RESEARCH OTHER TRANSACTION AGREEMENT ANNOUNCEMENT

for the

Department of Defense

Congressionally Directed Medical Research Programs

Neurofibromatosis Research Program

Clinical Trial Consortium Award

Funding Opportunity Number: W81XWH-21-NFRP-CTCA

SUBMISSION AND REVIEW DATES AND TIMES

- Questions to Program Office Deadline: 8:00 a.m. Eastern time (ET), September 03, 2021
- Pre-Application Submission Deadline: 5:00 p.m. ET, September 17, 2021
- Invitation to submit full proposal: September 24, 2021
- Application Submission Deadline: 11:59 p.m. ET, October 29, 2021
- End of Application Verification Period: 5:00 p.m. ET, November 05, 2021
- Peer Review: December 2021
- Programmatic Review: January 2022
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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2021 (FY21) Neurofibromatosis Research Program (NFRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2371 (10 USC 2371). The execution managing agent for this research announcement is the Congressionally Directed Medical Research Programs (CDMRP). The NFRP was initiated in 1996 to provide support for research of exceptional scientific merit that promotes the understanding, diagnosis, and treatment of neurofibromatosis (NF) including NF type 1 (NF1) and type 2 (NF2) and schwannomatosis. Appropriations for the NFRP from FY96 through FY20 totaled $362.85 million (M). The FY21 appropriation is $20.0M.

Military Relevance: The underlying causes of NF have a direct relationship to tumor formation in many non-cancer sarcomas and malignant cancers requiring extensive treatment and inpatient services. From 2009–2018, there were 2,469 new cases of NF within the Military Health System (MHS); 44% of these cases were predominately family members of active and reserve component Service Members. In addition, from 2009–2018 there were 6,609 Department of Defense (DOD) beneficiaries who had outpatient or inpatient encounters totaling 15,389 hospital bed days. NFRP-supported research is paving the way to finding treatments for individuals with NF that impact military Service Members, Veterans, and their beneficiaries.

FY21 NFRP Vision: The vision of the FY21 NFRP is to decrease the clinical impact of NF. To this end, the NFRP seeks to support innovative, high-impact research that will foster new directions for and address neglected issues in NF research; sponsor multidisciplinary and multi-institutional collaborations that will bring new perspectives to the field; promote translational and clinical studies to move promising ideas from bench to bedside; and develop a balanced portfolio of meritorious research related to all aspects of NF1, NF2, and schwannomatosis.

B. Award Information

The NFRP Clinical Trial Consortium Award mechanism was first offered in FY06, and subsequently in FY11 and FY16, with awards being made as grants or cooperative agreements. This FY21 research announcement is being offered through a different type of award mechanism, a Research Other Transaction Award (rOTA) under the authority of 10 USC 2371.

The FY21 NFRP Clinical Trial Consortium Award is intended to support a major goal/product-driven consortium of exceptional institutions and investigators that will accelerate the clinical translation of basic NF research and ultimately decrease the impact of the disease. The objectives of the rOTA are the conception, design, development, and conduct of collaborative Phase I and II clinical evaluations of promising therapeutic agents for the management or treatment of NF1, NF2, and schwannomatosis.

1 Data provided by the Armed Forces Health Surveillance Branch based on electronic records from the Defense Medical Surveillance System. Does not include care received outside the MHS.
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.

Additionally, a rOTA has several features that differ from those of the previous award types offered for the NFRP Clinical Trial Consortium. 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. Please also note that the government’s funds will not be front-loaded, with certain matches being required before additional government funds are made available. 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 in addition to state or local government agencies, institutions of higher education, or other nonprofit organizations.

General Information

The NFRP Clinical Trial Consortium requires collaboration of multiple organizations and individuals for the purpose of rapidly executing clinical trials. Therefore, the offeror must have a demonstrated history of collaborative research in such a structure.

Studies supported by this award will include:

- Phase 1 and Phase 2 trials which are the primary focus of this award.
- Certain observational trials with appropriate justification and at the discretion of the USAMRAA Agreements Officer. To be included, observational studies will require review by the NFRP Advisory Board and Program Office.
- Correlative studies as a part of a trial funded by this award may be considered.
- Support for repositories/tissue collection from NFRP Clinical Trial Consortium clinical trials supported may be considered based on the availability of long-term funding, priorities, and resources.

The participants will be jointly responsible for prioritizing, proposing, conducting, and analyzing Phase I and Phase II clinical trials focused on therapeutic interventions for NF1, NF2, and schwannomatosis. A final report cumulating the findings for all supported clinical trials will provided at the end of the term of the agreement. For additional reporting information, see Article IV of the draft agreement.
It is expected that the NFRP Clinical Trial Consortium will consist of an Operations Center and associated Clinical Trial Sites. The Operations Center may also serve as a trial site. The Operations Center must apply to this announcement through a single application. An award will be made to the Consortium (if it constitutes a separate legal entity) or to the Operations Center. The agreement will be structured to allow the Operations Center to fund approved Consortium-associated studies at the Clinical Trial Sites. The Operations Center will provide management for the Clinical Trial Sites. The Operations Center will be responsible for the overall management of the Consortium including technical, programmatic, reporting, financial and administrative matters.

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 Sections III.B.1 and 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, consortium model rOTA and is subject to negotiation upon selection of the most advantageous offeror.

Award selection will be based on evaluation of the available capabilities, organization of the NFRP Clinical Trial Consortium (including the proposed participation of for-profit entities), feasibility of the collective group to accomplish the overall award objectives (see Section III.B, Application Review Process), and their Resource Share Plan. During the performance period of the award, the Operations Center and all Clinical Trial Sites will be responsible for working collaboratively to identify new clinical trials for implementation by the Consortium.

The NFRP Clinical Trial Consortium will develop concepts for Clinical Trials and the Consortium Steering Committee will determine which trials will be presented in proposal to the government. Collectively, each Clinical Trial Site Principal Investigator (PI) and the Consortium Director will constitute the Consortium Steering Committee, which will be responsible for proposing and conducting Phase I and II clinical evaluations of promising therapeutic agents for the management or treatment of NF, as well as determining which Consortium Trial Sites will participate in each study. The Operations Center staff will be responsible for facilitating and coordinating this process. Representatives from the NFRP Program Office will sit on the Steering Committee. The Steering Committee can also have other members, such as representatives from the other partner organizations and industry. The government anticipates that once the Steering Committee identifies and recommends funding a Clinical Trial to the government, the Operations Center will provide the supporting documentation to the government for final approval. Proposed clinical trials will be submitted in a Research Project Proposal for scientific and programmatic review by the NFRP Advisory Board. Submitted Research Project Proposals should include the protocol and all associated forms, a Statement of Work with payment milestones, and a budget for the trial. The NFRP Advisory Board will provide a recommendation to the USAMRAA Agreements Officer.

The USAMRAA will execute a Project Approval Letter detailing critical aspects of the project and will negotiate as needed with the Operations Center and performer. As will be detailed in the agreement between the government and the awardee, certain clauses and provisions of the agreement will be required to flow down to each individual Project Approval Letter. However,
the terms and conditions of each Project Approval Letter may be customized through negotiation.

The Project Approval Letter will include all specific requirements expected to be included in the negotiated agreement between the awardee and the clinical trial performer. Full execution of the Project Approval Letter requires bilateral signatures between the USAMRAA Agreements Officer and the Consortium Authorized Organizational Representative.

Modifications to existing Project Approval Letters are expected as the need arises. The government anticipates that clinical trial performers will communicate requests to modify their agreements with the Coordinating Center, who will communicate with the USAMRAA and CDMRP. Situations may occur where clinical trial performers will communicate directly with the USAMRAA and CDMRP, but all revisions to the Project Approval Letters will require bilateral signatures from the USAMRAA Agreements Officer and the Consortium Authorized Organizational Representative.

The NFRP intends to allocate up to $25M to support the NFRP Clinical Trial Consortium over 10 years, subject to availability of funding. The Consortium will be funded initially for up to a total of $5M with allocations from the FY21 NFRP congressional appropriation. See Section I.D., Funding, for additional information.

1. **Consortium Structure**

   **Operations Center.** The NFRP Clinical Trial Consortium will consist of one central Operations Center that will be responsible for facilitating the rapid selection, design, execution, and analysis of clinical trials within the Consortium and will provide the administrative, protocol development and review, regulatory, statistical, resource, and data management and storage functions necessary to facilitate Consortium clinical trials in a timely manner. The Operations Center must contain multidisciplinary expertise and extensive experience in developing and conducting multi-institutional clinical trials of treatment approaches in support of NF research.

   The Consortium Director will serve as the PI for the application, must be located at the Operations Center, and must provide evidence of prior experience with the design and administration of multi-institutional clinical studies. The Consortium Director must also demonstrate a broad understanding of research, including knowledge of the current state of clinical studies and clinical priorities related to NF. It is expected that a succession plan will be provided to account for any unforeseen change in the Consortium Director.

   The application should identify and describe core facilities (i.e., pathology, radiology, etc.) available at the Operations Center and at any member organizations that will serve as official Consortium research core facilities.

   **Clinical Trial Sites.** The NFRP Clinical Trial Consortium will consist of a minimum number of five Clinical Trial Sites necessary to effectively participate in multiple trials. All sites must be identified and have clinical trials experience and multidisciplinary expertise in supporting NF1 and/or NF2 and/or schwannomatosis clinical research. The exact number of
sites is to be proposed by the applicant and inclusion as a Clinical Trial Site must be based on factors including:

- Lead Site PIs’ commitment to and experience in NF clinical research. Applications are expected to include a succession plan to account for any unforeseen change in the Lead Site PI.

- Evidence of multidisciplinary clinical and/or laboratory expertise within the institution that could serve as the basis for the development of clinical protocols by the NFRP Clinical Trial Consortium.

- Demonstration of adequate resources for coordinating with the Operations Center and other sites.

- Demonstration of adequate resources and expertise for data management, and maintenance of data security/confidentiality.

- Evidence of institutional commitment to using facilities and resources in the conduct of Consortium studies as required.

- Documentation of procedures to resolve intellectual and material property issues.

- Demonstration of adequate resources and expertise in NF patient recruitment and processing, including specimen collection.

- Ability to enroll adequate numbers of evaluable individuals with NF1, NF2, or schwannomatosis per year into Consortium-sponsored studies or to provide such unique expertise or facilities to otherwise justify inclusion as a site.

Additional competencies of proposed sites may be identified and justified as being essential to the success of the Consortium.

**Steering Committee.** Collectively, each Clinical Trial Site PI and NFRP Clinical Trial Consortium Director will constitute the Consortium Steering Committee, which will be responsible for proposing and conducting Phase I and II clinical evaluations of promising therapeutic agents for the management or treatment of NF and for determining which Consortium Trial Sites will participate in each study. The Operations Center staff will be responsible for facilitating and coordinating this process. Representatives from the NFRP Program Office will serve as members of the Steering Committee. The Steering Committee can also have other members, such as representatives from the other partner organizations, including advocacy and industry.

**NFRP Advisory Board.** The United States Army Medical Research and Development Command (USAMRDC) will appoint members to the NFRP Advisory Board that will be comprised of selected members of the NFRP Programmatic Panel, representatives from the Program Office, and additional ad hoc representatives (as needed). The role of the Board will be to advise the NFRP regarding NFRP Clinical Trial Consortium progress and
activities. The Board will also be involved in the review of newly proposed and ongoing clinical trials throughout the award.

2. Proposed Clinical Trials

It is expected that the NFRP Clinical Trial Consortium will conduct **clinical trials** addressing the varied manifestations of NF. Two of these studies must be initiated during the first year of the award. Proposed studies should include a range of scope, size, and type that represents the overall goals of the Consortium and needs of the NF community. **Clinical trials that include an adult patient population are encouraged.**

Clinical trials will be submitted for scientific and programmatic review by the NFRP Advisory Board. These submissions will include the protocol and all associated forms, a Statement of Work with payment milestones, and a budget. Approval to proceed from the NFRP Advisory Board is necessary to implement a clinical trial.

**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 the electronic Biomedical Research Application Portal (eBRAP) at [https://ebrap.org/eBRAP/public/Program.htm](https://ebrap.org/eBRAP/public/Program.htm).

In addition to clinical trials funded through the FY21 NFRP Clinical Trial Consortium, the Consortium is encouraged to submit additional applications to the NFRP when additional funding opportunities are announced. Funding from additional sources including industry, the private sector, and other federal organizations is also encouraged.

3. Summary of Responsibilities

**Responsibilities of all Consortium Participants.** Procedures for the NFRP Clinical Trial Consortium, while proposed by the Operations Center staff, should be fully developed and agreed upon by all participants working collaboratively. The process will be codified in a Manual of Operations or Standard Operating Procedures (SOPs), which will be provided with the application.

**The Consortium Operations Center will:**

- Provide the Consortium Director, who will be the primary liaison with the USAMRDC Agreements Officer Technical Representative (AOTR) and Science Officer (SO).
• Ensure that the Consortium adheres to the planned timeline and milestones for overall study execution.

• Manage the Consortium organizational structure.

• Manage Consortium-developed procedures for prioritization and implementation of clinical studies proposed by or through Consortium members.

• Manage procedures to ensure that all sites maintain compliance with local Institutional Review Boards (IRBs) and the USAMRDC Human Research Protection Office (HRPO) for the proper conduct of clinical studies and the protection of human subjects.

• Provide a Consortium Clinical Research Manager who will oversee the efforts of the Research Coordinators at each of the Clinical Trial Sites. The Consortium Clinical Research Manager will be responsible for coordinating and facilitating clinical protocol approval, patient accrual, and study activities across all sites.

• Ensure that all investigators file an Investigational New Drug application with the U.S. Food and Drug Administration (FDA) and obtain authorization prior to conducting clinical research using biologics or drugs. Prior to conducting clinical research using a medical device, all investigators must obtain a risk determination from an accredited IRB. If the device is deemed a Significant Risk by the IRB, investigators must file an Investigational Device Exemption with the FDA and obtain authorization prior to conduction clinical research. All sponsors must maintain a Trial Master File in accordance with the International Council for Harmonization and manage procedures for ensuring compliance with FDA requirements for investigational agents, devices, and procedures.

• Manage a communications plan and a real-time communications system between the Operations Center and Clinical Trial Sites.

• Manage standardization and, when appropriate, centralized review of imaging, histopathology, neuropsychological, and other data through committees and scientific core facilities. Use of the Response Evaluation in Neurofibromatosis and Schwannomatosis (REiNS) criteria for response data is encouraged.

• Manage Consortium-developed quality assurance and quality control mechanisms for study monitoring, including but not limited to:

  ○ On-site monitoring program (to include safety);

  ○ Management plan for the handling, distribution, and banking of specimens and imaging products generated from Consortium studies;

  ○ Registration, tracking and reporting of participant accrual;
o Timely medical review, rapid reporting, and communication of adverse events, as well as establishment of a safety committee to provide timely analysis of adverse events; and

o Interim evaluation and consideration of measures of outcome.

- Manage Consortium-developed comprehensive data collection and data management systems that address the needs of all Clinical Trial Sites in terms of access to data, data security, and data integrity measures.
- Implement statistical execution plans/support for all Consortium clinical studies.
- Manage costs to support the Clinical Trial Sites, including provision of the personnel, equipment, and materials required to conduct approved clinical studies.
- Manage Consortium-developed intellectual and material property issues among organizations participating in the Consortium.
- Manage Consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Develop, organize, and submit quarterly written progress reports, annual reports, and a final written comprehensive report to the USAMRDC.
- Oversee site performance monitoring and evaluations.

**Clinical Trial Sites will:**

- Designate a lead site PI and develop a succession plan in case of departure of the site PI; the site PI must participate fully in the Consortium Steering Committee.
- Identify potential studies and develop proposals in accordance with the Consortium SOPs for consideration for funding by the NFRP during the performance period of the award.
- Collaborate with other Consortium Clinical Trial Sites.
- In accordance with Consortium-developed guidelines, maintain a minimum combined accrual across all Consortium-associated studies, as well as a maximum contributed percentage for each individual study in accordance with Consortium-developed guidelines.
- Provide a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Trial Sites and the Consortium Clinical Research Manager at the Operations Center to expedite and guide clinical protocols through regulatory approval processes, as well as coordinate patient accrual and study activities across sites.
- Implement the Consortium’s core data collection methodology and strategies.
• Comply with Consortium-developed quality assurance and quality control procedures, as appropriate, including:
  ○ Participation in an on-site monitoring program to be managed by the Operations Center;
  ○ Implementation of the Consortium-developed management plan for acquisition and aggregation of protocol-specified specimens, biological fluids, and relevant clinical data to the appropriate laboratories for testing or storage necessary for the conduct and analyses; and
  ○ Submission of appropriate data and materials to allow for verification and review of protocol-related procedures (e.g., pathology, imaging techniques, surgical methods, and therapeutic use).

• Implement procedures established by the Operations Center for ensuring compliance with FDA requirements for investigational agents, as appropriate.

• Implement procedures established by the Operations Center to meet local IRB and USAMRDC HRPO requirements for the conduct of clinical trials and the protection of human subjects.

• Serve as a resource or core for the conduct of protocol-specified laboratory projects (including correlative studies), as appropriate.

• Participate in Consortium-developed procedures for the timely publication of major findings.

• Participate in Consortium-developed procedures for resolving intellectual and material property issues among organizations participating in the Consortium.

• Participate in preparation of written and oral annual briefings to the NFRP Advisory Board and USAMRDC staff at 1-day meetings to be held in the National Capital Region.

• Assist with the preparation of quarterly written progress reports, annual reports, and a final comprehensive report.

• Prepare for a site visit audit if requested by the NFRP.

4. Performance Metrics

Applicants must provide a plan for the number and types of clinical trials the NFRP Clinical Trial Consortium expects to execute. Within the first year of the performance period, at least one NF1 and one NF2 or schwannomatosis-focused study must be initiated. A timeline outlining the overall plan for study initiation, performance, and analyses will be developed, with clear milestones to which the Consortium will be held accountable. The government reserves the right to suspend and/or terminate the award if the recipient fails to meet this requirement. The Consortium Steering Committee will determine appropriate overall
minimum and maximum accrual metrics for the Clinical Trial Sites per trial as part of the Consortium SOPs. Each Clinical Trial Site is expected to have the ability to enroll adequate numbers of evaluable individuals with NF1, NF2, or schwannomatosis per year into Consortium-sponsored studies, OR to provide such unique expertise or facilities to otherwise justify inclusion as a site. For individual clinical trials, the Operations Center should ensure the maintenance of an overall patient accrual per year that is appropriate for the target population. The Consortium SOPs should also contain a plan to address underperforming sites, as well as a succession plan for any unforeseen change in the Consortium Director. The Operations Center will be required to submit quarterly and annual written reports that outline accrual and retention statistics, any problems with study execution, and actions to disseminate study results.

5. Oversight of the Consortium

The NFRP Advisory Board, which is comprised of government and non-government personnel, will be appointed by the USAMRDC. The NFRP Advisory Board will make recommendations to the NFRP regarding progress and proposed NFRP Clinical Trial Consortium studies prior to implementation, and it may recommend future trials to the Consortium. The Consortium must present written and oral briefings to the NFRP Advisory Board and USAMRDC. Based on these reports and presentations, the Board will advise the AOTR. USAMRDC staff will evaluate progress, provide feedback, and recommend modifications as needed to facilitate the success of the Consortium. The Consortium Steering Committee, through the Consortium Director, will be expected to maintain monthly, or more frequent, contact with a government appointed AOTR/SO. The USAMRAA Agreements Officer will issue final approvals to release funds for initiation of any proposed clinical trial via the Project Approval Letter.

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 Research Protections (ORP), HRPO, prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DOD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. The HRPO reviews and approves the participation of each site in the clinical trial. Refer to Appendix 3 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.

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 4, Section H.
C. Eligibility Information

- The Consortium Director at the Operations 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.

- 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.

- Eligible investigators must apply through an organization. Organizations eligible to apply include federal agencies, national, international, for-profit, nonprofit, public, and private organizations.

- An intramural investigator is defined as a DOD military or civilian employee working within a DOD laboratory or medical treatment facility or working in a DOD activity embedded within a civilian medical center. Submissions from intramural (DOD) organizations are allowed and encouraged for this research announcement. 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.**

D. Funding

A single award will be made to the NFRP Clinical Trial Consortium. The Operations Center, as the Consortium Manager, will provide funding support for the selected Clinical Trial Sites.

- The maximum period of performance for this initial award is 10 years. The USAMRDC may consider extending this period of performance 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 $25M, of which $5M is currently available, contingent upon the availability of federal funds for this program. Funding for any trials proposed after the FY21 funding cycle is contingent upon receipt of future congressional appropriations.
• Indirect costs are to be budgeted in accordance with the organization’s most recently federally negotiated rate. No budget will be approved by the government using an indirect rate exceeding the organization’s negotiated rate.

• The PI may request up to $25M in total costs (direct + indirect costs) for the full proposed period of performance (up to 10 years) to cover Operations Center costs and Consortium activities outside of costs directly associated with a clinical trial. This will be partially funded using allocations from the FY21 NFRP congressional appropriation. A budget for the Operations Center should be submitted using the SF424 Research & Related (R&R) Budget Form. Separate estimated budgets for each projected clinical trial should be described in the Budget Justification section.

• For individual clinical trials, funding will be based upon negotiated milestones and deliverables as identified in the Project Approval Letter.

• All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

• 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:

• Travel costs for the Consortium Director and site PIs to disseminate project results at one annual 1-day briefing with the NFRP Advisory Board and USAMRDC staff. For planning purposes, it should be assumed that the meeting will be held in the National Capital Region.

May be requested for (not all-inclusive):

• Salary support

• Implementation of Consortium-developed standardization plan, data management program, real-time communications system, and administration plans for the Consortium

• Support of Consortium-related meetings, teleconferences, and travel among participating investigators

• Costs associated with the external scientific peer review of clinical studies/research

• Purchase of computers, specialized software, and specialized software licenses for clinical study sites when required to fulfill Operations Center-specific tasks

• Purchase of minor equipment necessary for specimen collection and data storage and transfer
- Costs associated with using Consortium Core facilities
- Costs associated with conducting the IRB review of the clinical protocols and informed consent/assent forms
- Research-related subject costs
- Clinical research costs
- Costs associated with the supply or availability of intervention(s)
- Other costs directly associated with planning and developing the Consortium

May not be requested for:

- Travel costs for investigator(s) to travel to scientific/technical meeting(s) in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project outcomes from the FY21 NFRP Clinical Trial Consortium Award.

Awards to intramural (DOD) agencies and other federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or FS 7600A. Direct transfer of funds from the recipient to a DOD agency is not allowed except under very limited circumstances. Refer to Appendix 1, General Application Instructions, Section VIII, for budget regulations and instructions for the SF424 R&R Budget Form. *For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section VIII of Appendix 1.*

The CDMRP expects to allot approximately $5M from the FY21 budget and the remaining funds from future years’ appropriations to fund approximately 1 NFRP Clinical Trial Consortium Award application, depending on the quality and number of applications received. Funding of applications received in response to this research announcement is contingent upon the availability of Federal funds for this program.

**D.1 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 vs. 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 majority of the 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 subrecipients, unrecovered indirect costs, services or property that are submitted by the applicant or any subrecipients, 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 (1) pre-application submission through eBRAP (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). Refer to Appendix 1, for registration and submission requirements for eBRAP and Grants.gov. All proprietary information must be marked as such in the proposal package.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 1 of for further information regarding Grants.gov requirements.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of
an organization’s representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific 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 as well as ensure proper ordering as specified in this research announcement.

*The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit 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.*

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.

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

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-21-NFRP-CTCA in Grants.gov ([https://www.grants.gov/](https://www.grants.gov)).

**B. Pre-Application Submission Content**

*The pre-application process should be started early to avoid missing deadlines. There are no grace periods.* During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

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

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

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” 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.
  
  - FY21 Programmatic Panel members closely associated with clinical trial sites included in submitted proposals may not be involved in preparation of the application. Inclusion of Programmatic Review Panel members must clearly be identified, including their role in the NFRP Clinical Trial Consortium and a conflict of interest (COI) mitigation strategy. For questions related to Programmatic Panel member inclusion in the application, contact the AOTR.
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 FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the government.

**Tab 4 – Conflicts of Interest**
- List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

**Tab 5 – Pre-Application Files**
- **White Paper (four-page limit):** For the purposes of this research announcement, a white paper is considered the pre-proposal. Provide a description of the consortia structure. Describe the experience of the consortium or planned consortium members, including clinical trials conducted, collaborations and partnerships developed, sites, and expertise at each location. Provide references to demonstrate productivity and outcomes from clinical trials conducted and enrollment data. The white paper will be evaluated to determine whether it meets the intent of the research announcement, specifically clinical trials directed at NF manifestations. 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.

**Pre-Application Screening**

**Pre-Application Screening Criteria**
To determine the technical merits of the pre-application and the relevance to the mission of the NFRP, white papers will be screened based on the following criteria:
- The offeror has demonstrated experience of the consortium or planned consortium members. The offeror has demonstrated productivity and outcomes from clinical trials conducted and enrollment data.
- White paper indicates clinical trials directed at NF manifestations will be conducted with the funds from the award.
Notification of Pre-Application Screening Results

Following the white paper screening, PIs will be notified as to whether or not they are invited to submit a full-applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their white paper. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this research announcement. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Application Submission Content

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

Applications will not be accepted unless the PI has received notification of invitation.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See 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):

1. SF424 R&R Budget Form Application for Federal Assistance Form: Refer to Appendix 1 for detailed information.

2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 6. For all attachments,
ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (80-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the key features of the NFRP Clinical Trial Consortium in detail using the outline below.

- **Overall Structure and Goals:**
  - Identify major gaps in the field that the Consortium seeks to address.
  - Describe the broad research goals of the Consortium and how the Consortium structure is suited to meet its goals.
  - Identify all proposed sites, ad hoc sites, and future potential sites. Include descriptions of any committees and/or working groups. Reference and include Consortium SOPs/Manual of Operations and by-laws in Attachment 8.
  - Describe the overall structure of the Consortium. Describe the overall management structure; the method of making payments to consortium members; the means of ensuring and overseeing member’s efforts on research projects; provisions for a member’s resource-sharing contributions; and provisions for ownership and rights in intellectual property developed previously or under the agreement. If the Consortium is not fully incorporated, provide the management plan in the consortium’s manual of operations (or, articles of collaboration) in Attachment 8.

- **Operations Center Expertise and Resources:**

Describe the following:

- Previous experience of the Operations Center, the Consortium Director/PI, and key personnel with the design, administration, and day-to-day management of multi-institutional clinical studies.
- A succession plan for the Consortium Director and lead PIs for the Clinical Trial Sites to account for any unforeseen change.
- Information technology infrastructure and resources necessary to coordinate and implement proposed trials, and a plan for making those resources available.

- Key core facilities and resources available to support Consortium-initiated clinical trials.

- Plans for addressing human subject protection requirements as described by HRPO, as well as coordinating IRB submissions and approvals at participating sites.

- Plans for oversight and coordination of Clinical Trial Sites. Include relevant personnel and organizational experience with implementing multi-institutional real-time communications.

- Plans for monitoring site performance, including strategies to deal with sites with low performance and missed patient recruitment goals.

○ Clinical Trial Site(s) Expertise and Resources

Describe the following:

- Current, ad hoc, and potential future Clinical Trial Site(s).

- Previous experience of key personnel at each site with the development and conduct of clinical studies, specifically any multi-institutional clinical trials that demonstrate past experience and willingness to participate in the Consortium.

- Any site-specific areas of clinical research interest or expertise, such as novel drugs, surgical interventions, and imaging techniques. Include a description of the multi-disciplinary capabilities of each site.

- Patient populations at each current and potential future Clinical Trial Site; and elaborate on the ability to enroll adequate patient numbers into Consortium-sponsored studies. Provide an estimate of case enrollment/patient load and the track record of research in this area for each Clinical Trial Site and each Site PI.

- Resources and expertise available within each Clinical Trial Site for the care of NF1 and/or NF2 patients.

- Resources and expertise of each participating Clinical Trial Site for data management and maintenance of data security/confidentiality.

- Previous experience and demonstrated success from conducting multi-institutional trials, including success in recruitment and accruals for past trials.
o Clinical Trial Development and Implementation:
  - Include a projection of the types of clinical trials to be conducted by the
    Consortium over the entire award period.
  - Include in tabular format a summary of potential trial concepts currently under
    consideration.
  - Outline a plan for the conceptualization, design, development, and prioritization
    of potential future Consortium trials for implementation. Include a mechanism
    for determining Clinical Trial Site participation.
  - Describe plans for coordinating the submission, review, and implementation of
    clinical trials within the Consortium. Include plans for appropriate
    approvals/clearances from the FDA, when applicable.
  - Describe any novel approaches to clinical trial design or novel concepts that will
    facilitate efficiency in conducting trials.
  - Describe the strategy for the inclusion of women and minorities appropriate to the
    objectives of the study, including a description of the composition of the proposed
    study population in terms of sex/gender, racial, and ethnic group, and an
    accompanying rationale for the selection of subjects.

o Study Management and Monitoring:
  - Describe plans for real-time communication among all organizations participating
    in the Consortium (including the rapid dissemination of adverse events). Include
    a named Consortium Clinical Research Manager who will interact with other
    individual Clinical Trial Site research coordinators to guide clinical protocols
    through the regulatory approval processes, coordinate participant accrual, and
    coordinate study activities across sites.
  - Outline procedures for quality assurance, quality control, safety, and study
    monitoring, including an independent safety oversight group to invoke stopping
    rules as necessary after defined adverse events.

o Specimen Handling and Distribution: Describe plans and methods for the
  handling, distribution, analysis, banking, and security of any specimens and/or
  imaging products generated from Consortium-sponsored studies.

o Fiscal Administration: Describe previous experience with the financial
  management of multi-institutional clinical research studies. Outline a strategy for
  achieving financial self-sufficiency of the Consortium after the end of the
  performance period for the NFRP Clinical Trial Consortium Award. Describe any
  plans to leverage existing clinical or translational funding programs and infrastructure
  for the proposed Consortium.
Conflict of Interest Management: Describe how the Consortium will avoid/mitigate conflicts of interest between institutions, study personnel and with any members of current or potentially future members of the NFRP Programmatic Panel.

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: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

- Intellectual Property
  - Should the applicant intend to use, in the performance of this program, pre-existing, legally protected, and perfected intangible property, and for which no federal funds had been used in the development of said property, the applicant must:
• Clearly identify all such property;

• Identify the cost to the federal government for use or license of such property, if applicable; or

• Provide a statement that no property meeting this definition will be used on this project.

  – Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

  – 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.

  – Inclusion Enrollment Report: Provide a plan for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

• Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.” The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. Do not include proprietary or confidential information. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  o Technical abstracts are used by all reviewers. Of particular importance, programmatic reviewers may not have access to the full application and therefore rely on the technical abstract for appropriate description of the proposed research project’s key aspects. Clarity and completeness within the space limits of the technical abstract are highly important.

The technical abstract should be structured as follows:

  – Background: Describe the general management and organizational structure of the NFRP Clinical Trial Consortium. Outline the management and clinical expertise of Consortium personnel at the Operations Center and Clinical Trial Sites.

  – Objectives: Describe the Consortium’s overall clinical research goals and agenda.

  – Research Plan: Briefly describe the clinical studies the Consortium plans to pursue during the performance period.
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.

Consumer reviewers refer to the lay abstract and other components of the application package.

The lay abstract should be composed using the outline below:

- Clearly describe, in a manner readily understood by lay persons, the clinical objectives and rationale for the application.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the Consortium’s clinical research.
  - 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 of this Consortium to advancing the field of NF research or the impacts on NF patient treatment, quality of life, or patient care?

Attachment 5: Statement of Work (10-page limit): Upload as “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. The suggested SOW format is provided at https://ebrap.org/eBRAP/public/Program.htm. 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 Operation Center and within individual clinical trials. 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) a statistical plan that includes methods to monitor the quality and consistency of data collection, as well as outcomes; (3) a plan for real-time data transfer; and (4) data security measures.
Provide a copy of a Manual of Operations or SOPs by which the Consortium will operate. Also include documents that describe governance and guidelines by which the Consortium membership operates, including, but not limited to, the agreements of collaboration (or other partnership documents) between institutions.

• Attachment 9: Data and Research Resources Sharing Plan: Upload as “DataSharing.pdf.” Describe how data and resources (i.e., tissues, samples, methods) generated during the performance period of the project may be shared with the research community (if applicable). The Consortium represents significant investment from the NFRP, and it is encouraged that the Consortium consider ways to work with the NF research community through collaborations. Refer to Appendix 4, Section H, for more information about the CDMRP’s expectations for making data and research resources publicly available.

• Attachment 10: Collaborating DOD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.” If a military facility (MHS facility, research laboratory, treatment facility, dental treatment facility, or DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DOD Military Facility Budget Form, which is 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 Appendix 1 for detailed information.

• Attachment 11: Representations (extramural submissions only): Upload as “RequiredReps.pdf”. All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 6, Section B, Representations.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to Appendix 1 for detailed information.

• PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

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

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

• Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

4. 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 SF424 R&R Budget Form. 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. Give an estimate of how many trials the Consortium will plan to perform.

• 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. Recipients 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 recipients performing research outside of the United States will be determined at the time of application submission.
5. **Project/Performance Site Location(s) Form**: Refer to the Appendix 1 for detailed information.

**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 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.

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

**D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific 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.

**E. 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.

**F. Other Submission Requirements**

Refer to Appendix 5 for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to Appendix 1 for information on Grants.gov registration requirements.
III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRDC, based on technical merit, the relevance to the mission of the DOD and NFRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the research announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. 

The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section III.B.2., Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.army.mil/about/fundingprocess.shtml.

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

B. Application Review Process

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

   a. **Consortium Structure and Goals**

      - The degree of impact the overall goals of the Consortium are likely to have on the clinical evaluation of promising therapeutic agents for the management or treatment of NF1, NF2, and schwannomatosis.

      - How appropriate the proposed overall organizational structure of the Consortium is to rapidly developing and implementing clinical trials for NF1, NF2, and schwannomatosis.

      - How effectively the Operations Center addresses a plan to oversee and coordinate all Consortium Clinical Trial Sites.
○ How effectively the Operations Center and each Clinical Trial Site will function as an integrated unit.

○ To what degree the appropriate resources are provided for full participation at each Consortium Site.

○ How effectively the Consortium has established methods of making payments to consortium members, the means of ensuring the and overseeing member’s efforts on research projects, provisions for member’s resource sharing contributions, and provisions for ownership and rights in intellectual property developed previously or under the agreement.

• Operations Center Expertise and Resources

○ To what extent the Operations Center’s experience, track record, and expertise are appropriate with respect to the ability to manage and oversee multi-institutional NF clinical studies.

○ How effectively the plan for the establishment and maintenance of core facilities and other resources will support Consortium activities.

○ How appropriate are the ability and experience of the organization with the financial management of multi-institutional research studies?

• Clinical Trial Sites Expertise and Resources

○ How appropriate the research teams’ background, track record, and expertise are at each Clinical Trial Site with respect to the successful conduct of NF studies and participation in multi-center clinical studies.

○ Whether the organizations have demonstrated access to appropriate patient populations for conduct of Consortium clinical studies.

• Clinical Trial Development and Implementation

○ The degree to which plans for conceptualization, design, development, and prioritization of clinical trials within the performance period are appropriate.

○ How well the planned trials address critical needs of the NF patients.

○ How well the Consortium has outlined a plan for the inclusion of women and minorities the proposed studies.

• Study Management and Monitoring

○ How appropriate the plans are for real-time communication among all organizations participating in the Consortium, including complete and timely reporting, review, and appropriate responses to adverse events (including
suspension of a trial, modification of a trial protocol, or cessation of a trial) in facilitating Consortium activities.

- The extent of the named Consortium Clinical Research Manager’s experience with guiding clinical protocols through the regulatory approval processes, coordinating participant accrual, and coordinating study activities across sites.

- How adequate the outlined procedures are for quality assurance, quality control, safety, and study monitoring with regard to conducting multi-institutional clinical studies.

- How appropriate the plans are for specimen handling, distribution, analysis, banking, and security with regard to facilitating Consortium activities.

- **Data Management**
  - The degree to which the overall approach to data collection, management, analysis, and security measures is appropriate.
  - How clearly the PI and key personnel have demonstrated effective application of methods to monitor quality and consistency of data collection, and methods to measure outcomes in previously conducted clinical trials.
  - How adequate the plan is for real-time data transfer with regard to supporting the Consortium-associated activities.

- **Personnel**
  - The extent to which the PI and other key personnel at the Operations Center have expertise in the design, administration, and financial management of multi-institutional NF clinical studies, including the distribution and management of funds.
  - The extent to which the Clinical Site PIs have expertise in the conduct of clinical trials.
  - The extent to which the levels of effort are appropriate for successful conduct of the proposed work.
  - The qualifications of the Consortium Clinical Research Manager, who will interact with all Clinical Trial Site Research Coordinators to coordinate regulatory approvals and Consortium activities.
  - The extent to which all participating personnel are willing to commit adequate time, resources, and human subjects to the Consortium.

- **Cost/Resource Sharing Plan**
o 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 though consideration of the factors provided in Section D.1, Resource Share, of this document.

o The extent to which the applicant has demonstrated access to the resources proposed as part of their resource share

o The extent to which the applicant has provided a suitable resource share tracking process.

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

- **Budget**
  o Whether the budget is appropriate for the proposed research and within the limitations of this research announcement.

- **Data and Resource Sharing**
  o How well-detailed 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 details of the plan to access 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.
    - The appropriateness of the milestones with respect to making the data or research resource(s) available.

- **Application Presentation**
  o To what extent the writing, clarity, and presentation of the application components influenced the review.

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

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the FY21 NFRP, as evidenced by the following:**
      o Adherence to the intent of the award mechanism
C. Recipient Qualification

For general information on required qualifications for award recipients, refer to Appendix 4.

D. Application Review Dates

All application review dates and times are indicated on the title page of this research announcement.

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- White paper exceeds page limit.
- White paper 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.

B. Modification

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

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

- An FY21 NFRP Programmatic Panel member 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 FY21 NFRP Programmatic Panel members can be found at [https://cdmrp.army.mil/nfrp/panels/panels21](https://cdmrp.army.mil/nfrp/panels/panels21).** If a Current Programmatic Panel member is identified as a potential collaborator/key personnel in the performance of Consortium activities, a COI mitigation plan must be included.

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

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website ([https://cdmrp.army.mil/about/2tierRevProcess.shtml](https://cdmrp.army.mil/about/2tierRevProcess.shtml)). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government.

- Total costs as shown on the Research and Related Budget form exceed the maximum allowed by this research announcement.

**D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

**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

A. Award Notice

Awards will be made no later than September 30, 2022.

B. Post Award Administrative Requirements

Intellectual property. Under OTs, the allocation of IP rights under the Bayh-Dole Act (35 USC Sections 201-204) for patents, and 10 USC Sections 2320–2321 for technical data do not apply. The government’s initial negotiations position for intellectual property are outlined in the draft agreement.

C. Pre-Award Meeting

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

VI. VERSION CODES AND AGENCY CONTACTS

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: Jason Kuhns (jason.d.kuhns.civ@mail.mil)

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

C. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the 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
<table>
<thead>
<tr>
<th>Grants.gov Application Components</th>
<th>Upload Order</th>
<th>Action</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R) Budget Form Application for Federal Assistance</td>
<td></td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
<tr>
<td>Attachments Form</td>
<td></td>
<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf.”</td>
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<tr>
<td></td>
<td></td>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
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<td></td>
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<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf.”</td>
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<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf.”</td>
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<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf.”</td>
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<td></td>
<td></td>
<td>Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name “DataSharing.pdf.”</td>
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<td>Collaborating DOD Military Facility Budget Form(s): Upload as Attachment 10 with file name “MFBudget.pdf,” if applicable.</td>
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<td></td>
<td>Representations (extramural submissions only): Upload as Attachment 11 with file name “RequiredReps.pdf” if applicable</td>
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</tr>
<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>Attach PI Biographical Sketch (“Biosketch_LastName.pdf”) to the appropriate field.</td>
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<td>Attach PI Previous/Current/Pending Support (“Support_LastName.pdf”) to the appropriate field.</td>
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<td></td>
<td>Attach Biographical Sketch (“Biosketch_LastName.pdf”) for each senior/key person to the appropriate field.</td>
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<td></td>
<td>Attach Previous/Current/Pending (“Support_LastName.pdf”) for each senior/key person to the appropriate field.</td>
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<tr>
<td>Research &amp; Related Budget</td>
<td>Complete as instructed. Attach Budget Justification (“BudgetJustification.pdf”) to the appropriate field.</td>
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<tr>
<td>Project/Performance Site Location(s) Form</td>
<td>Complete form as instructed.</td>
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</tbody>
</table>
VIII. RESOURCES

Department of Defense Other Transactions Guide

These sites provide additional information on OTs:

- Defense Acquisition University Contracting Community of Practice: [https://www.dau.mil/cop/contracting/Pages/Default.aspx](https://www.dau.mil/cop/contracting/Pages/Default.aspx)
- U.S. Army: [https://tardec.army.mil/](https://tardec.army.mil/)

These sites, hosted by the Defense Pricing and Contracting office of the Assistant Secretary of Defense for Acquisition, provide additional resources on OTs:

- See the “Specific Policy Areas” site for a list of recent policies: [https://www.acq.osd.mil/dpap/cpic/cp/specific_policy_areas.html](https://www.acq.osd.mil/dpap/cpic/cp/specific_policy_areas.html)
APPENDIX 1
GENERAL APPLICATION INSTRUCTIONS

I. HELPFUL INFORMATION

A. Research Announcement Applicant Organizations

Applications may be submitted by extramural organizations and intramural Department of Defense (DOD) 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.

B. 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/](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, Administrative Actions). 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 III.A.5, Research & Related Budget and Section III.A.7, Suggested DOD Collaborating Military Facility Budget Format.

II. eBRAP REGISTRATION AND PRE-APPLICATION SUBMISSION


A. Registration Requirements (All Applicants) eBRAP Registration

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission. A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific 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.

*eBRAP does not confirm the accuracy of file content.*

**PIs must be registered in eBRAP to submit a pre-application.**

**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 with an Open Researcher and Contributor ID (ORCID) identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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, then 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, before the full application submission deadline, the organization’s eBRAP registration must be complete to allow for processing, viewing, and modifying of the full application package components.

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.

A. 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. Follow the instructions in the research announcement for each Tab.

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 are no grace periods.**

### 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 Section 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://www.grants.gov/web/grants/applicants/organization-registration.html](https://www.grants.gov/web/grants/applicants/organization-registration.html).

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

1. **DUNS Number**

The applicant organization and all subrecipient/subawardee organizations must have or obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique identification number provided by the commercial company Dun & Bradstreet. If an organization does not have a DUNS number, an authorized business official of the organization can request one by calling 866-705-5711 or by registering online ([https://fedgov.dnb.com/webform](https://fedgov.dnb.com/webform)). Organizations located outside of the United States can request and register for a DUNS number online via web registration ([https://fedgov.dnb.com/webform](https://fedgov.dnb.com/webform)). Web registration can take 1-2 business days.

**Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):**

instead of the DUNS number as of December 2020. All federal awards including but not limited to contracts, grants, and cooperative agreements will use the UEI, and the DUNS will be phased out as the identifier within SAM. During the transition phase (July 2019 – December 2020), the DUNS number remains the official identifier. Organizations should continue to register in SAM using the DUNS number assigned by Dun & Bradstreet. As of December 2020, the SAM-generated UEI will be the official identifier for applicants. 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.)

2. SAM Registry

The applicant organization must be registered as an entity in SAM (https://www.sam.gov) and receive confirmation of an “Active” status before submitting an application through Grants.gov. 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. 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./

Applications will be rejected by Grants.gov (1) if the organization’s entity registration in SAM is not active or (2) if 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?”

3. 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/Request). On average, CAGE code or NCAGE code validation in SAM occurs within 3 business days after the TIN is validated.

4. 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/OrcRegister).

An AOR must first register with the Grants.gov credential provider at https://apply07.grants.gov/apply/OrcRegister 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, is crucial for valid and timely submissions.

5. 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.
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://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html](https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html). A no-cost compatible version of Adobe Reader can be downloaded at [http://get.adobe.com/reader/otherversions/](http://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.*

*Math 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 III.C, 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.

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

- **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.

- **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.

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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.

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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 III.C, 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 4. 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.

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.

Follow the directions in the research announcement for the required attachments.

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).

IV. Figure 2. PI’s eBRAP User Name
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 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
5. Research & Related Budget

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

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

\textbf{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.}

\textbf{For Federal Agencies:} An application from a federal agency must include in the budget justification a \textbf{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.

\textbf{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 \textbf{Section 7, 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.

\textbf{Section A: Senior/Key Person}

- \textbf{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 recipient’s or the subrecipient’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 recipient with recipient 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 for travel associated with the execution of the proposed work: 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 Agreements Office.

- 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:** Supplies means all tangible personal 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 by the PI.

- 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. These costs can be presented in table format instead of individual budget forms.

  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 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 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.

- 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.

Provide documentation to support the indirect cost rate (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document) via eBRAP ([https://eBRAP.org](https://eBRAP.org)).


**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
7. **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(s) 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 recipient.

**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 recipient 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 are 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, the Comptroller’s (or equivalent) ability to accept and process award funds appropriately, etc.

Prior to the issuance of any award utilizing the funding method described above, written approval from the U.S. Army Medical Research Acquisition Activity’s (USAMRAA’s) Senior Contracting Officer (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 Contracting Officer’s Representative/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 recipient before work between the organization 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. 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. See the first page of the research announcement (Section I, Overview of the Funding Opportunity) 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.

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 Research & Related Budget fails eBRAP validation or if the Project Narrative or the Research & Related Budget need to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the
application submission deadline. 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://www.grants.gov/web/grants/applicants/track-my-application.html) and entering the Tracking Number.

V. 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 AOR.
- **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to Appendix 4 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 Form:** 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 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](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 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 in the bottom 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 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.

• **Total Costs**: This section is calculated automatically from the data provided.

*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 FY20 funding will be obligated by **September 30, 2021**. 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 FY20 funding not obligated by September 30, 2021 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

All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review.

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

The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DOD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DOD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DOD-funded award will require HRPO review of the entire protocol (DOD and non-DOD funded). DOD human subjects protection requirements may be applied to non-DOD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in Attachment 5: Statement of Work. Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones.

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 ORP to ensure that DOD regulations are met. All expectations described below are consistent with the DOD Instruction (DoDI) 3216.01, “Use of Animals in DOD Programs,” as issued September 13, 2010, available at https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations and DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research,” as issued on November 8, 2011, and available at https://www.dtic.mil/whs/directives/corr/pdf/321602p.pdf.
1. 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 will not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training (https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections). The USAMRDC ORP is the Action Office (usarmy.detrick.medcom-usamrdc.other.hrpo@mail.mil) for this Army policy. HRPO must review the use of cadavers, including postmortem specimens, for compliance with the Army Cadaver Use Policy. Additional requirements apply to activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.

Award recipients 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.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

Written approvals to begin the activity will be issued under separate notification to the recipient.

Questions regarding submission of human cadaver research for USAMRDC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrdc.other.hrpo@mail.mil.

2. 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 ORP HRPO at USAMRDC.

All USAMRDC-supported research involving the secondary use of human data, records, human tissue, or human specimens (hereafter referred to as data/specimens) must be reviewed for compliance with federal and DOD human subjects protection requirements and approved by the ORP prior to implementation. USAMRDC ORP HRPO review includes assessing the source of the data/specimens and whether the initial manner and consent for the data/specimen collection permits use in the DOD-funded research protocol. HRPO review, approvals, and determinations for specimen research are based upon the nature of the research, the source of the data/specimens, use and/or disclosure of identifiable health information, privacy and confidentiality protections, and whether the individual providing the data/specimens allowed the use of their data/specimens for research.
NOTE: The protocol submitted for HRPO review should 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, HRPO 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) requires at §.114(b) 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. The DOD is a Common Rule department; thus the provisions apply to DOD-funded research. Applicants must provide a written plan for single IRB review arrangements at the time of proposal submission or award negotiation.

For additional guidance and instructions on HRPO review of any DOD-funded research activities involving access, use, and analysis of data/specimens, investigators should submit the HRPO Submission Form for Secondary research found on the ORP HRPO website. 

3. Research Involving Human Subjects

In addition to local IRB review, investigators must submit all USAMRDC-funded research protocols involving human subjects for review and approval by the USAMRDC ORP HRPO prior to implementation of the research. The focus of this review is to validate the IRB review as appropriate and ensure that DOD, Army, and USAMRDC regulatory requirements have been met.

Questions regarding applicable human subjects protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrdc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrdc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).

ORP HRPO-required language must be inserted into the consent form, and compliance with DOD regulations may require that additional information be included in the protocol.

The ORP HRPO ensures that DOD-supported and/or -conducted research complies with specific DOD laws and requirements governing research involving human subjects. These laws and requirements may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read “Information for Investigators” at https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo. The time to approval depends greatly on adherence to the requirements described within. If the protocol
has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. **Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.** Research projects involving information collection activities as defined in DoDI 8910.01, “Information Collection and Reporting,” require coordination and PI submission to additional DOD agencies.

Specific requirements for HRPO submission and review of research involving human subjects can be found at [https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo](https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo).

1. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federal-Wide Assurance or DOD Assurance.

2. **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 may be required during the regulatory review process.

3. **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.
   - In the event that 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.

4. **Intent to Benefit:** The requirements of 10 USC 980, which are applicable to DOD-sponsored research, must be considered. 10 USC 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative for the subject.”

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an experimental subject in a DOD-supported study unless the research is intended to benefit each subject enrolled in the study, including subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of experimental subject as defined in DoDI 3216.02 is a much narrower definition.
of human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact HRPO at usarmy.detrick.medcom-USAMRDC.other.hrpo@mail.mil if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.

Research Monitor Requirement: For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol. The IRB must approve a written summary of the monitor’s duties, authorities, and responsibilities.

The research monitor’s duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI’s institution. Research monitor functions may include:

- Observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- Overseeing study interventions and interactions;
- Reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- Overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- Will have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report; and
- Will have the responsibility for promptly reporting his or her observations and findings to the IRB or other designated official and the HRPO.
A curriculum vitae or biographical sketch and documentation of human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects’ Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI’s institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

(5) Military Personnel Volunteers: The following is important information for research projects proposing to include military personnel as volunteers.

- **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with Service-specific requirements.

  A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

  Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order Service members to participate in a research study.

  For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted Service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized.

- **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off-duty or on-leave during the time they are participating in the protocol.

- **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the
Uniform Code of Military Justice, including incarceration and dishonorable discharge.

(6) **Site Visits:** The USAMRDC ORP HRPO 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.

*Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues are posted at [https://mrdrdc.amedda.army.mil/index.cfm?pageid=research_protections.hrpo](https://mrdrdc.amedda.army.mil/index.cfm?pageid=research_protections.hrpo).*

(7) **Protocol Submission Format:** The ORP HRPO 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. A HRPO Protocol Submission Form should be completed and submitted with each protocol.

(8) **Research involving the use of FDA-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.

**A. 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 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).

B. 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-PC20####). 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-PC20#####-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 will 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.

C. Research Involving Recombinant DNA Molecules

The recipient assures that all work involving the use of recombinant DNA will be in compliance with guidance provided at https://osp.od.nih.gov/biotechnology/nih-guidelines/.
APPENDIX 3
ADMINISTRATIVE INFORMATION

A. Disclosure of Proprietary Information

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

B. Marking of Proprietary Information

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

C. 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.

D. Freedom of Information Act Requests

Certain types of information submitted to the DOD in a process having the potential for award of an OT are exempt from disclosure requirements of 5 USC §552 [the Freedom of Information Act (FOIA)] for a period of five years from the date the Department receives the information. Specifically, 10 USC §2371(i), as amended, provides that disclosure of this type of information is not required, and may not be compelled, under FOIA during that period if a party submits the information in a competitive or noncompetitive process having the potential for an award of an OT.

Offerors are required to mark business plans and technical information that are to be protected for five years from FOIA disclosure with a legend identifying the documents as being submitted on a confidential basis.

E. Information Release

A recipient 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 will identify the award number and include a statement acknowledging the federal sponsoring agency. The release will 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, through the (insert program name) under Award No. (W81XWH-20-1-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://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.acuro](https://mrdc.amedd.army.mil/index.cfm?pageid=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/](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/biosafety](https://www.cdc.gov/biosafety))

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

F. 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 will 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.

G. 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).

**H. 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 basic research, clinical studies, surveys, and other 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 assistance agreement:

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large surveys 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://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique))

- **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://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique))

- **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](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. PI will 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.

I. Inquiry Review

If an application is not recommended for funding, 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. A perceived factual error is an error in the review (peer or programmatic) that is restricted to, or based on, a fact. Inquiries in response to funding recommendations should be submitted to the USAMRAA Agreements Officer through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel 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. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA Agreements Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.
APPENDIX 4
QUALIFICATION AND RESTRICTIONS INFORMATION

A. Recipient Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients 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://home.army.mil/detrick/index.php/my-fort/all-services/legal-assistance-office) 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:** Uniform resource locators (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](mailto:support@grants.gov)) for written confirmation that the file will be accepted or for other guidance.*
APPENDIX 6
NATIONAL POLICY REQUIREMENTS

A. Certification

Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients 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

All extramural applicants are required to complete the representations below and submit with each application. 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 form, represents:
Representation Regarding the Prohibition on Using Funds Under Other Transaction 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 subrecipients 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 subrecipients 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.
## APPENDIX 7
### ACRONYM LIST

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACURO</td>
<td>Animal Care and Use Review Office</td>
</tr>
<tr>
<td>ADP</td>
<td>Automated Data Processing</td>
</tr>
<tr>
<td>AOR</td>
<td>Authorized Organizational Representative</td>
</tr>
<tr>
<td>AOTR</td>
<td>Agreements Officer Technical Representative</td>
</tr>
<tr>
<td>AVI</td>
<td>Audio Video Interleave</td>
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<tr>
<td>CAGE</td>
<td>Commercial and Government Entity</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CDMRP</td>
<td>Congressionally Directed Medical Research Programs</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
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<tr>
<td>CRADA</td>
<td>Cooperative Research and Development Agreement</td>
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<td>Department of Defense Instruction</td>
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<td>DTIC</td>
<td>Defense Technical Information Center</td>
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<td>DUNS</td>
<td>Data Universal Numbering System</td>
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<td>electronic Biomedical Research Application Portal</td>
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<td>Eastern time</td>
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<tr>
<td>F&amp;A</td>
<td>Facilities and Administrative</td>
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<td>Funding Authorization Document</td>
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<td>General Services Administration</td>
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<td>Description</td>
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<td>HIPAA</td>
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<td>Human Research Protection Office</td>
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<td>Institutional Animal Care and Use Committee</td>
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<td>IP</td>
<td>Intellectual Property</td>
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<tr>
<td>IR&amp;D</td>
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<td>Joint Photographic Experts Group</td>
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<td>Million</td>
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<td>PI</td>
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<tr>
<td>RDT&amp;E</td>
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<tr>
<td>REiNS</td>
<td>Response Evaluation in Neurofibromatosis and Schwannomatosis</td>
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<td>RM</td>
<td>Resource Manager</td>
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<td>System for Award Management</td>
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<td>Senior Contracting Officer</td>
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<td>SF</td>
<td>Standard Form</td>
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