications in response to a research announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications may be an allowable cost that can be included in the indirect/facilities and administrative cost as specified in the organization’s applicable cost principles.
 - Currency: All costs must be entered in U.S. dollars. Partners performing research outside of the United States should include the cost in local currency, the rate used for converting to U.S. dollars, and the justification/basis for the conversion rate used. Foreign currency exchange rates for partners performing research outside of the United States will be determined at the time of application submission.

II.D.5. Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to Appendix 1, General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to Appendix 1, General Application Instructions, Section IV.A.5, for detailed information.

II.D.6. R&R Subaward Budget Attachment(s) Form (not applicable): Separate Subaward Budget forms are not required with the application. **Subaward budgets will be requested during negotiations.**

All direct and indirect costs of any Phase 1 and/or Phase 2 subaward must be included in the direct costs of the primary award. The primary award (including the direct and indirect costs of any subawardees) will not exceed the cost limit stated in the research announcement.

II.D.7. Collaborating DOD Military Facilities Form (not applicable): The Collaborating DOD Military Facilities Form is not required with the application. This form will be requested during negotiations if applicable

II.E. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov.

Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific research announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the research announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.F. Submission Dates and Times

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

II.G. Other Submission Requirements

Refer to [Appendix 5](#) for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subpartner organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to [Appendix 1](#) for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

III.A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is evaluated for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 process to gain protected evaluation information or to influence the evaluation process.

Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards.

Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

III.B. Application Review Process

III.B.1. 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 framework for the Clinical Network is described, and includes key operations, as well as relationships between groups within the organizational structure. How well the framework is conducive to a collaborative environment, and describes rules and/or guidelines by which the Network Sites will work together to achieve its goals in a logical, fair, and unbiased manner.
 - 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., Constitution and by-laws and operating manuals). Whether these plans include: (1) an intellectual and material property plan for the Clinical Network; (2) plans for a single IRB; and (3) plans to manage real or perceived conflicts of interest.
- **Personnel and Resources**
 - How well key personnel and their projected roles and contributions to the Clinical Network are identified and include the Network Director and a Clinical Research Manager, at a minimum. Whether the level of effort proposed for the Network Director 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 and/or consortia awards.
 - The degree to which the Network Director 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, challenges) that could impact the 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.
 - Whether there is a succession plan for the Network Director in the event of an unforeseen change.
 - **Network Coordination**
 - Whether plans are in place to coordinate with the RTRP Clinical Network Steering Committee.

- 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 plans are sufficient for avoiding/mitigating conflicts of interest between institutions and study personnel.
 - Whether there are plans to coordinate and facilitate at least two internal Clinical Network review meetings during Phase 1, to include all Network Site PIs, key collaborators, and the RTRP Clinical Network Steering Committee. Whether plans for these meetings include face-to-face discussions as well as back-up plans should in-person gatherings be restricted or otherwise infeasible.
 - Whether there are plans to coordinate regularly scheduled meetings (via teleconference or other media platform) during Phase 2 to facilitate discussion of clinical trial progress among Network Sites. 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 CPG Development**
 - To what degree the plans for development, review, revision, and finalization of standardized VCA protocols and CPGs 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 trials (one each for both face and hand transplantation) are appropriate and utilize the standardized protocols and SOPs developed during Phase 1.
 - Whether a plan for the inclusion of women and minorities is described and is appropriate for the objectives of the study.

- **Clinical Trial Management**
 - How well plans are developed for ensuring compliance with FDA requirements during Phase 1 for investigational agents, devices, and procedures, 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 OHRO review during Phase 1, site visits, training) to ensure that clinical trials are initiated (i.e., open for enrollment) within 2 months of Phase 2 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 all 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.

- **Data Management Plan**
 - The degree to which the overall approach to data collection, management, transfer, analysis, and security measures is appropriate.
 - The degree to which the data management plan will monitor quality and consistency of data collection and analysis.

- How adequate the plan is for real-time data transfer among Network Sites and the Coordinating Center for supporting Network-associated activities.
- The degree to which the data security measures are appropriate for protecting data confidentiality, integrity, and availability.

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

- **Cost/Resource Sharing Plan**

- The extent to which the applicant has demonstrated a commitment to a 50/50 resource share. If the applicant has proposed a different resource share, the extent to which the proposed share is justified through consideration of the factors provided in [Section I.F. Resource Share](#), of this document.
- The extent to which the applicant has demonstrated access to the resources proposed as part of their resource share.
- The extent to which the applicant has provided a suitable resource share tracking process.

- **Budget**

- Whether the total costs exceed the allowable total costs as published in the research announcement.
- Whether the budget ensures RTRP Funding for Network Sites for their participation.
- Whether the budget is appropriate for the proposed research.

- **Data and Resource Sharing**

- How well-detailed and appropriate the Data and Research Resources Sharing Plan is, including but not limited to:
 - The description of the type of data or research resource(s) to be made publicly available.
 - The appropriateness of the milestones with respect to when the data or research resource(s) will be made available.
 - The details of the plan for how the VCA research community can gain access to data or research resources.
 - The appropriateness of plans to ensure the data or research resource(s) is/are accessible after the period of performance expires.

- **Application Presentation**

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

III.B.2. Programmatic Review

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

Stage 1:

- **Ratings and evaluations of the peer reviewers**
- **Relevance to the mission of the FY22 RTRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Programmatic relevance to FY22 RTRP Clinical Network Award Focus Areas
 - Relative impact and military relevance

Stage 2: Applicants will be required to give an oral presentation. In the event a PI is invited to the Programmatic Review, Stage 2, but is unable to attend, CDMRP Staff and the Agreements Officer will consider alternative arrangements on a case-by-case basis.

Each presentation will include a 30-minute talk by the PI/Network Director, followed by a 20-minute question-and-answer session with RTRP Programmatic Panel members. The following questions will be the topics for discussion during the PIs' talk and the question-and-answer session. PIs who are selected should prepare a presentation consisting of no more than 10 slides (not including title slide) that specifically address:

- How institutional support, cost share opportunities, and available facilities and resources will facilitate successful completion of Clinical Network objectives.
- How successful collaboration and communication will be promoted among Network Sites to facilitate achievement of objectives.
- How financial compensation will be managed to Network Sites for participation in Phase 1 (protocol/CPG development) and Phase 2 (Clinical Trials) of the Clinical Network.
- How standardized protocols and CPGs will be developed in a fair and unbiased manner in Phase 1, and how conflicts will be addressed throughout this process.

- How maximum enrollment will be achieved in Phase 2 across Network Sites for both clinical trials (i.e., face transplant, hand transplant), and how the outreach strategy will include military, Veteran, and civilian populations, as well as women and minorities.

During the second stage of programmatic review, the following criteria will be used:

- How well institutional support, cost share opportunities, and available facilities and resources will facilitate successful completion of Clinical Network objectives.
- How well plans for collaboration and communication will be promoted among Network Sites to facilitate achievement of objectives.
- How well financial compensation to Network Sites will be managed for participation in Phase 1 (protocol/CPG development) and Phase 2 (Clinical Trials) of the Clinical Network.
- How equitably plans to develop standardized protocols and CPGs support a fair and unbiased process, and how effectively conflicts will be addressed.
- How effectively plans for clinical trial recruitment support maximum enrollment across Network Sites, and how inclusive the outreach strategy will be of military, Veteran, and civilian populations, as well as women and minorities.

III.C. Partner Qualification

For general information on required qualifications for award partners, refer to [Appendix 4](#).

III.D. Application Review Dates

All [application review dates and times](#) are indicated on the title page of this research announcement.

III.E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

IV.A. Rejection

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

- LOI exceeds page limit.
- LOI does not meet the intent of the research announcement.

The following may result in administrative rejection of the application:

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

IV.B. Modification

Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal (LOI) and Project Narrative.

IV.C. Withdrawal

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

- An FY22 RTRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY22 RTRP Programmatic Panel members can be found at <https://cdmrp.army.mil/rtrp/panels/panels22>.*
- The application fails to conform to this research announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn.
- Total costs as shown on the Research and Related Budget form exceed the maximum allowed by this research announcement.

IV.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 Agreements Officer for a determination of the final disposition of the application.

IV.E. Proposal Revisions

The potential award will be based on the government's proposal evaluation and subsequent exchanges with the applicant. The government reserves the right to reject all proposals and to make no award, depending upon the quality of the proposals submitted and the availability of funds.

The Agreements Officer may request or allow proposal revisions to clarify and document understandings reached during negotiations. The Agreements Officer may establish a cut-off date only for receipt of final proposal revisions. The request for final proposal revision will advise the offeror that the final proposal revision will be in writing and the government intends to make award without further revisions.

V. ADMINISTRATION AND SECURITY

V.A. Award Notice

Awards will be made no later than September 30, 2023.

V.B. Post Award Administrative Requirements

Intellectual property. Under Other Transactions (OTs), the allocation of IP rights under the Bayh-Dole Act (35 USC 201-204) for patents, and 10 USC 3771-3772 for technical data do not apply. The government's initial negotiations position for intellectual property are outlined in the draft agreement.

V.C. Pre-Award Meeting

At the government's discretion, the Network Director, Network Site PIs, and Clinical Research Manager or other personnel may be requested to participate in a pre-award meeting at the government's expense.

VI. AGENCY CONTACTS

VI.A. Program Office Points of Contact

Questions related to this research announcement content can be directed to the Agreements Officer up until two weeks prior to the application submission date on the title page of this

research announcement. Questions and answers may be posted to the Grants.gov website to ensure all applicants are provided with the same information.

Agreements Officer: Christopher Meinberg (Christopher.L.Meinberg.civ@health.mil)

VI.B. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

VI.C. Grants.gov Contact Center

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

VII. 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"	
	Sample Cost/Resource Sharing Plan: Upload as Attachment 6 with file name "Cost_Resource Share.pdf"	
	Data Management Plan: Upload as Attachment 7 with file name "DataPlan.pdf"	
	Manual of Operations and By-Laws: Upload as Attachment 8 with file name "Manual.pdf"	
	Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name "DataSharing.pdf"	
	Impact Statement: Upload as Attachment 10 with file name "Impact.pdf"	
	Military Relevance Statement: Upload as Attachment 11 with file name "MilRel.pdf"	
	Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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

1 **VIII. RESOURCES**

2 Department of Defense [Other Transaction \(OT\) Guide | Adaptive Acquisition Framework](#)
3 [\(dau.edu\)](#) and [Other Transactions guide \(dau.edu\)](#).

4 These sites provide additional information on OTs:

- 5 • *Defense Advanced Research Projects Agency:* <https://www.darpa.mil/>
- 6 • *U.S. Army:* <https://acc.army.mil/contractingcenters/acc-nj/index.html>
- 7 • *U.S. Air Force: Transformational Innovation web page:*
8 <https://ww3.safaaq.hq.af.mil/Home/Air-Force-Transformational-Innovation-AO-Prime/>

9 This site, hosted by the Defense Pricing and Contracting office of the Assistant Secretary of
10 Defense for Acquisition, provide additional resources on OTs:

- 11 • *See the “Specific Policy Areas” site for a list of recent policies:*
12 <https://www.acq.osd.mil/asda/dpc/cp/policy/other-policy-areas.html#fpi>

13

GENERAL APPLICATION INSTRUCTIONS

APPENDICES 1 - 7

APPENDIX 1 SUBMISSION INFORMATION

I. HELPFUL INFORMATION

A. Tips for Success



This symbol marks helpful hints throughout this document.



This symbol refers the reader to the research announcement for specific instructions.

B. Research Announcement Applicant Organizations

Applications may be submitted by extramural organizations and intramural Department of Defense organizations, defined as follows:

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, government, and research institutes. ***Extramural Submission:*** *Application submitted by a non-DOD organization to Grants.gov.*

Intramural DOD Organization: A DOD laboratory, DOD Military Treatment Facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission:*** *Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or Military Treatment Facility or in a DOD activity embedded within a civilian medical center.*

Applications from an intramural DOD organization or from an extramural non-DOD federal organization may be submitted through a research foundation.

C. Pre-Application and Full Application Portal Systems

The electronic Biomedical Research Application Portal (eBRAP) <https://ebrap.org>, is a secure web-based system that allows Principal Investigators (PIs) to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov, receive communications from the Congressionally Directed Medical Research Programs (CDMRP), and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

The eBRAP platform allows an organization's representatives and PIs to view and modify certain components of the full application submissions associated with them. It will validate full application files against the specific research announcement requirements, and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy and to ensure proper ordering as specified in the research announcement.

Grants.gov (<https://grants.gov>) is a federal system required to be utilized by agencies to receive and process extramural grant applications. **Extramural organizations** submit full applications to Grants.gov only **after** submission of a pre-application through eBRAP.

D. Current Funding Opportunities

All funding opportunities currently offered through the U.S. Army Medical Research and Development Command (USAMRDC), including those issued by the CDMRP, may be viewed at <https://grants.gov>; users should enter Assistance Listing (AL) Number 12.420 when searching for CDMRP funding opportunities on Grants.gov. Information about funding opportunities may also be found on the CDMRP website at <https://cdmrp.health.mil/funding/> and on CDMRP's eBRAP website at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants who subscribe to program-specific news and updates under "Email Subscriptions" on eBRAP's home page (<https://ebrap.org/eBRAP/programSubscription/Subscribe.htm>) will receive email notification of CDMRP funding opportunity releases. Email notifications of funding opportunities are sent as a courtesy; applicants should subscribe on Grants.gov to receive notifications of updates and new grant opportunity postings (<https://grants.gov/web/grants/manage-subscriptions.html>).

E. Receiving Emails from CDMRP, eBRAP, and Grants.gov

To help ensure that all email correspondence is delivered correctly and is not treated as spam, keep your email address up to date in eBRAP (intramural and extramural applicants) and/or Grants.gov (extramural applicants), and place the following domains into your safelist: health.mil, eBRAP.org, and Grants.gov. Use the same email address when submitting both the pre-application and the full application.

The applicant is responsible for using the latest version of the full application package. It is incumbent upon the applicant to check for published updates to the funding opportunity and the application package prior to submission. Applications submitted without the required components of the full application package may be rejected. Applicants are encouraged to sign up to receive notifications of changes to the funding opportunity (<https://grants.gov/>) through either (1) the "Send me change notification emails" link on the Synopsis page for the specific research announcement or (2) by responding to the Grants.gov prompt *when first downloading the Grants.gov application package* (extramural applicants only).

F. Agency Contacts

- 1. eBRAP Help Desk:** Questions related to research announcement content or submission requirements, as well as questions related to submission of pre-applications (extramural and intramural submissions) or full applications (intramural submissions only) through eBRAP, should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time. Response times may vary depending on the volume of inquiries. The eBRAP Help Desk will not provide Grants.gov submission assistance.

Phone: 301-682-5507 (Monday through Friday, 8:00 a.m. to 5:00 p.m.)

Email: help@eBRAP.org

2. **Extramural Submissions – Grants.gov Contact Center:** Questions related to application submission through the 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).

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

Email: support@grants.gov

G. Application Submission Overview

Application submission is a two-step process.

STEP 1. Pre-application submission: All pre-applications for both extramural and intramural organizations *must* be submitted through eBRAP (<https://eBRAP.org/>).

STEP 2. Full application submission: Full applications must be submitted through the online portals as described below.

Extramural Application Submissions: Full applications from extramural organizations *must* be submitted through Grants.gov Workspace (refer to [Section III, Application Submission for Extramural Organizations](#)). Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DOD or other federal organizations or investigators are considered extramural submissions. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn.

Intramural Application Submissions: Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Intramural organizations that are unable to submit to Grants.gov should submit through eBRAP (refer to [Section IV, Application Submission for Intramural Organizations](#)). Intramural organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

All pre-application and application components must be submitted by the deadlines stipulated on the first page of the research announcement. Failure to meet any of the deadlines will result in application rejection.



Submission of applications from U.S. federal agencies and those proposing collaborations with military facilities have unique requirements. Budget requirements and restrictions apply. See [Section II.D.4, Research & Related Budget](#), in the research announcement and “[Section III.A.8, Suggested DOD Collaborating Military Facility Budget Format](#)” in Appendix 1.

II. eBRAP REGISTRATION AND PRE-APPLICATION SUBMISSION

General eBRAP registration information is provided below (Section II.A). For detailed instructions, refer to the eBRAP User Guide (<https://ebrap.org/eBRAP/public/UserGuide.pdf>) for eBRAP registration and <https://grants.gov> for Grants.gov registration.

A. Registration Requirements (All Applicants)

eBRAP Registration

All PIs must register in eBRAP to submit a pre-application.

PIs are encouraged to start the registration process for eBRAP early to ensure sufficient time for completion prior to the submission deadline. There is no grace period.

During eBRAP registration, the PI must request to be affiliated with their organization from the list of organizations already registered with eBRAP. If the PI's organization is not already registered with eBRAP, the PI must invite an Authorized Organizational Representative (AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application submission deadline in order for the pre-application to be submitted. *However, the organization's eBRAP registration must be completed before the full application submission deadline to allow for processing, viewing, and modifying select components of the full application package.*

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

Extramural Submissions: *Application submitted by a non-DOD organization to Grants.gov.* Applicants should ensure that their name and email address are the same as the name and email address on the Standard Form 424 Research and Related (SF424 Research & Related) Form of the Grants.gov application package submitted through Grants.gov Workspace.

Intramural Submissions: *Application submitted by a DOD organization for an intramural investigator who is a DOD military or civilian employee working within a DOD laboratory or Military Treatment Facility or in a DOD activity embedded within a civilian medical center.* Applicants should ensure that their name and email address are the same as the name and email address that will be provided within the full application package through eBRAP for intramural applicants.

PIs are encouraged to utilize an Open Researcher and Contributor ID (ORCID) identifier and enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP. An ORCID will be required if an application is subsequently recommended for funding.

B. Content and Form of Pre-Application Submission



For specific instructions regarding content of the pre-application submission components, refer to the research announcement.



All pre-application components must be submitted through eBRAP (<https://eBRAP.org/>) by the deadline specified in the research announcement. Click on “Submit” and “Confirm Submission” to complete the pre-application submission.

During pre-application submission, the PI must identify a Business Official from the list of Business Officials registered with eBRAP. If the PI’s Business Official is not already registered with eBRAP, the PI must invite the Business Official to register. ***This invitation to register must be sent prior to the pre-application deadline. The Business Official’s registration must be completed prior to the full application deadline to allow the Business Official to view, modify, and verify the application in eBRAP after submission.***

During pre-application submission, the PI must select the performing organization (site at which the PI will perform the proposed work) and contracting organization (organization submitting on behalf of the PI) and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited to allow submission of the pre-application.

The pre-application consists of the following components, organized in eBRAP by separate tabs:

- **Tab 1 – Application Information:** Enter the application information as described in eBRAP before continuing the pre-application. Submission of application information includes assignment of primary and secondary research classification codes, which can 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. Click on “Save.”
- **Tab 2 – Application Contacts:** Enter contact information for the PI. Enter the name of the organization’s Business Official responsible for sponsored program administration. Depending on screen resolution, scrolling horizontally may be necessary to locate the box to “Invite an AOR” to register the performing and/or contracting organizations. Click on “Add Organizations to this Pre-application.” The Business Official must be either selected from the eBRAP list or invited to allow the pre-application to be submitted. **If the Business Official cannot be found in eBRAP, an invitation must be sent to them to register in eBRAP.**
- **Tab 3 – Collaborators and Key Personnel:** Enter the name, organization, and role of all collaborators and key personnel associated with the application. Click on “Save.”

CDMRP does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Unless otherwise noted in the research announcement (e.g., Partnering PIs), applicants should assign the role of each participant in accordance with the participant’s respective involvement in the project.

No member of the [FY22 RTRP Programmatic Panel](#) may be named as being involved in the research proposed or found to have assisted in the pre-application or application processes.

If formal collaboration with military facility personnel is planned (i.e., included in the application in performance of the research), those military facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

- **Tab 4 – Conflicts of Interest:** To avoid conflicts of interest during the screening and review processes, 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). Click on “Save.”
- **Tab 5 – Pre-Application Files:** Upload all documents as PDF as specified in the research announcement. Documents should conform to the formatting guidelines outlined in [Appendix 5](#). Click on “Upload.”
 - eBRAP will truncate characters exceeding the limit specified for each data field as specified in the research announcement.
 - eBRAP will not allow a document to be uploaded in the “Required Files” tab if the number of pages exceeds the limits specified in the research announcement.
- **Tab 6 – Submit Pre-Application:** Enter eBRAP password and click the “Submit” button. Click the “Confirm Submission” button to complete the pre-application submission. *This finalizes the pre-application process.*



The pre-application is not submitted until Tab 6 is complete. Pre-applications not completed remain in DRAFT status.

Following completion of pre-application submission, the status of the pre-application in eBRAP will change from “DRAFT” to “SUBMITTED” and a confirmation email will be sent to the PI and named Business Official. *An applicant with a pre-application in DRAFT status after the pre-application submission deadline is ineligible to submit an application. Check the status of the pre-application. There is no grace period.*

III. APPLICATION SUBMISSION FOR EXTRAMURAL ORGANIZATIONS

Grants.gov applicants must apply online using Workspace. Workspace is a shared online environment where members of a grant team (investigators and business officials) may simultaneously access and edit different webforms within an application. Applicants must create a Workspace, invite grant team members to join the Workspace, complete the required forms, and submit their application Workspace package.

To apply through Grants.gov, an organization must first complete the Grants.gov registration process. *Allow up to 8 weeks for the completion of the Grants.gov registration process.* Registering early is advised.

Foreign organizations doing business outside of the United States are also required to complete the Grants.gov registration process, in addition to fulfilling supplementary requirements for doing business with the U.S. government.

If business is conducted with the federal government on a continuing basis, it is likely that some of the required actions have already been completed. Detailed information, links, automated tools, and checklists are available at <https://grants.gov/web/grants/applicants/organization-registration.html>.

The following steps are required as part of the Grants.gov registration process:

1. Unique Entity Identifier (UEI) and System for Award Management (SAM)

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

SAM validates organization information and electronically shares the secure and encrypted data with federal agencies’ finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an electronic business (E-Biz) POC, and a government business POC during the SAM registration process. ***Entity registrations in SAM have an annual expiration. Verify the status of your organization’s Entity registration in SAM well in advance of the application submission deadline.*** An organization can register in SAM online at <https://www.sam.gov/SAM/>. If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least 2 weeks to receive this information from the U.S. Internal Revenue Service. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination to direct the federal award to a qualified applicant.

Additional information and step-by-step registration directions are detailed in the SAM User Guide and other GSA training materials in the Help area at <https://www.sam.gov/SAM/>.

Applications will be rejected by Grants.gov if (1) the organization's Entity registration in SAM is not active or (2) during the SAM registration process, the organization did not answer "Yes" when asked "Do you want to be eligible for grants and other federal assistance?"

2. Commercial and Government Entity (CAGE) Code

The applicant organization must have a CAGE code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE codes. CAGE codes will be assigned to registrants as their SAM registration advances through the validation process. Foreign registrants in SAM must be assigned a North Atlantic Treaty Organization CAGE code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the organization is located or by visiting the website (<https://cage.dla.mil/Home/UsageAgree>). On average, CAGE code or NCAGE code validation in SAM occurs within 3 business days after the TIN is validated.

3. Authorized Organizational Representative

Each organization must have an AOR who is registered with Grants.gov (individual PIs do not register with Grants.gov). An AOR must be a member of the Grants.gov Workspace grant team as the Business Official authorized to submit the completed Workspace application package. An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before application submission, the AOR must be registered to submit on behalf of the organization at Grants.gov (<https://apply07.grants.gov/apply/register.faces>).

An AOR must first register with the Grants.gov credential provider at <https://apply07.grants.gov/apply/register.faces> to obtain a username and password. Once an AOR has completed the Grants.gov registration process, Grants.gov will notify the E-Biz POC of the registration. The E-Biz POC will then log in to Grants.gov and assign and authorize the appropriate roles, which may include the AOR role, thereby giving the AOR permission to complete and submit applications on behalf of the organization. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

At the time of application submission to Grants.gov, the AOR is certifying to the best of their knowledge that all information provided in the application is current, accurate, and complete.

For applications submitted through Grants.gov, the name of the AOR submitting the application is inserted into the application's signature line, serving as the electronic signature.



Individuals who make legally binding commitments on behalf of an organization must be authorized as AORs by the E-Biz POC. This step, often overlooked by applicants, is crucial for valid and timely submissions.

4. Grants.gov Workspace

Applicants must create a Grants.gov Workspace, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Once the Workspace has been created, participants (grant team members) can be added and the required forms can be completed and reviewed before submitting.

Each application submission must include the completed Grants.gov application package of forms associated with the specific research announcement in Grants.gov (<https://grants.gov/>).

Applicants who prepare the application outside Workspace must download the individual PDF forms from Grants.gov, complete and save the forms, and upload them to Workspace. A compatible and identical version of Adobe Reader must be used to view, complete, and submit an application package consisting of PDF forms if more than one person accesses the application package. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. ***Grants.gov will reject an application package that is opened at any time by an individual with an incompatible version of Adobe Reader.*** Rejected applications must be resubmitted using a new Grants.gov application package and a supported version of Adobe Reader prior to the application submission deadline. It is the applicant’s responsibility to verify their Adobe Reader’s compatibility with Grants.gov: <https://grants.gov/web/grants/applicants/adobe-software-compatibility.html>. A no-cost compatible version of Adobe Reader can be downloaded at <https://get.adobe.com/reader/otherversions/>. All contributors to the application must use matching compatible versions of Adobe software when editing and preparing application components outside Workspace. The use of different software versions will result in corruption of the submitted file.

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

Any modifications to the Project Narrative or Budget Form require submission of a changed/corrected Grants.gov application package to Grants.gov prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be modified during the application verification period.

The application submission deadline and the end of the application verification period in eBRAP are stated on the first page of the respective research announcement. See [Section II.E, Applicant Verification of Grants.gov Submission in eBRAP](#), for additional details.

A. Grants.gov Application Package Components

1. SF424 (Research & Related), Application for Federal Assistance Form

All appropriate information must be entered into this form to allow for auto-population of subsequent forms in the Grants.gov application package.

- **Block 1 – Type of Submission.** For original submissions, select the “Application” box. For changes that must be made after the original submission, the complete Grants.gov

application package must be resubmitted with the “Changed/Corrected Application” box selected.

- **Block 2 – Date Submitted.** Enter the date the application is submitted.

Applicant Identifier. Enter the submitting organization’s Control Number, if applicable. If there is no Organization Control Number, leave this field blank.

- **Block 3 – Date Received by State and State Application Identifier.** Not applicable.
- **Block 4a – Federal Identifier Box.** Enter in the eBRAP log number assigned during pre-application submission.

Figure 1. Enter the eBRAP log number in Block 4a.

4. a. Federal Identifier

b. Agency Routing Identifier

c. Previous Grants.gov Tracking ID

- **Block 4b – Agency Routing Identifier.** Not applicable.
- **Block 4c – Previous Grants.gov Tracking ID.** For changed/correct applications, enter the Grants.gov Tracking Number for the original application.
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. “Person to be contacted on matters involving this application” is the Business Official.
- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue Service. If applying from an organization outside the United States, enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select “New” for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant’s Project.** Enter the same project title as used for the pre-application.

- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, enter 00-000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the application. If outside the United States, select the appropriate country from the drop-down menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget.
- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option b., “NO, program is not covered by E.O. 12372.”
- **Block 17 – Complete Certification.** Select the “I agree” box to provide the required certifications and assurances. *By checking “I Agree” on the SF424 (R&R) block 17 you agree to abide by the following statement: “By signing this application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel certify that the current and pending support provided on the proposal is current, accurate and complete; (B) agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.” (U.S. Code, Title 18, Section 1001). Checking “I agree” confirms compliance with the [National Policy Requirements, Appendix 6](#).*
- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL (SFLLL) to disclose lobbying activities pursuant to Title 31 of United States Code, Section 1352 (31 USC 1352).
- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization’s authorized representative. The “Signature of Authorized Representative” is automatically completed upon submission of the Grants.gov application package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.

If a revised Project Narrative or Research & Related Budget Form document is needed, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID found in Block 4.c. of the SF424 Research & Related Form prior to the full application submission deadline.

2. Attachments Form

Grants.gov does not validate for the presence of attachments on the Attachments Form.

Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to view, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific research announcement requirements, and discrepancies will be noted in both the email and in the Full Application Files tab. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the research announcement. See [Section II.E, Applicant Verification of Grants.gov Submission in eBRAP](#), for additional details.

Each attachment in the Attachments Form must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in [Appendix 5](#). For all attachments, ensure that the file names are consistent with the guidance listed in the research announcement and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire Grants.gov application package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that a file exceeding the maximum size will be accepted.



For specific instructions regarding content and page limits of the Project Narrative, Supporting Documentation, and all other attachments to this Grants.gov form, refer to the research announcement.



All documents that require signatures must be signed. Both electronic and hand signatures will be accepted. Any document that is signed by hand should be scanned at a resolution of 100-150 dots per inch.

The following must be included as attachments:

Attachment 1: Project Narrative: Attach as a PDF file named “ProjectNarrative.pdf”.

The Project Narrative is the main body of the application. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators; web addresses) 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.

Submission of a Project Narrative that exceeds the page limit specified in the research announcement will result in administrative rejection of the application.



Attachment 2: Supporting Documentation: Combine and attach as a single PDF file named “Support.pdf”. Include only supporting documentation as indicated in the research announcement. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed or the application may be administratively withdrawn.

All applications are provided fair and thorough reviews. Letters of support not requested in the research announcement, such as those from members of Congress, will be removed from the application package.

For a list and descriptions of required supporting documents, refer to the research announcement.

Attachment 3: Technical Abstract: Attach as a PDF file named “TechAbs.pdf”. Abstracts of all funded research projects will be posted on the CDMRP website at <https://cdmrp.health.mil>. *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.

The Technical Abstract will be posted publicly and will be included in the award agreement. Do not include proprietary or confidential information.

Attachment 4: Lay Abstract: Attach as a PDF file named “LayAbs.pdf”. Abstracts of all funded research projects will be posted on the CDMRP website at <https://cdmrp.health.mil>. *Do not include proprietary or confidential information. Do not duplicate the technical abstract.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The Lay Abstract will be posted publicly. Do not include proprietary or confidential information.

Attachment 5: Statement of Work (SOW): Attach as a PDF file named “SOW.pdf”. The SOW is an outline of specific aims of the proposed research project that establishes the project milestones during the performance period of the award. The SOW should contain sufficient detail to be informative as a stand-alone document. There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit.

SOW Format: PIs are strongly encouraged to use the suggested SOW format stated in the research announcement. Templates for SOW formats are available on the eBRAP “Program Announcement & Forms” page (<https://ebrap.org/eBRAP/public/Program.htm>). The SOW must be in PDF format prior to attaching.

For specific instructions regarding SOW content, refer to the research announcement.

Attachments 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the research announcement (e.g., “Impact.pdf”, “Innovation.pdf”, “Training.pdf”, “Transition.pdf”).



For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the research announcement, [Section II.D.2, Attachments Form](#).

3. Research & Related Personal Data

This form will be used by DOD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the Project Director (PD)/PI and all other persons identified as Co-PD(s)/Co-PI(s).

Each application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the “Next Person” button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to reviewers. Applicants who do not wish to provide some or all of the information should check or select the “Do not wish to provide” option.

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

The Degree Type and Degree Year fields on the Research & Related Senior/Key Person Profile (Expanded) form will be used by DOD as the source for career information. In addition to the required fields on the form, applicants must complete these two fields for all individuals that are identified as having the project role of PD/PI or Co-PD/Co-PI on the form. Additional senior/key persons can be added by selecting the “Next Person” button.

Include the requested information for each person who will contribute significantly to the proposed research project.

In the “PROFILE – Project Director/Principal Investigator” section, enter the PI’s User Name provided by eBRAP into the data field labeled “Credential, e.g., agency login” (Figure 2).

Figure 2. PI's eBRAP User Name

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

Position/Title: Department:

Organization Name: Division:

* Street1:

Street2:

* City: County/ Parish:

* State: Province:

* Country: USA: UNITED STATES * Zip / Postal Code:

* Phone Number: Fax Number:

* E-Mail:

Credential, e.g., agency login:

Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. Use of this document is optional. The NIH Biographical Sketch may also be used. Each biographical sketch must be in PDF format prior to attachment. Page limitations will be specified in the research announcement.

- **PI Biographical Sketch:** This file must be titled “Biosketch_LastName.pdf” where “LastName” is the last name of the PI.
- **PI Previous/Current/Pending Support:** This file must be titled “Support_LastName.pdf” where “LastName” is the last name of the PI.

For all previous (award period of performance ending within the past 5 years), current, and pending (includes period of time awaiting funding status and/or period of time awaiting start date) research support, include the title, time commitments, supporting agency, name and address of the funding agency’s procuring Contracting/Grants Officer, performance period, level of funding, brief description of the project’s goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

List all positions and scientific appointments, both domestic and foreign, held by senior/key personnel that are relevant to an application, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

Report all resources and other support for all individuals designated in an application as senior/key personnel – including for the PI and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information must be provided about all current support for ongoing projects, whether such support is provided through

the applicant organization, through another domestic or foreign organization, or is directly provided to an individual who supports the senior/key personnel's research efforts.

Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.

Provide the total award amount for the entire award period covered (including facilities and administrative costs), as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior/key personnel involved.

If there is no previous, current, or pending support, enter "None." An updated previous, current, and pending support document will be required if an award is recommended for funding.

- **Key Personnel Biographical Sketches:** Each file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the respective individual.
- **Key Personnel Previous/Current/Pending Support:** Each file must be titled "Support_LastName.pdf" where "LastName" is the last name of the respective individual. Refer to content requirements under "PI Previous/Current/Pending Support" listed above.

Note: Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of monetary value and/or where they are based. This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.).

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

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

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

5. Research & Related Budget

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must be submitted on the Grants.gov Research & Related Budget Form. For limits on funding amounts, types of costs, and period of performance, refer to the research announcement. The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. ***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.*** At the time of application submission to Grants.gov, the AOR is certifying to the best of their knowledge that all costs are current, accurate, and complete.

If the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.

No budget will be approved by the government exceeding the cost limit stated in the specific research announcement or using an indirect rate exceeding the organization’s negotiated rate.

Budget Instructions: Complete the Research & Related Budget Form following the instructions below. Begin by entering the organizational UEI number, Budget Type, Name of Organization, and anticipated start and end dates. ***Ensure that the UEI number is entered accurately or Grants.gov will reject the application.***



For all federal agencies or organizations collaborating with federal agencies applying to the research announcement, special restrictions apply to the budget and are described below.

- **For Federal Agencies:** An application from a federal agency must include in the budget justification a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their period for obligation expires and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.
- **For Collaborating Military Facilities:** An application from an organization that includes collaboration with 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) must submit a DOD Military Budget as instructed in [8. Suggested Collaborating DOD Military Facility Budget Format](#), below. The costs per year should be included on the Grants.gov Research & Related Budget form under subaward costs.

Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the Research & Related Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3 of the Research & Related Budget Form (Other Direct Costs, Consultant Services).
- **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Identify and explain in the budget justification any proposed adjustments to rates or salaries. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. *For most federal agencies, funding cannot be applied toward federal salaries and therefore these salaries should not be included in the requested budget.*
- **Level of Effort (Calendar, Academic, and Summer Months):** For each senior/key person, including unpaid personnel, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
- **Project Role:** Identify the role of each senior/key person listed. Describe their specific functions in the budget justification.

Section B: Other Personnel

- **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.

- **Level of Effort (Calendar, Academic, and Summer Months):** For each project role category, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period. *For most federal agencies, funding cannot be applied toward federal salaries and therefore these salaries should not be included in the requested budget.*
- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description. Equipment is tangible personal property (including information technology systems) having a useful life of more than 1 year and a per unit acquisition cost that equals or exceeds the lesser of (a) \$5,000 or (b) the partner's or the subpartner's capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

- Special test equipment to be fabricated for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the partner with partner funds, would be capitalized for federal income tax purposes.

In addition, requests for equipment must include a rationale for estimated costs.

Section D: Travel. Travel costs may include:

- Costs to attend scientific/technical meetings per year as specified in the research announcement: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be justified with additional documentation and is subject to approval by the Grants Officer.
- Costs to attend required meetings (if applicable): Include the meeting name if identified in the research announcement and a statement in the budget justification confirming that the PI will attend the required meeting.

- Costs for travel associated with the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be justified with additional documentation and is subject to approval by the Grants Officer.
- Funds to an extramural organization may not be used to cover travel costs for DOD military and civilian employees. All approved travel costs for DOD military and civilian employees will be paid by the government through a direct fund transfer. Proposed travel costs for DOD military and civilian employees should be included on the DOD Military Budget (Suggested DOD Military Budget Format).

Section E: Participant/Trainee Support Costs. Enter the funds requested for tuition/fees, health insurance, stipends, travel, subsistence, and other costs.

Section F: Other Direct Costs

- **Materials and Supplies:** “Materials and Supplies” means all tangible property, including a computing device, acquired under an award that does not meet the definition of equipment. The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.
 - If a computer/software purchase is requested, include the following in the budget justification:
 - Detailed explanation for why purchase of computer/software is required to complete the proposed research project.
 - Statement verifying that the requested computer/software is not currently available for use.
- **Publication Costs:** Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.
- **Consultant Services:** Whether or not funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.
- **Automated Data Processing (ADP)/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider’s computer service rates. See the “Materials and Supplies” bullet above regarding the purchase of computers.

- **Subaward/Consortium/Contractual Costs:** Include the total funds requested for (1) all subaward/consortium organization(s) proposed for the research project and (2) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the Research & Related Subaward Budget Attachment(s) Form.

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 Suggested DOD Collaborating Military Facility Budget Format, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including the Justification section, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.



All direct and indirect costs of any Phase 1 and/or Phase 2 subaward must be included in the direct costs of the primary award. No budget will be approved by the government exceeding the cost limit stated in the specific research announcement or using an indirect rate exceeding the organization’s negotiated rate.

- **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.
- **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and are a minor portion of the overall budget. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. ***Costs for the construction of facilities are not allowable.***
- **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified in the budget justification. Organizationally provided services should be supported by the organization’s current cost/rate schedule.

Include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs. Include the total direct costs (A-F).

Section H: Indirect Costs. The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a federal agency, indicate the source of the approval.

Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved

rate agreement). Also indicate if the rate(s) is an on-site or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

Organizations can also visit the DHHS (<https://www.hhs.gov/about/agencies/asa/psc/indirect-cost-negotiations/index.html>), the Office of Naval Research (<https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award>), and the Defense Contract Audit Agency (<https://www.dcaa.mil/>) for additional information on indirect rates.

Section I: Total Direct and Indirect Costs. Include total costs for the proposed research project.

Section K: Budget Justification. Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to Section K of the Research & Related Budget.

Applications from **federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.



Organizations must provide sufficient detail and justification so the government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

6. Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the “Next Site” button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to the Project/Performance Site Location(s) form. Each additional research site requesting funds will require a subaward budget.

7. Research & Related Subaward Budget Attachment(s) Form (if applicable)

Complete a separate detailed Research & Related Budget including a budget justification for each subaward (subgrant or contract) in accordance with the instructions listed above. Title each individual subaward, “Research & Related Budget,” with the name of the subawardee/ subpartner organization, and attach to the Research & Related Subaward Budget Attachment(s) Form.



All direct and indirect costs of any Phase 1 and/or Phase 2 subaward must be included in the direct costs of the primary award. The primary award (including the direct and indirect costs of any subawardees) will not exceed the cost limit stated in the research announcement.

A description of services or materials that are to be provided under the subaward is required. Organizations must provide sufficient detail and justification so that the government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

8. Suggested DOD Collaborating Military Facility Budget Format

This section addresses requirements and procedures when a military facility will be a collaborator in performance of an extramural project.

Budget Form: Complete a separate “Suggested DOD Collaborating Military Facility Budget Format” for each military facility involved in the project, which is available for download on the eBRAP “Funding Opportunities and Forms” web page (<https://eBRAP.org>). Do not complete the Grants.gov Research & Related Subaward Budget Attachment Form.

Direct Costs:

- **Salaries:** Include the positions/titles/ranks and levels of effort of all DOD civilian and military personnel expected to work on the extramural project, whether or not salaries/fringe benefits are proposed. Salaries/fringe benefits may be reimbursed, either directly by the federal government to the facility or through the extramural award to the facility, but only under certain limited circumstances, which will be discussed during negotiations. Extramural organizations may provide personnel to work at intramural DOD partnering organizations. The extramural personnel costs should not be included here but on each organization’s Research & Related Budget Form (Sections A and B).
- **Travel:** Include costs to be incurred by DOD civilian and military personnel. However, these costs cannot be reimbursed through the extramural award. All approved travel costs of DOD military and civilian employees will be paid by the government through a direct fund transfer. Some restrictions apply. Processes will be discussed during negotiations.
- **Consultants, Equipment, Materials, Supplies, Other, etc.:** Include all anticipated direct costs. The military facility should consider whether the applicant organization can purchase the items/resources and provide them to the facility. The organization may provide resources to the military facility, such as consultants, supplies, equipment, etc., acquired with award funds. If this is feasible, these funds should not be included on the applicant organization’s Research & Related Budget Form and should not be included on the Suggested DOD Collaborating Military Facility Budget Format.
- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DOD-established reimbursement rates (e.g., Institutional Review Board [IRB] fees, Institutional Animal Care and Use Committee [IACUC] fees), the military facility’s Resource Manager (RM)/Comptroller/Task Area Manager or equivalent Business Official must provide details of how the proposed rates/fees were determined. Rates/fees should be included in the Other Direct Costs line of the Research & Related Budget Form (Section F.8-10).

- **Indirect Costs:** If an indirect cost rate is proposed, include documentation to support the rate (i.e., cost pool(s) and what items are included in each pool). The military facility should consult with its RM office (or equivalent) for assistance in determining a rate.
- **Total Costs:** Include the facility's combined direct and indirect costs. Enter the total here and also include it in the Subaward/Consortium/Contractual Costs budget line on the Research & Related Budget Form (Section F.5 of the form.).

Budget Justification: Include a budget justification for each year, for each military facility. A description of services or materials that are to be provided by the collaborating military facility is required. The military facility researcher(s) should coordinate with their local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. Applicant organizations must provide sufficient detail and justification to enable the federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort. In addition, the military facilities' direct and indirect costs to be supported when performing collaborative research with the extramural organization must meet the requirements of the DOD's Financial Management Regulation (FMR) 7000.14-R.

Direct Fund by Federal Agency: If possible, the USAMRDC's RM office will "direct fund" (via a Funding Authorization Document [FAD], Military Interdepartmental Purchase Request [MIPR], or other authorized method) the collaborating military facility to support all costs to be incurred in performance of the military facility's portion of the research project. When direct funded, these funds **will not** be included in the award amount to the contractor or partner.

Funds Obligated on Extramural Award: If extraordinary circumstances exist whereby the USAMRDC RM office is not able to "direct fund" the military facility, the funds may be placed on the award and the contractor or partner may provide award funds to the military facility. If known at the time of submission, the military facility, in conjunction with the applicant organization, should provide a written justification for this funding method. Suggested areas to address include the research-related activities that will take place at the military facility, and the associated costs; when the activities will take place; why "direct funding" is not possible; why the applicant organization cannot provide the necessary resources and/or services; and the Comptroller's (or equivalent) ability to accept and process award funds appropriately.

Prior to the issuance of any award utilizing the funding method described above, written approval from the U.S. Army Medical Research Acquisition Activity (USAMRAA) Senior Contracting Official (SCO) will be required. SCO approval is not required at the time of submission. The justification will be considered by the USAMRAA Grants Officer in consultation with the applicant organization and the Grants Officer's Representative. If considered to be justified, the Contracting/Grants Officer will seek SCO approval.

Technology Transfer: The military facility researcher(s) should also coordinate with their technology transfer office, when applicable. The facility may require that a cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) be executed between the facility and the contractor or partner before work between the organizations can begin or funds can be provided to the military facility. The CRADA (or other

instrument) is not required at the time of application submission. A timeline for execution of the document will be established during negotiations.

B. Submission to Grants.gov

Grants.gov recommends submitting the application package *at least 24-48 hours prior to the close date* to provide time to correct any potential technical issues that may disrupt the application submission.

All applications must be received by the deadline indicated on the first page of the respective research announcement ([Section I, Overview of the Funding Opportunity](#)). Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of the application. Applicant AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of the application's timely submission.

C. Applicant Verification of Grants.gov Submission in eBRAP

The full application package submitted to Grants.gov may be viewed in eBRAP until the [end of the application verification period](#) identified on the front cover of the research announcement/ funding opportunity announcement.

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. ***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process.*** Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

After eBRAP has processed the full application and prior to the end of the application verification period, select components of the application package submitted to Grants.gov, ***with the exception of the Project Narrative and Research & Related Budget Form***, may be modified.

See [Section I, Overview of the Funding Opportunity](#), for specific full application submission and application verification deadlines.

Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific research announcement requirements, and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the research announcement.



eBRAP does not confirm the accuracy of the file content or the application package.

If either the Project Narrative or the Research & Related Budget fails eBRAP validation or if the Project Narrative or the Research & Related 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. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. The full application submission deadline and the end of the application verification period in eBRAP are stated on the first page of the specific research announcement ([Section I, Overview of the Funding Opportunity](#)).

D. Application Tracking

After a Workspace package has been successfully submitted, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the package. The number will be listed on the Confirmation page that is generated after submission. The submission of a Workspace package can be tracked from the Workspace or by visiting Grants.gov (<https://grants.gov/web/grants/applicants/track-my-application.html>) and entering the Tracking Number.

IV. APPLICATION SUBMISSION FOR INTRAMURAL ORGANIZATIONS

A. eBRAP Application Package Components

The eBRAP application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to “My Applications” and click on “Start Full Application”** for the log number under which the pre-application was submitted.

- **Tab 1 – Summary:** Provides a summary of the application information.
 - **Tab 2 – Application Contacts:** This tab will be populated by eBRAP. Add the name of the AOR.
 - **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to [Appendix 5](#) for detailed formatting guidelines.
1. **Application Component – Attachments:** Each attachment must be uploaded as an individual PDF file unless otherwise stated. Specific page limits are noted in the research announcement. Prepare Attachments as directed in the research announcement.
 2. **Research & Related Personal Data:** This form will be used by DOD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the PD/PI and all other persons identified as Co-PD(s)/Co-PI(s).

Each application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be

added by selecting the “Next Person” button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to merit reviewers. Applicants who do not wish to provide some or all of the information should check or select the “Do not wish to provide” option.

Upload the Research & Related Personal Data Form as “PersonalData_LastName.pdf” under the Key Personnel Application Components.

3. Application Component - Research & Related Senior/Key Person Profile

Each attachment must be uploaded as an individual PDF file unless otherwise stated. The Biographical Sketches and the Previous/Current/Pending Support for the PI and Key Personnel may be either attached to the Research & Related Senior/Key Person Profile (Expanded) Form or uploaded as individual files in the “Key Personnel” Application Component.

Research & Related Senior/Key Person Profile (Expanded): The Degree Type and Degree Year fields on the Research and Related Senior/Key Person Profile (Expanded) will be used by the DOD as the source for career information. In addition to the required fields on the form, applicants must complete these two fields for all individuals that are identified as having the project role of PD/PI or Co-PD/Co-PI on the form. Additional senior/key persons can be added by selecting the “Next Person” button.

Upload the Research & Related Senior/Key Person Profile (Expanded) as “KeyPersonnel_LastName.pdf” under the Key Personnel Application Components.

Include the requested information for each person who will contribute significantly to the proposed research project.

Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. Use of this document is optional. The NIH Biographical Sketch may also be used. Each biographical sketch must be in PDF format prior to attachment. Page limitations will be specified in the research announcement.

- **PI Biographical Sketch:** This file must be titled “Biosketch_LastName.pdf” where “LastName” is the last name of the PI.
- **PI Previous/Current/Pending Support:** This file must be titled “Support_LastName.pdf” where “LastName” is the last name of the PI.
 - *For all previous (award period of performance ending within the past 5 years), current, and pending (includes period of time awaiting funding status and/or period of time awaiting start date) research support, include* the title, time commitments, supporting agency, name and address of the funding agency’s procuring Contracting/Grants Officer, performance period, level of funding, brief description of the project’s goals, and list of the specific aims. If applicable,

identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

- If there is no previous, current, or pending support, enter “None.” An updated previous, current, and pending support document will be required if an award is recommended for funding.

- **Key Personnel Biographical Sketches:** Each file must be titled “Biosketch_LastName.pdf” where “LastName” is the last name of the respective individual.
- **Key Personnel Previous/Current/Pending Support:** Each file must be titled “Support_LastName.pdf” where “LastName” is the last name of the respective individual. Refer to content requirements under “PI Previous/Current/Pending Support” listed above.

4. **Application Component – Budget Form:** Complete the Suggested DOD Military Budget Format and Justification section. Begin by entering the PI name, eBRAP Log number, and period of performance fields at the top of the Suggested DOD Military Budget Format.
DOD Civilian and Military Personnel: Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any federal employee, as those costs were to have been included in infrastructure costs. If salary support is requested, sufficient justification must be provided in the budget justification section.

DOD Military Budget Instructions:

- **Name:** Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable), and support staff.
- **Role on Project:** Identify the role of each participant listed. Describe their specific functions in the proposed research in the budget justification.
- **Type of Appointment (Months):** List the number of months per year reflected in an individual’s contractual appointment with the applicant organization. The government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.
- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.

- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small “Calculate Salary” checkbox located in the lower portion of the field. Calculate the salary request by multiplying an individual’s organizational base salary by the percentage of effort on the project.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.
- **Totals:** Calculated automatically from the data provided.
- **Major Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit.
- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies.
- **Travel Costs:** PIs are responsible for budgeting for all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DOD per diem rates. Travel costs may include:
 - Travel costs for the PI to attend a required In-Progress Review meeting each year.
 - Travel costs for up to one investigator to travel to one scientific/technical meeting per year.
 - Travel costs between collaborating organizations.
- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.
- **Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical services, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization’s current cost/rate schedule. These items should be described in detail and clearly justified.
- **Contract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency’s procedures. **All direct and indirect costs of any partnership/**

collaboration costs must be included in the total direct costs of the primary award. The nature of the partnership/collaboration should be described in the Budget Justification section.

- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period and for the entire proposed period of support.
- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the Justification section. The government reserves the right to disallow any indirect costs not sufficiently justified. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. Refer to [Section I.E, Funding](#), of the research announcement for detailed information.
- **Total Costs:** This section is calculated automatically from the data provided.
- **Fee:** A profit or fixed fee is not allowable on awards or on subawards.

Budget Justification Instructions: Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section of the Suggested DOD Military Budget. Itemize direct costs within each budget category for additional years of support requested beyond year one.

- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the DOD Military Budget. The plan delineates how all FY22 funding will be obligated by **September 30, 2023**. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable. Any FY22 funding not obligated by September 30, 2023 may be withdrawn by the issuing Comptroller.

5. Application Component: Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the “Next Site” button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

- **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.

- **Tab 5 – Submit/Request Approval Full Application**

Once all components have been 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 validate files

against the research announcement requirements, and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the application submission. eBRAP will notify your RM/Comptroller/Task Area Manager or equivalent Business Official by email to log into eBRAP to review and approve the full application package prior to the approval deadline.

The full application package submitted to eBRAP may be viewed in eBRAP until the end of the application verification period. After eBRAP has processed the full application, PIs will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Research & Related Budget Form***, may be modified. Modifications to application components may only be made after the Business Official has set the status to “Return to PI” for the PI to make changes, or “Draft” for the Business Official to make changes. See the first page of the research announcement for specific full application submission and application verification deadlines.

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

APPENDIX 2 REGULATORY REQUIREMENTS

A. Research Protections Review Requirements

The USAMRDC OHARO ensures that research conducted, contracted, sponsored, supported, or managed by the DOD and involving human subjects, human anatomical substances, human data, human cadavers, or animals is conducted in accordance with federal, DOD, Army, USAMRDC, and international regulatory requirements.

All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local IACUC of record. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects.

All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, human data, or human cadavers must be reviewed and approved by the USAMRDC OHARO, (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review.

PIs and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until regulatory documents are submitted and approved by the USAMRDC OHARO to ensure that DOD regulations are met. All expectations described below are consistent with DOD Instruction (DODI) 3216.01, “Use of Animals in DoD Programs,” and DODI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research.”

Additional information is available at
https://mrdc.health.mil/index.cfm/collaborate/research_protections

1. Research Involving Animal Use

The ACURO must review and approve all animal use funded by the award prior to the start of working with animals, including amendments to ongoing projects. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” For guidance, visit the ACURO website at https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro. *Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*

2. Research Involving Human Subjects

The OHRO ensures that DOD-supported research complies with specific laws, regulations, and requirements governing human subjects research. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and***

complete documents to the OHRO. Studies taking place in international settings may require additional time for completion of OHARO OHRO reviews.



NOTE: The protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the approved SOW. If the DOD-funded activities have been added to an ongoing/existing protocol that is not DOD-funded, OHRO will require the PI to write a stand-alone protocol that is limited to those activities supported under the DOD award.

Effective 20 January 2020, The Revised Common Rule (i.e., the 2018 Requirements) at 45 CFR 46.114(b) requires that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency rely upon approval by a single IRB for the portion of the research that is conducted in the United States. These provisions apply to DOD-funded research. Applicants must provide a written plan for single IRB review arrangements at the time of application submission or award negotiation.

Questions regarding applicable human subjects protection regulations, policies, and guidance should be directed to the local IRB or the OHARO OHRO (usarmy.detrick.medcomusamrdc.otherhrpo@health.mil). For in-depth information and to access OHRO protocol submission forms, refer to the OHARO OHRO website (https://mrhc.health.mil/index.cfm/collaborate/research_protections). Key requirements found in the OHARO OHRO guidance document, “Information for Investigators – Human Subjects Research” include:

- **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federalwide Assurance (FWA) or DOD Assurance.
- **Training:** Personnel involved in human subjects research must have completed appropriate training in the protection of human subjects per institutional requirements. Documentation confirming completion of appropriate training will be required during the OHARO OHRO review process.
- **Informed Consent Form:** The following must appear in the consent form:
 - A statement that the DOD is providing funding for the study.
 - A statement that representatives of the DOD are authorized to review research records.
 - If Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DOD must be listed as one of the parties to whom private health information may be disclosed.
- **Access to DOD-Affiliated Personnel for Research:** See the guidance document, “A Primer for Conducting Department of Defense (DOD) Funded Human Research With Military Populations,” at [Conducting Research Military Pop DoD May 2021.pdf](#)

(copy/paste the following URL into your browser to open the link)

https://mrdc.health.mil/assets/docs/orp/Conducting_Research_Military_Pop_DoD_May_2021.pdf

- **10 USC 980 Waiver:** If the applicant proposes to conduct a trauma clinical trial or other planned emergency research subject to the requirements for exception from advanced informed consent under 21 CFR 50.24, the applicant should plan for 3-6 months of additional time for the OHARO OHRO to review the submission and request a waiver of 10 USC 980 from the Secretary of the Army or the DOD Office of Human Research Oversight.

3. Research Involving the Secondary Use of Data/Specimens

Research involving the use of human data and/or specimens not otherwise subject to institutional review requires a determination letter (e.g., stating that the project does not constitute “human subjects research” or can be considered “exempt human subjects research”) from the PI’s human subjects protection office as well as a concurrence from the OHARO OHRO.

All USAMRDC-supported research involving the secondary use of human data, human biospecimens (hereafter referred to as data/specimens) must be reviewed for compliance with federal and DOD human subjects protection requirements and approved by the OHARO OHRO prior to implementation. For additional guidance and instructions on OHARO OHRO review of DOD-funded research activities involving access, use, and analysis of data/specimens, see the guidance document, “Information for Investigators – Research with Data/Specimens,” found at https://mrdc.health.mil/index.cfm/collaborate/research_protections.



NOTE: *The protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the SOW. If the DOD-funded activities have been added to an ongoing/existing protocol that is not DOD-funded, OHRO will require the PI to write a stand-alone protocol that is limited to those activities supported under the DOD award.*

4. Additional Information/Requirements

Site Visits: The USAMRDC OHARO OHRO conducts site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

Protocol Submission Format: The OHARO OHRO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions.

Research Involving the Use of U.S. Food and Drug Administration-Regulated Products (i.e., drugs, devices, in vitro diagnostics) in which the focus of the study is on the safety or effectiveness of the product requires IRB review in accordance with 21 CFR 50 and 21 CFR 56.

Clinical Trial Registry: PIs are required to register applicable clinical trials individually on <https://clinicaltrials.gov/> using a Secondary Protocol ID number designation of “CDMRP-eBRAP Log Number” (e.g., CDMRP-PC22#####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated “CDMRP-eBRAP Log Number-A, B, C, etc.” (e.g., CDMRP-PC22#####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see <https://prsinfo.clinicaltrials.gov/>, click on “Support Materials (including data element definitions)”) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85. PIs conducting phase 3 clinical trials shall submit results of analyses of group differences on the basis of sex/gender, race, and/or ethnicity to clinicaltrials.gov at the time of final report submission. If final analyses of sex/gender and race/ethnicity are not available at the time of the final technical report, a justification and plan ensuring completion and reporting of the analyses must be submitted to USAMRAA.

Research Involving Recombinant DNA: The partner must assure that all work involving the use of recombinant DNA will be in compliance with guidance provided at [Biosafety and Recombinant DNA Policy – Office of Science Policy \(nih.gov\)](https://www.nih.gov/biosafety-and-recombinant-dna-policy-office-of-science-policy).

5. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (RDT&E), education, or training activities involving human cadavers or human anatomical substances obtained from cadavers (postmortem samples) shall not begin until the USAMRDC OHARO grants approval in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training (copy/paste the following URL into your browser to open the link) (https://mrdc.health.mil/assets/docs/orp/Army_Policy_for_Use_of_Human_Cadavers.pdf). The USAMRDC OHARO is the Action Office for this Army policy.

Additional requirements apply to activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.

Award partners must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Specific requirements for submission and review of RDT&E, education, and training involving cadavers and postmortem specimens can be found at https://mrdc.health.mil/index.cfm/collaborate/research_protections.

Written approvals to begin the activity will be issued under separate notification to the partner. Questions regarding submission of human cadaver research for USAMRDC OHARO review and approval should be directed to the OHARO at usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil.

C. Use of DOD or Department of Veterans Affairs (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. Access to the target active-duty military patient population(s) and/or DOD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/Co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including 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. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should 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.

Access to certain DOD or VA patient populations, resources, or databases may only be obtained by collaboration with a DOD or VA investigator who has a substantial role in the research and may not be available to a non-DOD or non-VA investigator if the resource is restricted to DOD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DOD or non-VA investigator collaborating with the DOD and/or VA. If access cannot be confirmed at the time of application submission, the government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

APPENDIX 3 REPORTING REQUIREMENTS AND ADMINISTRATIVE INFORMATION

A. Reporting Requirements for Awards

The government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the government will be described in each award and may include:

- Technical/Scientific:
 - In addition to annual progress reports, the Terms and Conditions of the award will indicate any additional reporting required.
 - Final progress report
 - Quad Chart: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>, and as an attachment to a standard post-award progress report under Special Reporting Requirements if required by the terms and conditions of the award.
 - USAMRDC research progress reporting requirements and instructions can be found at https://mrdc.amedd.army.mil/index.cfm?pageid=research_resources_technical_reporting.
- Fiscal (SF425 “Federal Financial Report”):
 - Annual reports
 - Final report
- Regulatory:
 - Research Involving Human Subjects: For DOD awards that include funding to support research with human subjects, the USAMRDC’s OHRO requires submission of institutional continuing review reports and study event reports. Instructions are found at https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.
 - The USAMRDC’s OHRO will no longer require submission of local IRB annual continuing review materials for studies that no longer require continuing review under the 2018 Revised Common Rule (49 CFR Part 11).
 - Research Involving Animals: For DOD awards that include funding to support animal studies, staff from the USAMRDC’s ACURO will contact the Network Director regarding submission requirements and deadlines.
 - Public Health Service (PHS) Inclusion Enrollment Report: This is used to report the sex/gender, race, and ethnicity of study participants that will be enrolled in the clinical

research (both planned and actual). The PHS Inclusion Enrollment Report format is a fillable PDF form that may be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm> and completed for submission with the application.

B. Post-Award Organization and Principal Investigator Changes

Transfer of Award to New Organization: Unless restricted by the specific research announcement, a change in organizational affiliation will be considered on a case-by-case basis by the USAMRAA Grants Officer. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a study site/clinical trial at its location. Organization transfers are not allowed in the last year of the performance period.

Change in Principal Investigator: Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

C. Disclosure of Proprietary or Confidential Information

Do not include proprietary or confidential information in a pre-application or abstract. Proprietary information should only be included in a full application if necessary for evaluation.

Evaluators must agree that proprietary or confidential information in the application will be used for evaluation purposes only and will not be further disclosed or used. All applications may be subject to public release under the Freedom of Information Act (FOIA).

Applications for funded projects will be subject to public release under the FOIA to the extent that they are incorporated in an award document; applications that are not selected for funding will not be subject to public release.

D. Marking of Proprietary or Confidential Information

Conspicuously and legibly mark any proprietary or confidential information that is included in the application.

E. Inquiry Review Process (IRP)

Although not required by law or acquisition regulation, CDMRP offers a courtesy to all applicants in an effort to maintain high integrity in its review processes. If an application is not recommended for funding and a factual or procedural error is believed to have occurred during the review of the application, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 business days will not be considered.

The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the application, as defined below:

- **Factual error:** An error in the review (peer or programmatic) that is restricted to, or based on, fact. Differences of opinion between reviewers or between reviewer(s) and an applicant are not factual errors.
- **Procedural error:** An error in the review (peer or programmatic) that is restricted to review process adherence. Review process did not follow the procedures as outlined in the research announcement describing peer and programmatic review (e.g., documents requested in the research announcement and submitted with the original application were left out of the peer or programmatic review package).

Inquiries should be submitted through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel consisting of CDMRP staff will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. The determination of an error in the review process is not a guarantee of funding. The final determination of the IRP and the funding decision are not subject to appeal. Questions related to the IRP prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.

F. Information Service

Applicants may use the technical reference facilities of the U.S. Department of Commerce National Technical Information Service (<https://www.ntis.gov>) to obtain information about existing research to avoid duplication of scientific and engineering effort.

G. Freedom of Information Act Requests

The FOIA (5 USC 552) provides a statutory basis for public access to official government records. The definition of “records” includes documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (www.usdoj.gov/oip/index.html).

When a FOIA request asks for information contained in a successful application that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRDC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRDC’s intent to release and will be provided a reasonable opportunity to assert available action.

H. Information Release

A partner of an award will be required to agree to the release of information pertaining to the research and development supported by the federal agency. “Information” includes but is not

limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

The following statements must be included in all information releases:

- (1) All releases shall identify the award number and include a statement acknowledging the federal sponsoring agency. The release shall also contain a statement that the opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DOD. The requirement with specific language will be included in the award notice. Below is an example:

“This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command, in the amount of (*insert total costs*), through the (*insert program name*) under Award No. (HT9425-23-1-XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”

- (2) “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the ACURO website (https://mrhc.health.mil/index.cfm/collaborate/research_protections/acuro).
- (3) “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<https://www.nih.gov/>)
- (4) “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” (<https://www.cdc.gov/safelabs/resources-tools.html>)

Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding.

I. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DOD definition of “Contracted Fundamental Research.” The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

J. Sharing of Application Information

The USAMRDC shares application information with other federal funding agencies (e.g., NIH, National Science Foundation, VA) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the CDMRP website and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, duplication of effort can be avoided, allowing for the support of more investigators with federal funds. The CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on CDMRP-funded awards including awardee information and published results are shared on the Defense Technical Information Center (DTIC).

K. Sharing of Data and Research Resources

The CDMRP intends that information, data, and research resources generated under awards funded by the research announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

Data and research resources generated by funded research should be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public. The expectations for sharing of data and research resources apply to all types of research funded by the research announcement. This includes all data and research resources generated during the project's period of performance as annotated in the award:

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large research data collections that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases. (Adapted from <https://sharing.nih.gov/data-management-and-sharing-policy>)
- **Final Research Data** are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens. (Adapted from <https://sharing.nih.gov/data-management-and-sharing-policy>.)
- **Research Resources** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools, methods, laboratory equipment and machines. (Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf.)

Data and research resources generated from CDMRP-funded research should be made as widely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data and third-party intellectual property.

By sharing and leveraging data and research resources, duplication of effort can be avoided, allowing for the support of more investigators with federal funds. The USAMRDC believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Depending on the research announcement, the PI may be required to participate in the following:

- **Traumatic Brain Injury:** If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (<https://fitbir.nih.gov>).
- **Clinical Trials:** If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (<https://www.clinicaltrials.gov/>).

For additional information on CDMRP's expectations and policies for data-sharing, refer to "Policy on Sharing Data & Research Resources," available on eBRAP under Resources and Reference Material at <https://ebrap.org/eBRAP/public/Program.htm>. For unique data-sharing guidelines and requirements, refer to the instructions in the specific research announcement.

L. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (35 USC 200 et seq.), the partner and collaborators may elect to retain title to their subject inventions, subject to meeting the reporting and patent filing requirements and retained rights to the U.S. government. The U.S. government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Instructions in the award concerning subject inventions must be followed.

APPENDIX 4 QUALIFICATION AND RESTRICTIONS INFORMATION

A. Partner Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified partners only. The USAMRDC utilizes the Exclusions within the Performance Information functional area of SAM to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at <https://www.sam.gov/SAM>. The USAMRDC also reviews and considers information about the applicant in the Office of Management and Budget (OMB)-designated integrity and performance system, currently the Federal Awardee Performance and Integrity Information System (FAPIIS), prior to making an award, as described in the research announcement, Section E.3.

B. J-1 Visa Waiver

Each organization, including organizations located outside of the United States, is responsible for ensuring that the personnel associated with any application recommended for funding are able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

Note: The federal government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (<https://www.state.gov/j/ct/list/c14151.htm>). Additional information on J-1 Visa Waivers can be located at the following Department of State website: travel.state.gov/visa/temp.

C. Post-Employment Restrictions

There are certain post-employment restrictions on former federal officers and employees as defined in 18 USC 207. Post-employment restrictions may exist if a former federal officer or employee participates in the proposed project; the situation should be addressed with the USAMRDC Office of the Staff Judge Advocate at Fort Detrick (<https://installations.militaryonesource.mil/military-installation/fort-detrick/legal/legal-assistance>) prior to expending time and effort in preparation of an application.

APPENDIX 5 FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ among the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** Each attachment to the full application forms must be uploaded as an individual file in the format specified in the research announcement. All contributors to the application must use matching compatible versions of Adobe software for all PDF documents when editing and preparing application components. The use of different software versions will result in corruption of the submitted file.
- **Font Size:** 12 point, not condensed.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bitmap and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs, or web addresses, directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the research announcement (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Individual attachments should be no larger than 20 MB. *If the file size for the entire Grants.gov application package will or may exceed 200 MB, applicants should contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that the file will be accepted or for other guidance.*

APPENDIX 6 NATIONAL POLICY REQUIREMENTS

The National Policy Requirements are available in full text at <https://usamraa.health.mil/Pages/Resources.aspx>. For additional regulatory requirements regarding safety, surety, and environmental requirements, and for use of animal and human subjects in research, refer to this General Applications Instructions, [Appendix 1](#).

A. Certification

Certification of compliance with the national policy requirement regarding lobbying activities is required from all partners of awards over \$100,000. Submission of this certification is required by 31 USC 1352 and is a prerequisite for making or entering into an award over \$100,000. Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (Research & Related) (Application for Federal Assistance) Form.

B. Representations

Extramural applicants are required to complete the representations below and submit with each application only if the organization is a Corporation and the response to item (2) or (3) is in the affirmative. The form for completion and submission is posted in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Upload the form into Grants.gov under Attachments.

Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations Under Any Federal Law

At the time of application submission, the applicant organization represents that it:

- (1) Is _____ Is not _____ a Corporation (“Corporation” means any entity, including any institution of higher education, other non-profit organization, or for-profit entity that has filed articles of incorporation). If the organization is a corporation, complete (2) and (3) below.
- (2) Is _____ Is not _____ a Corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.
- (3) Is _____ Is not _____ a Corporation that was convicted of a criminal violation under any federal law within the preceding 24 months.

NOTE: If the applicant organization responds in the affirmative to either (2) or (3) of the above representations, the applicant is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the government’s interests. The applicant organization therefore will be required to provide information about its tax

liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

In accordance with DOD appropriations, the following representation is required. The applicant, by its signature on the SF424 Research & Related, represents:

Representation Regarding the Prohibition on Using Funds Under Grants and Cooperative Agreements with Entities That Require Certain Internal Confidentiality Agreements.

By submission of its application, the applicant represents that it does not require any of its employees, contractors, or subpartners seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subpartners from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a federal department or agency authorized to receive such information. Note that (1) the basis for this representation is a prohibition in Section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235) and any successor provision of law on making funds available through grants and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) Section 743 states that it does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a federal department or agency governing the nondisclosure of classified information.

National Policy Requirements

The partner must comply with the following requirements, as applicable. The full text of National Policy Requirements is available at <https://usamraa.health.mil/Pages/Resources.aspx>. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act

- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements
- FY21 National Defense Authorization Act (NDAA) Section 223(a), (a1) 18 USC 1001

APPENDIX 7 ACRONYM LIST

A&R	Alteration and Renovation
ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AL	Assistance Listing (formerly known as Catalog of Federal Domestic Assistance [CFDA])
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CPG	Clinical Practice Guidelines
CRADA	Cooperative Research and Development Agreement
DA PAM	Department of the Army Pamphlet
DHHS	Department of Health and Human Services
DOD	Department of Defense
DODI	Department of Defense Instruction
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
E-Biz	Electronic Business
eBRAP	electronic Biomedical Research Application Portal
EC	Ethics Committee
EIN	Employer Identification Number
F&A	Facilities and Administrative
FAD	Funding Authorization Document
FAPIS	Federal Awardee Performance and Information System
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FMR	Financial Management Regulation
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
FY	Fiscal Year
G&A	General and Administrative

GOR	Grants Officer Representative
GSA	General Services Administration
HIPAA	Health Information Portability and Accountability Act
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property
IPR	In-Progress Review
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRP	Inquiry Review Process
JPEG	Joint Photographic Experts Group
M	Million
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
MPEG	Moving Picture Experts Group
NCAGE	North Atlantic Treaty Organization Commercial and Government Entity
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
NPC	Non-Profit Corporation
OMB	Office of Management and Budget
ORCID	Open Researcher and Contributor ID
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
PD	Project Director
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
POC	Point of Contact
R&R	Research and Related
RDT&E	Research, Development, Test and Evaluation
RM	Resource Manager
rOTA	Research Other Transaction Agreement
RTRP	Reconstructive Transplant Research Program
SAM	System for Award Management
SCO	Senior Contracting Official
SF	Standard Form
SOP	Standard Operating Procedure
SOW	Statement of Work

TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
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
WAV	Waveform Audio