# I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

**Defense Health Program** 

**Congressionally Directed Medical Research Programs** 

# **Neurofibromatosis Research Program**

# Neurofibromatosis Research Academy - Scholar Award

**Announcement Type: Modified** 

Funding Opportunity Number: HT9425-23-NFRP-NFRA-SA

Assistance Listing Number: 12.420 Military Medical Research and Development

#### SUBMISSION AND REVIEW DATES AND TIMES

• **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 21, 2023

• Application Submission Deadline: 11:59 p.m. ET, October 5, 2023

• End of Application Verification Period: 5:00 p.m. ET, October 12, 2023

• **Peer Review:** November 2023

• **Programmatic Review:** February 2024

This program announcement must be read in conjunction with the General Application Instructions, version 803. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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# II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

# **II.A. Program Description**

Applications to the Fiscal Year 2023 (FY23) 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 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). 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 FY22 totaled \$402.85 million (M). The FY23 appropriation is \$25M.

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

The vision of the NFRP is to decrease the clinical impact of neurofibromatosis. The mission of the NFRP is to promote research directed toward the understanding, diagnosis, and treatment of NF1, NF2, and Schwannomatosis to enhance the quality of life for persons with these disorders that impact Service Members, Veterans, and the general public.

#### II.A.2. FY23 NFRP Areas of Emphasis

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.

**Areas of Emphasis:** The FY23 NFRP strongly encourages research applications that specifically address the critical needs of the NF community in one or more of the Areas of Emphasis listed below. Applicants are encouraged to include materials and data from diverse populations in their research.

- NF2 and Schwannomatosis-related areas (e.g., hearing, balance, schwannoma, ependymoma, meningioma, LZTR1, SMARCB1)
- Endpoint validation, biomarker discovery, and technological innovation for assessments
- Application of data science

- Non-tumor manifestations not limited to:
  - o Pain
  - o Cognitive manifestations
  - o Sleep
- Heterogeneity of NF-related phenotypes
- Genetics, genomics, epigenetics, systems biology, metabolomics, or similar approaches
- Preclinical efficacy studies
- Target identification and drug discovery
- Nutritional, environmental, and other modifiers of NF
- Health services research

Note: Not all Areas of Emphasis are applicable to every award mechanism. If the proposed research project does not address at least one of the FY23 NFRP Areas of Emphasis, justification should be provided that it addresses an important problem related to NF research and/or patient care.

**Definition of Health Services Research:** Health services research studies the access, costs, and quality of health care for individuals, families, organizations, institutions, communities, and populations. It is a multidisciplinary field of scientific investigation, including basic and applied research, that examines how social factors, financing systems, organizational structures and functions, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately health, well-being, and quantity and quality of life.

The goals are to identify the most effective ways to organize, manage, finance, and deliver high-quality care, reduce medical errors, and improve patient safety. For more information, multiple resources are available, including "Health Services Research: Scope and Significance," from the National Institutes of Health (NIH) publication *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*, found online at https://www.ncbi.nlm.nih.gov/books/NBK2660/.

**NFRP Research Resources Initiative:** Resources developed through NFRP funding that are available to the scientific community can be found at <a href="https://cdmrp.health.mil/nfrp/resources/nfrpresources">https://cdmrp.health.mil/nfrp/resources/nfrpresources</a>. Investigators are urged to leverage and contribute to these resources and include a sharing and distribution plan in the application within the Data and Research Resources Sharing Plan (<a href="https://chment.10">Attachment.10</a>). For more guidance on data sharing, refer to the General Application Instructions, Appendix 2, Section K.

## **II.A.3.** Award History

The NFRP Neurofibromatosis Research Academy - Scholar Award mechanism is being offered for the first time in FY23.

#### **II.B.** Award Information

The NFRP Neurofibromatosis Research Academy (NFRA) will bring together established investigators (Director and Deputy Director) and early-career independent investigators (Scholars) to develop successful, highly productive neurofibromatosis researchers that will conduct research with the aim of lessening the clinical impact of NF1, NF2, and Schwannomatosis. The NFRA is a unique, multi-institutional interactive virtual research academy focused on supporting innovative high-impact research in a collaborative research and career development environment. The NFRA will provide a framework of intensive monitoring and iterative guidance with proposed research, national networking, collaborations, and a peer group for Scholars.

The NFRA is a platform (see Figure 1 below) that consists of Scholars and their Career Guides (mentors), and it is managed by an Academy Director and Deputy Director (i.e., the NFRA Leadership). The Neurofibromatosis Research Academy Scholar (the investigator named as the Principal Investigator [PI] on the application) is expected to participate in all development and training activities hosted by the NFRA Leadership, such as participation in monthly webinars and one-on-one mentoring sessions. Additionally, the Scholar and Career Guide (mentor) are expected to communicate and collaborate with other members of the NFRA (other Scholars and Career Guides, NFRA Leadership), and build relationships within the neurofibromatosis patient and advocacy community.

The NFRA Leadership serves as a resource for the Scholars and Career Guides, assessing the progress of Scholars, and facilitating communication and collaboration among all Scholars and Career Guides, as well as with national NF research and advocacy communities. In addition to fostering scientific development, the NFRA, through its Leadership, provides opportunities for professional and leadership development of the Scholars to include skills and competencies needed to fund and manage a productive laboratory. The NFRA leadership team will also provide opportunities to NFRP FY23 (and subsequent year awardees) Early Investigator Research Award and NFRP FY23 (and subsequent year awardees) New Investigator Award - Early-Stage Investigator researchers to engage with NFRP NFRA Scholars.

This FY23 funding opportunity is soliciting Scholars to join the NFRA. This award mechanism enables the Scholar to pursue a neurofibromatosis project that may be basic, translational, and/or clinical research, and addresses at least one of the FY23 NFRP Areas of Emphasis under the guidance of a Career Guide. The Career Guide is not required to be at the same institution as the Scholar; however, if the (primary) Career Guide is from a different institution, a secondary Career Guide at the Scholar's institution is needed.

In addition to activities described above, the Scholar, and their (primary) Career Guide, are required to attend a DOD NFRP biennial multi-day NFRA workshop. In alternate years, they must also attend a DOD NFRP NFRA 1-day workshop.

The NFRP encourages applications from Scholars whose ability to commit to conducting neurofibromatosis research is limited by minimal resources or a lack of resources, such as a qualified Career Guide at their institution, access to NF research tools, opportunities for establishing collaborations, or other obstacles. The NFRP also welcomes applications from existing researchers who are new to NF and encourages applications from underrepresented minorities and persons.

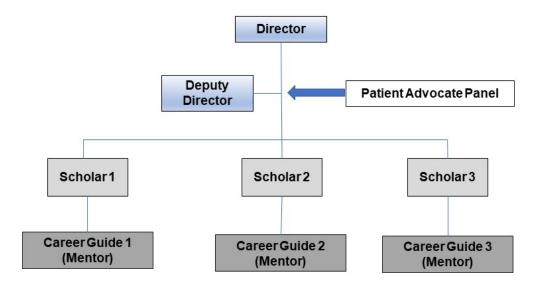


Figure 1: Structure of the FY23 NFRP Neurofibromatosis Research Academy: Director and Deputy Director will be the NFRA Leadership

The critical components of the Neurofibromatosis Research Academy - Scholar Award:

- Principal Investigator: The PI must be an early-career researcher or physician-scientist within 7 years of completion of their terminal degree by the time of the application deadline (excluding time spent in residency, clinical training, or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Postdoctoral fellows are not considered independent and are not eligible for this award mechanism. The PI's record of accomplishments and the proposed research will be evaluated regarding their potential for contributing to the FY23 NFRP Areas of Emphasis. The PI's organization must demonstrate a commitment to the PI through confirmation of laboratory space and at least a 50% level of time and effort to conduct NF research and Academy activities during the period of performance under this award.
- Career Guide: The Scholar must designate a Career Guide. The Career Guide must be an experienced neurofibromatosis researcher, as demonstrated by a strong record of funding and publications. In addition, the Career Guide must demonstrate a commitment to advancing the PI's career in neurofibromatosis research and be willing to commit at least 5% effort for mentoring and participating in NFRA activities such as offsite meetings and webinars. The Career Guide must also be committed to fully participating in the NFRA, to include interacting with other NFRA Scholars and Career Guides and potentially serving on the NFRA Advisory Board as requested by NFRA Leadership. Career Guides are not required to be at the same institution as the Scholar; however, if the Career Guide is from a

different institution, a secondary Career Guide at the scholar institution is needed. In addition to activities described above, the Scholar, with their Career Guide, is required to attend a DOD NFRP biennial multi-day NFRA workshop. In alternate years, they must also attend a DOD NFRP NFRA 1-day workshop.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (<a href="www.nature.com/nature/journal/v490/n7419/full/nature11556.html">www.nature.com/nature/journal/v490/n7419/full/nature11556.html</a>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit <a href="Attachment 11">Attachment 11</a>, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <a href="https://arriveguidelines.org/arrive-guidelines.">https://arriveguidelines.org/arrive-guidelines.</a>

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY23 NFRP NFRA-SA should not exceed \$750,000. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately \$3.6M to fund approximately three Neurofibromatosis Research Academy - Scholar Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made

from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is *not* required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of *all required and complete* documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page <a href="https://mrdc.health.mil/index.cfm/collaborate/research\_protections/hrpo">https://mrdc.health.mil/index.cfm/collaborate/research\_protections/hrpo</a> for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research *must* rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical trials are not allowed under this funding opportunity. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical

research are in vitro studies that utilize human tissues that cannot be linked to a living individual. *Note:* Studies that meet the requirements for exemption under §46.104(d)(4) of the Common Rule are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

Research Involving Animals: All research funded by the FY23 NFRP Neurofibromatosis Research Academy – Scholar Award involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. *Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Application Instructions, Appendix 1, for additional information.

# **II.C.** Eligibility Information

## **II.C.1.** Eligible Applicants

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

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

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

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

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

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

## **II.C.1.b.** Principal Investigator

#### Scholar

To be named as the PI on the application, the Scholar:

- o Must be within 7 years of terminal degree as of the full application submission deadline.
  - A Statement of Eligibility (<u>Attachment 9</u>) is required with the submission of the full application.
  - Time spent as a medical resident, clinical training, or on family medical leave is excluded.
  - Time spent as a postdoctoral research fellow is not excluded.
- May be in a non-tenure track or tenure track position.
- o Must not have a career development award similar to the NFRA-SA concurrently.
- NFRA Scholars, are required to attend a DOD NFRP biennial multi-day NFRA workshop. In alternate years, they must also attend a DOD NFRP NFRA 1-day workshop.
- Must have an institutional commitment of laboratory space and at least a 50% level of time and effort to conduct NF research and Academy activities during the period of performance under this award.

#### Career Guide

To be named as the Career Guide on the application, the Career Guide:

- Must be an independent, established neurofibromatosis researcher at the level of Associate Professor or equivalent.
- Must have neurofibromatosis research funding (past and present).
- o Must have a record of neurofibromatosis publications in peer-reviewed journals.
- Must demonstrate a commitment to develop and sustain the Scholar's independent career in neurofibromatosis research.
- Must be committed to fully participating in the NFRA and potentially serving on the NFRA Advisory Board as requested by NFRA Leadership.
- Must demonstrate a commitment (at least 5% effort for mentoring and participating in NFRA activities such as offsite meetings and webinars) to develop and sustain the Scholar's independent career in NF research.

- An NFRA Career Guide can only commit to one NFRA Scholar during the entire period of performance for the award, with the ability to serve as a secondary Career Guide for another Scholar.
- A Career Guide does not have to be from the same institution as the Scholar; however, if the Career Guide is from a different institution, a secondary Career Guide at the scholar institution is needed.
- Career Guides are required to attend a DOD NFRP biennial multi-day NFRA workshop.
   In alternate years, they must also attend a DOD NFRP NFRA 1-day workshop."

Note: The PI and Career Guide are not required to be at the same organization. Neither the Director nor the Deputy Director of the NFRA can be listed as a Career Guide.

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

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

# **II.C.2.** Cost Sharing

Cost sharing/matching is not an eligibility requirement.

#### II.C.3. Other

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

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

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

# II.D. Application and Submission Information

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

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.

#### II.D.1. eBRAP and Grants.gov

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

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

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in <u>Section II.G</u>, <u>Federal Awarding Agency Contacts</u>.

#### Extramural Submission:

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

# Intramural DOD Submission:

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

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

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

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

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

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

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

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

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

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

The applicant organization and associated PIs identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at <a href="https://help.com/help@eBRAP.org">help@eBRAP.org</a> or 301-682-5507.

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

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

#### • Tab 1 – Application Information

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

#### • Tab 2 – Application Contacts

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

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

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

# Tab 3 – Collaborators and Key Personnel

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

<u>FY23 NFRP Programmatic Panel members</u> should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to <u>Section II.H.2.c</u>, <u>Withdrawal</u>, or contact the eBRAP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507.

#### Tab 4 – Conflicts of Interest

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

# • Tab 5 – Pre-Application Files

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is *not* required.

# • Tab 6 – Submit Pre-Application

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

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

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

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<a href="https://grants.gov/">https://grants.gov/</a>) for extramural organizations or through eBRAP (<a href="https://ebrap.org/">https://ebrap.org/</a>) for intramural organizations. See Table 1 below for more specific guidelines.

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view,

complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (<a href="https://www.grants.gov/web/grants/applicants/apply-for-grants.html">https://www.grants.gov/web/grants/applicants/apply-for-grants.html</a>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

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

**Table 1. Full Application Submission Guidelines** 

Extramural Submissions	Intramural DOD Submissions				
Application Package Location					
Download application package components for HT9425-23-NFRP-NFRA-SA from Grants.gov ( <a href="https://grants.gov">https://grants.gov</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for HT9425-23-NFRP-NFRA-SA from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).				
Full Application Pa	ckage Components				
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	Tab 1 – Summary: Provide a summary of the application information.  Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.				
Descriptions of each required file can be found under Full Application Submission Components:  • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:  • Attachments • Key Personnel • Budget • Performance Sites  Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.				

#### **Extramural Submissions**

#### **Intramural DOD Submissions**

#### **Application Package Submission**

# Create a Grants.gov Workspace.

Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.

#### Submit a Grants.gov Workspace Package.

An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.

Note: If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline. Do not password protect any files of the application package, including the Project Narrative.

Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).

Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. Do not password protect any files of the application package, including the Project Narrative.

## **Application Verification Period**

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

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

#### **Further Information**

Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is

Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Extramural Submissions	Intramural DOD Submissions
automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission.	
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	

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

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

Extramural Applications Only

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

Extramural and Intramural Applications

#### **Attachments:**

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

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

• Attachment 1: Project Narrative (10-page limit): Upload as 
"ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and nontext elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures,
drawings) used to describe the project. Inclusion of URLs (uniform resource locators)
that provide additional information to expand the Project Narrative and could confer an
unfair competitive advantage is prohibited and may result in administrative withdrawal of
the application.

Describe the proposed project in detail using the outline below.

 Background: Describe the proposed research and career development in detail using the outline below.

- Scholar's Research Career Goals (one-page limit recommended): Discuss the Scholar's record of accomplishments demonstrating the potential for becoming an independent investigator in NF research. Describe the Scholar's career goals and plans in NF research and how the proposed research and career development experience will promote an independent, sustainable career.
- Research Project and Feasibility (eight-page limit recommended): Concisely explain the project's specific aims to be funded by this application. Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for analysis.
   Address potential problem areas and present alternative methods and approaches.
- Describe how data will be collected, handled, and analyzed in a manner that is consistent with the study objectives.
- Describe the statistical plan including a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- If cell lines or animals are to be used, *justify why the proposed cell line(s) or animal model(s) were chosen*.
- If human subjects, human biological samples, or datasets will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples.
- If applicable, describe the strategy for the inclusion of women and minorities in the clinical research 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/or ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under "Resources and Reference Material" at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>.
- Preliminary and/or published data that are relevant to NF and the proposed research project are encouraged but not required.
- Hypothesis and Objective: State the hypothesis to be tested or the objective to be reached.
- Specific Aims: Concisely explain the proposed research project's specific aims to be funded by this application. If the proposed research project is part of a larger study, present only tasks that this award would fund.

- Project Coordination and Communication: Describe plans for communication, decision-making, allocation of resources, conflict resolution, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project.
- Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf". Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether 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 (five-page limit): Include a list of relevant publication URLs and/or patent abstracts. If articles 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 (one-page limit per letter): Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions. The letter(s) should address the following:

- No less than 25% effort committed to this award for the first 2 years.
- An institutional commitment of laboratory space and at least a 50% level of time and effort to conduct NF research and Academy activities during the period of performance under this award.
- Although not a requirement of this award mechanism, if applicable, describe any
  institutional support (e.g., supplies, staff, salary, start-up package) that may be
  provided for the 4 years of the NFRA Scholar Award.
- Letters of Collaboration (if applicable) (one-page limit per letter): Provide a signed letter from each collaborating individual or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Transcripts: Include a copy of the Scholars' transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the "Full Announcement" page in Grants.gov) in place of the transcript.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Inclusion Enrollment Plan (only required if clinical research is proposed):
   Provide an anticipated enrollment table(s) 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 Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>.

- Data Management Plan (two-page limit): Describe the data management plan in accordance with Section 3.c Enclosure 3, <u>DoD Instructions 3200.12</u>.
  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- 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.

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:

- Career Development and Sustainment: Summarize how the proposed research, participation in the NFRP NFRA, and the Career Development and Sustainment Plan (<u>Attachment 6</u>) will facilitate and sustain the Scholar's independent career at the forefront of neurofibromatosis research.
- Background: Present the ideas and scientific rationale supporting the proposed research project.
- Research Questions and/or Concepts: State the research question/concept to be tested. Provide scientific evidence or rationale that supports the research question/concept.
- **Specific Aims:** State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls. If tumors or derived cell lines will be studied, the name and definition of the materials should be included (e.g., name of the cell or pathological classification of the tissue).
- **Impact:** Briefly describe how the proposed research project will have short-term and/or long-term impact on NF research and/or patient care.
- 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. Do not duplicate the

*technical abstract.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the NF consumer community. Avoid overuse of acronyms and abbreviations, where possible.

Include the following elements, being sure to use language that will be *readily* understood by readers without a background in science or medicine.

- Describe the PI's career goals in neurofibromatosis research. How do the research and career development and sustainment plans support the PI in attaining these goals? Explain the PI's potential as a leader in neurofibromatosis research.
- State the FY23 NFRP Area(s) of Emphasis to be addressed by the research project.
- Describe the scientific rationale, objective, and aims for the proposed project.
- Describe the applicability of the research to neurofibromatosis patients and survivors.
  - What types of patients will the proposed research help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field of neurofibromatosis research. Basic research should have an ultimate goal of advancing the neurofibromatosis field and/or impacting patient care.
  - Describe the short-term and long-term goals that are related to patient care, outcomes, or survivorship. How will the proposed research benefit active-duty Service Members, Veterans, and other military beneficiaries?
  - How will the data and resources generated during the performance of the proposed research project be shared with the research community (scientific and advocacy organizations) and the public?
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf". The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>). Recommended strategies for assembling the SOW can be found at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>.

For the Neurofibromatosis Research Academy - Leadership Award mechanism, refer to the "Suggested SOW Strategy Generic Research" document for guidance on preparing

the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

- Attachment 6: Career Development and Sustainment Plan (three-page limit): Upload as "CareerSustain.pdf".
  - Discuss the Scholar's record of accomplishments (awards, honors, first author publications, publications in high-impact journals, presentations/speaking engagements, committees, etc.) demonstrating the potential for becoming an established investigator at the forefront of NF research.
  - Describe the Scholar's motivation and commitment to participating in the NFRA, to include networking and collaborating with the other Scholar/Career Guide pairs and the NFRA Leadership.
  - Describe the individualized career and professional development plan, which may include classes, workshops, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Include milestones to be achieved during the award period of performance and career pathways toward achieving the milestones. Explain how this development plan will enable the Scholar to obtain independent NF research funding and publish in peer-reviewed journals.
  - Explain how the Career Development and Sustainment Plan is supported by the environment; this should include a description of resources available to the Scholar at their institution, and, if different, at the Career Guide's institution. If the Scholar is impacted by resource limitations at their institution, explain how participation in the NFRA will help the Scholar overcome these obstacles.
  - Discuss how the Career Guide will assist the Scholar in not only developing, but also sustaining, a career as an independent neurofibromatosis researcher.
  - Outline how the Scholar and Career Guide, together, will evaluate the Scholar's progress of achieving and sustaining a productive and independent career in neurofibromatosis research.
- Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf". Using language readily understood by readers without a background in science or medicine, explicitly state how the proposed work addresses a critical problem in at least one of the FY23 NFRP Areas of Emphasis. Describe the pathway, both short-term and long-term, to making an impact on neurofibromatosis research and/or patient care and explain how the Scholar's specific career and research goals fit into that pathway. The relevance of all research, including basic, should relate to patient outcomes and how it benefits those affected by neurofibromatosis. Describe the potential impact of the proposed research on the health and well-being of Service Members, Veterans, their family members, and all people impacted by neurofibromatosis. Describe how the data and resources generated during the performance of the proposed research project will be shared with the research community (scientific and advocacy organizations) and the public.

• Attachment 8: Career Guide's Letter (three-page limit): Upload as "GuideLetter.pdf".

The Career Guide's letter should:

- Describe the Scholar's background and potential to become an established neurofibromatosis researcher.
- Describe the Career Guide's background and experience in neurofibromatosis
  research, success in acquiring funding in neurofibromatosis research, and record of
  mentoring and training early-career investigators. Describe the specific resources that
  will facilitate success for the Scholar.
- Specify the commitment of the Career Guide and their staff to the Scholar's
  professional development and career sustainment. If the Career Guide and Scholar
  are located at different organizations, describe how appropriate direction and
  oversight will be accomplished.
- Describe the Career Guide's motivation and commitment to participating in the NFRA.
- O Attachment 9: Statement of Eligibility (one-page limit): Upload as "Eligible.pdf". Provide a letter signed by the PI (the Scholar) and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements have been met. The letter should verify that the PI is no more than 7 years from their terminal degree. (Refer to Section II.C, Eligibility Information.) Include the organizational commitment for independent laboratory space and protection of at least 50% level of the PI's time and effort during the period of performance under this award to conduct NF research.
- Attachment 10: Data and Research Resources Sharing Plan (two-page limit): Upload as "ResourceSharing.pdf". Describe how data and resources generated during the performance of the proposed research project will be shared with the research community. If developing resources is part of the proposed research project, include the description of the type of data (animal models, tissue samples, methods) or other resources. Specifically describe the appropriateness of the milestones with respect to making the data or research resource(s) available and how the scientific community can obtain these data or research resource(s) after the period of performance expires. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. Describe how the data in the application follow the FAIR (Findable, Accessible, Interoperable, and Reusable) Data Principles for reproducible science found in "The FAIR Guiding Principles for scientific data management and stewardship."
  - The NFRP encourages sharing through the CDMRP website (https://cdmrp.health.mil/nfrp/resources/nfrpresources).
  - For general guidance on sharing, refer to the General Application Instructions, Appendix 2, Section K.

- Attachment 11: Animal Research Plan (if applicable, three-page limit): Upload as AnimalPlan.pdf. When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
  - Briefly describe the research objective(s) of the animal study. Explain how and why
    the animal species, strain, and model(s) being used can address the scientific
    objectives and, where appropriate, the study's relevance to human biology.
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Attachment 12: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- Attachment 13: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf". If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

# Extramural and Intramural Applications

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able

to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

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

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch\_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as "Support LastName.pdf".
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch LastName.pdf".
  - Include the Career Guide's biographical sketch.
  - If applicable, include the secondary Career Guide's biographical sketches.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support\_LastName.pdf".
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
  - Include the Career Guide's previous/current/pending support.
  - If applicable, include secondary Career Guide's previous/current/pending support.

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

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

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

#### • Extramural Applications Only

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

- Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- Intramural DOD Collaborator(s): Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as <a href="Attachment 13"><u>Attachment 13</u></a>. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

# II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (<a href="https://www.sam.gov/SAM/">https://www.sam.gov/SAM/</a>) and receive confirmation of an "Active" status before submitting an application through Grants.gov. As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

#### **II.D.4. Submission Dates and Times**

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

#### **Applicant Verification of Full Application Submission in eBRAP**

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

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

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

Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

#### **II.D.5.** Funding Restrictions

The maximum period of performance is 4 years.

The application's direct costs budgeted for the entire period of performance should not exceed \$750,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 4 years.

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

- Travel costs for the Scholar and Career Guide to attend a DOD NFRP 1-day NFRA Workshop with the NFRA Leadership and other NFRA members every other year.
- Travel costs for the Scholar and Career Guide to attend a biennial DOD NFRP multi-day NFRA Workshop with the NFRP staff, NFRA Leadership, and other Academy members.

May be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.
- Maximum allowable funding for the Career Guide(s) is \$30,000 per year in direct costs.
- Costs associated with participating in the NFRA (e.g., hardware and/or software for audio- or video-teleconferencing or web-based communications).
- Costs for one investigator to travel to two scientific/technical meetings per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results and/or attend workshops as designated in the Career Development and Sustainment Plan (<u>Attachment 6</u>) from/of the NFRP NFRA-SA.

Must not be requested for:

- Clinical trial costs
- Equipment

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

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

## **II.D.6. Other Submission Requirements**

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

# **II.E.** Application Review Information

#### II.E.1. Criteria

#### II.E.1.a. Peer Review

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

#### Scholar

- o The degree to which the Scholar's career goals are consistent with a commitment to pursuing and sustaining a career as an NF researcher.
- o The extent to which the Scholar is motivated and committed to participating in the NFRA with the other Scholar/Career Guide pairs and the Academy Leadership.
- How well the Career Guide's letter (and if applicable, secondary Career Guide's letter) supports the Scholar's potential for a productive, sustainable, and independent career in NF research.
- The extent to which the Scholar's record of accomplishments (e.g., awards, honors, first author publications, publications in high-impact journals, presentations/speaking engagements, committees, etc.) demonstrates their potential for becoming an independent investigator in NF research.

# • Research Project and Feasibility

- The extent to which the scientific rationale supports the research project and its feasibility
  as demonstrated by a review and analysis of the literature and relevant preliminary data
  (preliminary data do not need to come from the NF research field).
- How well the hypotheses, experimental design, methods, and analyses are developed and support completion of the aims.
- To what extent the power analysis demonstrates that the sample size is appropriate to meet the objectives of the study, and how well the statistical plan and analyses are developed and integrated into the project.
- o If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- How well potential problems are identified, and alternative approaches are addressed.

## Career Development and Sustainment Plan

- How well the application outlines an individualized Career Development and Sustainment Plan for the Scholar that is consistent with the NFRA and the Scholar's research goals.
- How well the individualized Career Development and Sustainment Plan will contribute to the overall professional development of the Scholar and prepare the Scholar for an independent and sustainable career in NF research.
- How well the Career Development and Sustainment Plan is supported by the environment at the Scholar's institution and, if different, at the Career Guide's institution.
- o How thorough the plans are for monitoring and evaluating the Scholar's progress in becoming an independent investigator in NF research.

# • Career Guide (and if applicable, Secondary Career Guide)

- The extent to which the Career Guide's (and if applicable, secondary Career Guide's) background, research experience, and funding history in NF will be supportive of the Scholar's career and professional development and transition to independence.
- How well the Career Guide's track record in preparing early-career investigators for careers in NF research indicates the potential for successful mentorship and development of the Scholar as an independent investigator.
- How well the Career Guide describes their motivation and commitment to participating in the NFRA, and why they will be an outstanding fit in the Academy irrespective of their accomplishments as a researcher and mentor to other early-career investigators.

#### Impact

- To what degree the anticipated results from the proposed research will make a contribution to the NFRP mission and will impact NF research and/or patient/survivor care.
- To what degree the proposed research project and commitment to participating in the Academy will facilitate professional growth and bring the PI to the forefront of NF research.

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

#### • Resources and Environment

The extent to which the proposed research project and career development of the Scholar are supported by the availability of facilities, equipment, staff, interaction with research colleagues, and other resources.

- The extent to which the institutional commitment supports the career development of the Scholar including time for research and participation in Academy activities.
- o If applicable, the degree to which the intellectual and material property plan is appropriate.

#### • Budget

- Whether the direct costs exceed the allowable direct costs as published in the program announcement.
- o Whether the budget is appropriate for the proposed research.

# • Application Presentation

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

# **II.E.1.b.** Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the Defense Health Program and FY23 NFRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - o Programmatic relevance to at least one of the FY23 NFRP Areas of Emphasis
  - Relative impact and innovation
  - Career potential of the Scholar

#### **II.E.2.** Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *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 <u>Section II.E.1.b</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found at <a href="https://cdmrp.health.mil/about/2tierRevProcess">https://cdmrp.health.mil/about/2tierRevProcess</a></u>. An information paper describing the funding recommendations and review process for the award mechanisms for the NFRP will be provided to the PI(s) and posted on the CDMRP website.

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

# II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

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

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

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

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

#### II.F. Federal Award Administration Information

#### **II.F.1. Federal Award Notices**

Awards supported with FY23 funds are anticipated to be made no later than September 30, 2024. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

**Pre-Award Costs:** An institution of higher education, hospital, or other non-profit or for-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

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

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

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

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

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

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

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

# **II.F.2.** Administrative and National Policy Requirements

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

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

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

Refer to full text of the latest <u>DoD R&D General Terms and Conditions</u> and the <u>USAMRAA General Research Terms and Conditions</u>: <u>Addendum to the DoD R&D General Terms and Conditions</u> for further information.

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

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

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

# II.F.3. Reporting

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

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

In-person presentations to the NFRP Programmatic Panel may be requested for this award mechanism.

The Award Terms and Conditions will specify if additional and/or more frequent reporting is required.

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

PHS Inclusion Enrollment Reporting Requirement (only required for clinical research studies and clinical trials): Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

# **II.G. Federal Awarding Agency Contacts**

# II.G.1. eBRAP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

#### II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

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

#### **II.H.** Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

#### **II.H.2.** Administrative Actions

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

#### II.H.2.a. Rejection

The following will result in administrative rejection of the application:

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

# II.H.2.b. Modification

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

#### II.H.2.c. Withdrawal

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

• An FY23 NFRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY23 NFRP Programmatic Panel members can be found at <a href="https://cdmrp.health.mil/nfrp/panels/panels23">https://cdmrp.health.mil/nfrp/panels/panels23</a>.

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<a href="https://cdmrp.health.mil/about/2tierRevProcess">https://cdmrp.health.mil/about/2tierRevProcess</a>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for application withdrawal.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The named Scholar on the application does not meet the eligibility criteria as described in Scholar Eligibility.
- A clinical trial is proposed.

#### II.H.2.d. Withhold

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

# II.H.3. Application Submission Checklist

<b>Application Components</b>	Action	Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"  Supporting Documentation: Upload as	
	Attachment 2 with file name "Support.pdf" Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf" Lay Abstract: Upload as Attachment 4 with	
	file name "LayAbs.pdf"  Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Career Development and Sustainment Plan: Upload as Attachment 6 with file name "CareerSustain.pdf"	
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"  Career Guide's Letter: Upload as	
	Attachment 8 with file name "GuideLetter.pdf"	
	Statement of Eligibility: Upload as Attachment 9 with file name "Eligible.pdf  Data and Research Resources Sharing Plan:	
	Upload as Attachment 10 with file name "ResourceSharing.pdf" Animal Research Plan: Upload as	
	Attachment 11 with file name "AnimalPlan.pdf"	
	if applicable (required for research projects involving animals)  Representations (extramural submissions	
	only): Upload as Attachment 12 with file name "RequiredReps.pdf"  Suggested Collaborating DOD Military	
	Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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

#### **APPENDIX 1: ACRONYM LIST**

ACOS/R&D Associate Chief of Staff for Research and Development

ACURO Animal Care and Use Review Office

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations

DOD Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

EC Ethics Committee

ET Eastern Time

FAD Funding Authorization Document

FAIR Findable, Accessible, Interoperable, and Reusable

FAPIIS Federal Awardee Performance and Integrity Information System

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

IPR In-Progress Review

IRB Institutional Review Board

LOI Letter of Intent

M Million
MB Megabytes

MIPR Military Interdepartmental Purchase Request

NF1 Neurofibromatosis Type 1 NF2 Neurofibromatosis Type 2

NFRA Neurofibromatosis Research Academy

NFRA – LA Neurofibromatosis Research Academy – Leadership Award

NFRA – SA Neurofibromatosis Research Academy – Scholar Award

NFRP Neurofibromatosis Research Program

NIH National Institutes of Health

OHARO Office of Human and Animal Research Oversight (previously Office of

Research Protections)

OHRO Office of Human Research Oversight (previously Human Research Protection

Office)

ORCID Open Researcher and Contributor ID, Inc.

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

SAM System for Award Management

SOW Statement of Work

STEM Science, Technology, Engineering, and/or Mathematics

UEI Unique Entity Identifier
URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA Department of Veterans AffairsA