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 - Leadership Award

Announcement Type: Modified

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

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: Stage 1:** January 2024
- **Invitation for Oral Presentations:** January 2024
- **Programmatic Review: Stage 2:** 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.1. NFRP Strategic Goals and FY23 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.

Strategic Goals: The NFRP's current strategic goals are:

- Foster basic and exploratory research
- Facilitate rapid testing of potential therapeutics
- Increase research capacity (***must be addressed for this award mechanism***)
- Encourage research in areas of critical interest to NF patients

Applicants are encouraged to review the NFRP's strategic plan for more information on its goals: https://cdmrp.health.mil/nfrp/pdf/NFRP%20Strategic%20Plan.pdf.

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:
    - Pain
    - Cognitive manifestations
    - 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 https://cdmrp.health.mil/nfrp/resources/nfrpresources. 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 (Attachment 9). For more guidance on data sharing, refer to the General Application Instructions, Appendix 2, Section K.

II.A.2. Award History

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

II.B. Award Information

All applications for this award must address at least the strategic goal "Increase research capacity" as stated in Section II.A.1 above.

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 that consists of Scholars and their Career Guides (mentors) from different institutions, and an Academy Director and Deputy Director (see Figure 1 below). The Academy Director and Deputy Director catalyze the growth and professional development of the Scholars in collaboration with their Career Guides, assess the progress of the Scholars, and facilitate communication and collaboration among all Academy members. ***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.*** The NFRA will give Scholars opportunities to operate in a collegial, highly dynamic, and cutting-edge center to lead neurofibromatosis research to a new frontier. The NFRA will provide a platform for Scholars to collaborate with leaders in the neurofibromatosis field and advance research for neurofibromatosis patients. 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 applications for an Academy Director and Deputy Director to lead the NFRA. The Academy Director and Deputy Director (referred to as Academy Leadership) must be established neurofibromatosis researchers and can be at different institutions. The Academy Leadership must demonstrate a strong record of mentoring and training early-career independent investigators, a commitment to leadership, the ability to

articulate methods toward research collaborations, and the ability to objectively assess the progress of all Scholars in the NFRA. Early-career independent investigators interested in applying to become a member of the NFRA should refer to the FY23 NFRP Neurofibromatosis Research Academy - Scholar Award program announcement (HT9425-23-NFRP-NFRA-SA). ***Note: An invited oral presentation is a requirement for application review of the NFRP NFRA-LA, as described in Section II.D.2.b, Full Application Submission Content.***

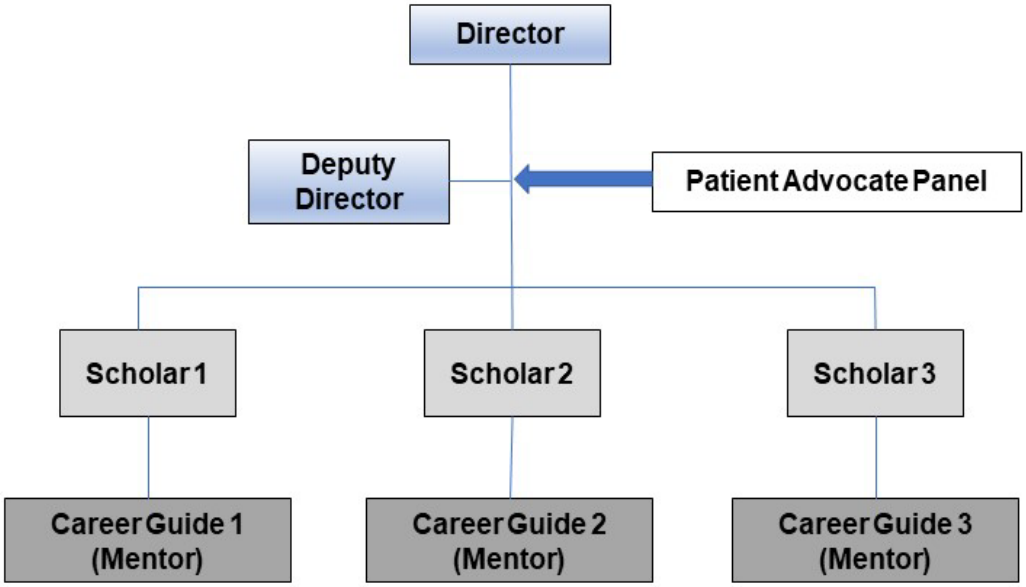

Figure 1: Structure of the FY23 NFRP Neurofibromatosis Research Academy: Director and Deputy Director will be the NFRA Leadership

Responsibilities of the Academy Leadership include, but are not limited to:

- Act as a resource for all Scholars and Career Guides in the Academy over the Scholars' 4-year period of performance.
- Facilitate communication and collaboration among all Scholars and Career Guides (including periodic interactive communication among all Academy members).
- Develop assessment criteria to evaluate the research progress made by all Scholars, as well as their career progression and sustainment as independent investigators in NF research.
- Conduct collaborative NF pilot project(s) that include Academy Scholars. These pilot projects should have the potential to improve collaboration within the Academy, as well as impact NF research and/or NF patients/survivors.
- Provide constructive critiques with the goal of advancing the research and professional careers of the Scholars and strengthening the mentorship of the Career Guides.
- Provide avenues to increase the promotion of the Academy and visibility of Scholars within NF research and advocacy communities (e.g., peer review, conferences, editorial boards).

- Support the professional development, to include laboratory management skills, of the Scholars into leading researchers through invited presentations by experts outside of the NFRA.

- Plan and host an annual 1-day workshop and, biennially, a multi-day workshop for all Scholars/Career Guide pairs as well as Academy graduates to present their research, share knowledge, and develop collaborative efforts within the NFRA. ***Scholars will be responsible for their own travel costs, funds for which are included in the FY23 NFRP Neurofibromatosis Research Academy - Scholar Award grant.***

- Include NFRP FY23 Early-Investigator Research Award (EIRA) and/or New Investigator Award - Early-Stage Investigators (NIA - ESI) in at least one meeting of the FY23 NFRA. These investigators will be responsible for their own travel costs, funds for which are included in their research awards.

- Establish a panel of patient advocates and Veteran(s) (i.e., the Patient Advocacy Panel) to inform the NFRA on the needs of the patient community.

- Establish the Career Guide Panel to facilitate collaborations among the NFRA participants including the Scholars, Director/Deputy Director, and the Career Guides.

The Neurofibromatosis Research Academy - Leadership Award is structured to support two Principal Investigators (PIs). The Academy Director will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The Deputy Director will be identified as the Partnering PI. The collaboration between the Academy Director and the Deputy Director should be supported by complementary expertise and experience. Initiating and Partnering PIs each have different submission requirements, as described in Section II.D.2, Content and Form of the Application Submission; however, both PIs should contribute significantly to the development of the proposed research project. The application should clearly demonstrate that both PIs have equal levels of input on the proposed Academy Leadership and clearly define the components to be addressed by each to support the success of the Scholars. While it is up to the Academy Director and the Deputy Director to define their roles, both Academy Leaders should have interactions with the Scholars; acting as administrative support does not fulfill the intent of the Deputy Director. If recommended for funding, each PI will be named to an individual award within the recipient organization.

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 - LA Award should not exceed **$1.3M**. 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 $2.08M to fund approximately one Neurofibromatosis Research Academy - Leadership Award application. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY23 funding opportunity will be funded with FY23 and FY25 funds, which will expire for use on September 30, 2029 and September 30, 2031, respectively.

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 https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo 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 NFRA – Leadership 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

Academy Director and Deputy Director:

- Must be an independent, established neurofibromatosis researcher at or above the level of associate professor or equivalent.
- Must have neurofibromatosis research funding (past and/or present).
- Must have a record of neurofibromatosis publications in peer-reviewed journals.
- Must demonstrate a commitment of at least 25% effort towards leading the Academy's activities.
- May be a research- or physician-scientist.

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 https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

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

II.D. Application and Submission Information

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

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

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 Section II.G, Federal Awarding Agency Contacts.

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 Table 1, Full Application Guidelines).

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

The Initiating PI (Academy Director) must complete the pre-application submission process and submit the contact information for the Partnering PI (Academy Deputy Director). The Partnering PI(s) will then be notified of the pre-application submission separately by email. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account. After associating the pre-application to their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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 help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the Initiating PI (Academy Director) 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 help@eBRAP.org or 301-682-5507.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

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

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

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

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

  The Initiating PI (Academy Director) must enter the contact information for the Partnering PI (Academy Deputy Director) in the Partnering PI section.

- **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 (https://grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

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

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

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-NFRP-NFRA-LA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for HT9425-23-NFRP-NFRA-LA from eBRAP (https://ebrap.org).
Full Application Package 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 • Additional Application Component(s)	**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 • Other **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least**	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent

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

The CDMRP requires separate full application package submissions for the Initiating PI (Academy Director) and the Partnering PI (Academy Deputy Director), even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique

eBRAP log number. ***Note: All associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.***

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 non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an uNFRAir competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below:

    - **Vision:** Describe the Academy Leadership's (Academy Director and Deputy Director) vision of the NFRA and how it will serve as a non-traditional, non-conventional training and research platform, including intensive mentoring and networking for the Scholars in a virtual environment. Describe the mission and roadmap as to how the Academy will develop highly productive neurofibromatosis researchers who will be recognized as leading researchers through a collaborative and interactive research training environment within the 5-year period of performance. Articulate the overall goals of the NFRA with respect to the FY23 NFRP Strategic Goal(s).

- **Background and Experience:** Describe the Academy Leadership's background and experience as established neurofibromatosis researchers. Describe the record of mentoring and training of early-career investigators and how this mentorship contributed significantly to the early investigators' careers. Explain how the complementary experience of both candidates contributes to the ideal leadership of the Academy.

- **Management of the Academy:** Clearly define the roles that will be filled by the Academy Director and Deputy Director in leading the NFRA. Describe how the Academy Leadership will facilitate communication and collaboration among all of the Scholars and their Career Guides (including periodic but not limited to virtual interactive meetings and annual and biennial in-person workshops), as well as the NF research and advocacy communities. Explain how the Academy Leadership will develop and communicate the criteria that will be used to evaluate the research progress made by all of the Scholars, as well as their career progression and sustainment as independent investigators in NF research. Identify measurable outcomes for the Scholars that are expected to be achieved by the end of the 4-year period of performance and how they will contribute to the professional development of the Academy members. Explain how the Academy Leadership will help the Scholars overcome the barriers in initiating and sustaining a career in neurofibromatosis research (e.g., grant writing, research and laboratory management, publications, professional networking, and committee memberships). Describe the integration of the FY23 EIRA and NIA - Early-Stage Investigators into the program to support potential collaborations with the Scholars.

- **Commitment to the Neurofibromatosis Research Academy:** Describe the Academy Leadership's commitment to leading the NFRA and to the success of this unique, interactive virtual academy in providing collaborative mentoring of Scholars with the goal of developing sustainable, independent careers as leaders in neurofibromatosis research at their institutions, nationally, and internationally.

- **Scholar Transition Support:** Describe how the Leadership team will foster the transition of a Scholar from post terminal degree to assistant professor (or equivalent) and on up to independent scientist with a track record of independent funding. Eligibility details for the NFRP FY23 NFRA Scholar Award are available at this link: Scholar Eligibility.

- **Research Projects:** Describe a minimum of three pilot projects proposed by the Academy Leadership that will be conducted in a collaborative effort by the Academy Leadership and Scholars. Describe the scientific rationale of the pilot projects. List the specific aims and rationale as to why these pilot projects will help launch a career in NF. Address potential problem areas and present alternative methods and approaches. If applicable, describe how the proposed research using animals meets the regulatory guidelines for appropriateness and robustness of experimental design.

    - If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Clearly

describe the tissue or tumor type to be studied, where applicable (e.g., encapsulated versus diffuse plexiform neurofibroma).

- If applicable, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnic group, and an accompanying rationale for the selection of subjects. If women and minorities are excluded, provide a rational justification for the exclusion. 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. Additional reporting information is included in Attachment 2 below.

- **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:** 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.

- **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.

- **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 https://ebrap.org/eBRAP/public/Program.htm.

- **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.

- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instruction 3200.12.

  - 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:

- Academy Leadership Plan

  As Academy Leadership, describe your vision for the successful continuation of the Academy as a non-traditional, non-conventional training platform in which the Scholars will develop partnerships, collaboration, and career growth to ensure their dedication and productivity as leading NF researchers.

- Describe the inclusion of the Patient Advocacy Panel and its relevance to the research and training program.

- Research Plan

  - Present the ideas and reasoning behind the proposed work.

  - Hypothesis: State hypothesis to be tested. Provide supporting evidence or rationale.

  - Specific Aims: State the specific aims of the study.

  - Study Design: Briefly describe the study design, including appropriate controls.

  - Impact: Describe how the proposed research will make an important contribution toward the goal of eliminating neurofibromatosis.

- **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.

  The lay abstract should be written using the outline below:

  - Describe the rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine.***

  - Describe the Academy Leadership Plan.

  - Describe the integration of patient advocates on the Patient Advocacy Panel.

- As Academy Leadership, describe your vision for the successful continuation of the Academy as a non-traditional, non-conventional training platform in which the Scholars will develop partnerships, collaboration, and career growth to ensure their dedication and productivity as leading NF researchers. ***(For awards not requiring a lay abstract with submission)*** Not required at time of submission. Leave Attachment 4 space blank.

- 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 (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the 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.

  Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI (Academy Director) and the Partnering PI (Academy Deputy Director) should be noted for each task.

- **Attachment 6: Sample Agenda (two-page limit): Upload as "SampleAgenda.pdf".** Provide a sample agenda for the first annual workshop to be led by the FY23 Academy Leadership. Explain how the format for the workshop is designed to stimulate the professional growth of the Scholars in both leadership and research skills.

- **Attachment 7: Patient Advocacy Panel (three-page limit): Upload as "PatAd.pdf."** Include the names of at least two patient advocates and at least one Veteran (the Veteran may be one of the patient advocates). Describe the Patient Advocacy Board. Articulate the patient advocates' and/or Veteran(s)' roles on the panel and how they will be integral to the training, networking, and collaboration of the Scholars. Clearly articulate how the patient advocates and Veteran(s) will have a meaningful role in the NFRP. Provide a letter from at least two patient advocates confirming their commitment to serving on the NF Patient Advocacy Panel.

- **Attachment 8: Impact Statement (one-page limit): Upload as "Impact.pdf".** State explicitly how the proposed research project addresses one or more of the FY23 NFRP Areas of Emphasis or, if the project does not address an Area of Emphasis, provide justification that the proposed research project addresses a critical problem in NF research and/or patient care. In lay language, describe how the NFRA will bridge the gaps in patient outcomes and care through the multidisciplinary training and support of the next generation of neurofibromatosis researchers. Justify the long-term impact of the

virtual academy on neurofibromatosis research. Describe how the FY23 NFRP Strategic Goal(s) are integrated into the Academy. 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 9: 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 10: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 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 (https://ebrap.org/eBRAP/public/Program.htm) 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".

- 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.

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.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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

- **Extramural Applications Only**

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

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

  - **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 11. (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.

  Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. ***Note:*** Applicants should complete a separate military budget using "Suggested Collaborating DOD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]) (Attachment 11) to show all direct and indirect costs. 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.

Application Components for the Partnering PI (Academy Deputy Director)

The Partnering PI (Academy Deputy Director) must follow the link in the email from eBRAP and, if not registered in eBRAP, must complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI (Academy Director).

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

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

  - **Attachment 10: Representations (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

  - **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The 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".

- 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.

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

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  - **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.)

  - **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using Suggested Collaborating DOD Military Facility Budget Format (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]), and upload to Grants.gov attachment form as Attachment 11. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

  - **Suggested DOD Military Budget Format**: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. ***NOTE:*** Applicants should complete a separate military budget using "Suggested Collaborating DOD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]) (Attachment 11) to show all direct and indirect costs. 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.

Additional Application Components

In addition to the complete application package, Neurofibromatosis Research Academy - Leadership Award applications for the Director and the Deputy Director also require the following:

- **Oral Presentation**

  Candidates for Academy Director and Deputy Director selected for Stage 2 Programmatic Review will be required to give an oral presentation (see Section II.E.1.b, Programmatic Review). In the event a PI is invited to the Programmatic Review, Stage 2 (see Section II.E.1.b, Programmatic Review), but is unable to attend, CDMRP Staff and the Grants Officer will consider alternative arrangements on a case-by-case basis.

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

- What conceptual or intellectual barriers do you consider as important to overcome in the career development and sustainment of investigators dedicated to NF research?

- Articulate the capabilities of the Academy Leadership to facilitate the Scholars' development of partnerships, collaborations, and career growth to ensure their dedication, commitment, and productivity as leading researchers in NF cancer.

- What are the proposed milestones and outcomes for the Scholars during the 4 years in the Academy?

- Briefly introduce your proposed neurofibromatosis pilot research projects that will be conducted as collaborative efforts with the Scholars. Briefly describe the metrics use to evaluate the outcomes of the research.

- Illustrate the significance of the Patient Advocacy Panel and how it will be integrated into the program.

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

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. ***As 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 Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

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

application submission deadline. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI (or PIs, if application involves multiple/Partnering PIs) 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 **5** years.

The anticipated **combined** direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications should not exceed **$1.3M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each 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 **5** years.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

- **Interim (In-Progress) Review (IPR)/Milestone Meetings:** Travel costs for the PI(s) for attendance and participation in at least one 2-day IPR should be requested.

- Costs associated with planning and holding the annual 1-day workshop (virtual or in-person) with Academy members, including costs associated with external speakers. (Do not include travel costs for the FY23 NFRP Neurofibromatosis Research Academy - Scholar Awardees or the FY23 NFRP Early-Investigator Research Award recipients and New Investigator Award - Early-Stage Investigator Award recipients; their travel costs will be covered by their FY23 NFRP Neurofibromatosis Research Academy - Scholar Award, FY23 NFRP EIRA, and FY23 NFRP NIA, respectively.)

- Costs associated with planning and holding the biennial multi-day in-person workshop in coordination with the NFRP Program staff, including costs associated with external speakers. In alternate years, they must also attend a DOD NFRP NFRA 1-day workshop. (Do not include travel costs for the FY23 NFRP Neurofibromatosis Research Academy - Scholar Awardees or the FY23 NFRP Early-Investigator Research Award recipients and New Investigator Award - Early-Stage Investigator Award recipients; their travel costs will be covered by their FY23 NFRP Neurofibromatosis Research Academy - Scholar Award, FY23 NFRP EIRA, and FY23 NFRP NIA, respectively.)

- These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Costs associated with establishing and maintaining a "virtual" academy (e.g., hardware and/or software for audio- or video-teleconferencing or web-based communications)

- Support for multidisciplinary collaborations, including travel

- Travel between/among institutions participating in the Academy

- Travel costs per Academy Leader to 1-day and biennial multi-day workshops

- Travel costs per Academy Leader to travel to scientific/technical meetings per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project outcomes or disseminate project results.

Must not be requested for:

- Clinical trial costs

- Tuition

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 listed in decreasing order of importance:

- **Academy Leadership**
    - To what extent the Academy Director's and Deputy Director's background and experience in neurofibromatosis research demonstrate their potential for leadership of the NFRA.
    - To what extent the Academy Leadership's record of mentoring and training early-career investigators in neurofibromatosis research indicates the potential for successful mentorship and career development of the Scholars.
    - To what degree the mentorship of the Director or Deputy Director contributed to the careers of past mentees.
- **Vision**
    - To what extent the vision of the NFRA supports the ideal to serve as a non-traditional, non-conventional training and research platform, including intensive mentoring and networking for the Scholars in a virtual environment.
    - Whether the mission and roadmap as to how the Academy will develop highly productive neurofibromatosis researchers who will be recognized as leading researchers through a collaborative and interactive research training environment within the 4-year period of performance is articulated and feasible.
    - Whether the overall goals of the NFRA with respect to the FY23 NFRP Strategic Goal(s) are described.

- **Management of the Academy**
    - Whether the roles that will be filled by the Academy Director and Deputy Director are clearly defined.
    - How well the Academy Leadership demonstrates commitment to leading the NFRA and to the success of the unique, interactive virtual academy.
    - To what degree the Academy Leadership will facilitate communication and collaboration among all the Scholars and their Career Guides (including periodic but not limited to virtual interactive meetings and annual and biennial in-person workshops), as well as the neurofibromatosis research and advocacy communities.
    - How well the Academy Leadership developed the criteria that will be used to evaluate the research progress made by all Scholars and how the evaluation will be communicated to the Scholars.
    - To what degree the Academy Leadership will evaluate career progression and sustainment of Scholars as independent investigators in neurofibromatosis research.
    - Whether measurable outcomes are identified for Scholars and whether they are achievable within the 4-year period of performance.
    - To what extent the Academy Leadership will help the Scholars overcome the barriers in initiating and sustaining a career in NF research (e.g., grant writing, research and laboratory management, publications, professional networking, and committee memberships).
    - To what degree the integration of FY23 EIRA and NIA - Early Stage Investigators into the program supports potential collaborations with Scholars.
- **Patient Advocacy Panel**
    - Whether the application describes the Patient Advocacy Panel and includes the names of at least two patient advocates and at least one Veteran.
    - To what extent the roles of patient advocates and Veteran(s) on the panel will be integral to the training, networking, and collaboration of the Scholars.
    - Whether the application articulates how the patient advocates and Veteran(s) will have a meaningful role in the NFRA.
- **Impact**
    - Whether the application describes how the NFRA will bridge the gaps in patient outcomes and care through the multidisciplinary training and support of the next generation of neurofibromatosis researchers.

- How well the application justifies the long-term impact of the virtual academy on the future of NF research.
- To what extent the FY23 NFRP Strategic Goal(s) are integrated within the NFRA.

- **Research Strategy and Feasibility**
  - Whether a minimum of three pilot projects has been described.
  - How well the scientific rationale of the pilot projects supports the specific aims.
  - Whether these pilot projects will help launch a career of the Scholars in NF.
  - To what degree the pilot projects will represent collaborative efforts by the Academy Leadership and Scholars.
  - How well the application addresses potential problem areas and presents alternative methods and approaches.
  - If applicable, for the proposed research project involving human subjects, whether the application describes the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnic group, and an accompanying rationale for the selection of subject. 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. If women and minorities are excluded, to what extent the application provides a rational justification.
  - If applicable, whether the application describes how the proposed research using animals meets the regulatory guidelines for appropriateness and robustness of experimental design.

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

- **Data and Resource Sharing**
  - How well the Data and Research Resources Sharing Plan is detailed, including but not limited to:
    - The description of the type of data or research resource(s) to be made publicly available.
    - The detailed plan for access to data or research resources.

- The appropriateness of plans to ensure the data or research resource(s) is/are accessible after the period of performance expires.
- The appropriateness of the milestones with respect to making the data or research resource(s) available.

  - How well the data in the application follows the FAIR Data Principles for reproducible science found in "The FAIR Guiding Principles for scientific data management and stewardship."

- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what degree the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - To what degree the quality and extent of institutional support/commitment are appropriate for the proposed research project.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the Defense Health Program and FY23 NFRP, as evidenced by the following:
    - **Stage 1:** During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:
        - Ratings and evaluations of peer review
        - Adherence to intent of award mechanism
        - Program portfolio composition
        - Relevance to at least one of the strategic goals (including "Increase research capacity")
        - Relative impact
        - Vision of Academy
    - **Stage 2 (Oral Presentation):** During the second stage of programmatic review, the following criteria will be used:
        - Capabilities to lead the Academy such that the Scholars develop partnerships, collaborations, and career growth to ensure their dedication, commitment, and productivity as leading researchers in NF.
        - Utilization of leadership skills to encourage partnerships, collaborations, resource sharing, and career growth for the Scholars.
        - Evaluation of the proposed milestones and outcomes for the Scholars during the 4 years in the Academy.
        - Justification of proposed NF pilot research projects that will be conducted as collaborative efforts with the Scholars. With respect to the pilot projects, the metrics used to evaluate the outcomes of the research.
        - The significance of the Patient Advocacy Panel and how it will be integrated into the program.

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 Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess. 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 Section I, Overview of the Funding Opportunity.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with 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 for-profit or non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.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

An organizational transfer of an award supporting the Initiating PI (Academy Director) or Partnering PI (Academy Deputy Director) is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

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

Refer to the General Application Instructions, Appendix 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 DoD R&D General Terms and Conditions and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions 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 (https://ebrap.org/eBRAP/public/Program.htm) 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 (https://ebrap.org/eBRAP/public/Program.htm) 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.
- Failure to submit all associated components (Initiating PI and the Partnering PI) by the application submission deadline.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An 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 https://cdmrp.health.mil/nfrp/panels/panels23***.

- 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 11.3 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 (https://cdmrp.health.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- 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.
- An application for which the named initiating PI (Academy Director) or partnering PI (Academy Deputy Director) does not meet the eligibility criteria.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- The application fails to address the FY23 NFRP Strategic Goal(s). The "***Increase research capacity***" strategic goal must be addressed for this award mechanism.
- The application fails to demonstrate access to the relevant study population or resources.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Sample Agenda: Upload as Attachment 6 with file name "SampleAgenda.pdf"		
	Patient Advocate Panel: Upload as Attachment 7 with file name "PatAd.pdf"		
	Impact Statement: Upload as Attachment 8 with file name "Impact.pdf"		
	Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name "ResourceSharing.pdf"		
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		

Application Components	Action	Initiating PI Completed	Partnering PI 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)**	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	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
EIRA	Early-Investigator Research Award
ESI	Early-Stage Investigator
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
NIA – ESI	New Investigator Award – Early Stage Investigator
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 Affairs