I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Neurofibromatosis Research Program

Early Investigator Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524NFRPEIRA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), September 12, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 3, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 8, 2024
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, October 10, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** February 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. 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."

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Neurofibromatosis Research Program (NFRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the NFRP in 1996 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the NFRP from FY96 through FY23 totaled $427.85 million (M). The FY24 appropriation is $25.0M.

The vision of the FY24 NFRP is to decrease the clinical impact of neurofibromatosis (NF). Toward this end, the NFRP promotes 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. ***The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.***

II.A.1. NFRP Strategic Goals and FY24 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 NF type 1 (NF1), NF type 2 (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.
- 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: To meet the intent of the funding opportunity, all applications should specifically address the critical needs of the NF community in one or more of the Areas of Emphasis listed below. All applications are also 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 FY24 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 our 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 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 Early Investigator Research Award mechanism was first offered in FY18. Since then, 22 Early Investigator Research Award applications have been received, and 12 have been recommended for funding.

II.B. Award Information

The Early Investigator Research Award supports NF-focused research opportunities for individuals in the early stages of their careers, ***under the guidance of a Designated Mentor***. This opportunity allows for early-stage investigators to develop a research project, investigate a problem or question in NF research, and further their intellectual development as an NF researcher of the future. The postdoctoral investigator is considered the Principal Investigator (PI) of the application and must exhibit strong potential for, and commitment to, pursuing a career as an investigator at the forefront of NF research; however, the PI is not required to have previous NF research experience. Applications must include at least one mentor, appropriate to the proposed research project, who has experience in NF research and mentoring as demonstrated by a record of active funding, recent publications, and successful mentorship. The Designated Mentor can be a junior faculty member, in which case the PI is encouraged to include a co-mentor with a more robust track record in NF research and mentorship. The selected mentor(s) should also demonstrate a clear commitment to the development of the PI toward independence as an NF researcher.

Participants will share data following the FAIR (Findable, Accessible, Interoperable, and Reusable) Data Principles for reproducible science found in "The FAIR Guiding Principles for scientific data management and stewardship" (https://www.nature.com/articles/sdata201618). Refer to the Data and Research Resources Sharing Plan document in Attachment 9.

The PI must outline an individualized, NF-focused Researcher Development Plan (Attachment 7). The Researcher Development Plan should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project and foster the PI's development as an independent NF researcher. An environment appropriate to the proposed mentoring and research project must be clearly described, although any deficiencies of resources and/or mentorship at the PI's institution can be mitigated through collaboration(s) with other institutions. If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution.

All application components for the Early Investigator Research Award are expected to be written by the PI, with appropriate direction from the mentor(s). The NFRP seeks applications that address the critical needs of the NF community as outlined in the FY24 NFRP Areas of Emphasis above. If the project does not address an Area of Emphasis, provide justification that the proposed research project addresses an important problem in NF research and/or patient care. Describe the anticipated outcomes (short-term gains) from the proposed research and how they

will be used as a foundation for future research projects. Explain the anticipated long-term gains from the proposed research project, including how the new understanding may ultimately contribute to the goal of advancing NF research and/or patient care.
This mechanism may be used to support studies using **pre-existing** specimens and/or data acquired from well-characterized, adequately controlled, and sufficiently powered patient cohorts. Preliminary data are not required but may be included.

Organizational Level Emphasis: The following areas of emphasis are broadly applicable to many CDMRP programs, not just the NFRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research, addresses the FY24 NFRP strategic priorities and/ Areas of Emphasis described in Section II.A.1, and meets the intent of the award mechanism.

Nuclear Medicine: Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

Women's Health: The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Metastatic Cancer Task Force: A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 NFRP priorities.

Rigorous Study Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

Military Service Involvement: Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If

the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

Clinical trials are not allowed under this funding opportunity. A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition 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 assess 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 data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Research Involving Animals: All research funded by the FY24 NFRP Early Investigator Research Award involving new and ongoing research with animals must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (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.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 NFRP EIRA Award should not exceed **$200,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.,

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $0.64M to fund approximately two Early Investigator Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements

II.C.1.b. Principal Investigator

The PI must:

- Be involved in a postdoctoral training or medical residency program
- Possess up to 4 years of continuous postdoctoral research experience by the Early Investigator Research Award application submission deadline
- Possess a doctoral degree (i.e., Ph.D., M.D./Ph.D., D.O./Ph.D.) or a clinical doctoral degree (i.e., M.D./D.O. or Ph.D. in a clinical discipline) from an accredited organization or program
- ***Commit at least 50% of their effort toward the proposed NF research project***

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/.

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

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

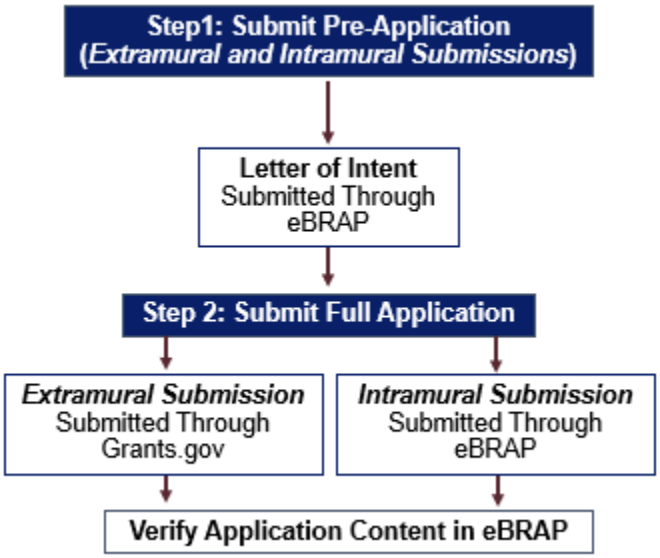
The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural

DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524NFRPEIRA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524NFRPEIRA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that 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).

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 NFRP Programmatic Panel members should not be involved in any pre-application or full 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.

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

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for each Partnering PI.

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

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted.
    - **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for one Designated Mentor, one co-mentor (if applicable), and one independent researcher who has scientific knowledge and interaction with the PI who will

provide letters of letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (6-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 that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Principal Investigator:** The applicant should describe their career goals and how the proposed research project and mentoring experience will promote their development toward becoming an independent NF researcher. The PI should discuss their research plans and career plans after the completion of this award.

- **Mentor(s):** Describe each mentor's background and experience in NF research. Explain how they will assist the PI throughout the period of performance in developing toward independence in NF research. Provide details on the amount and types of interactions between the mentor(s) and the PI. Describe the track record of the mentor(s) for mentoring early-stage investigators in NF research.

- **Research Project:** Describe the proposed research project, including the background, hypothesis/purpose and scientific rationale, broad objectives and specific aims, and methods (including appropriate controls). Address potential problem areas and present alternative methods and approaches. Include a statistical analysis of the proposed research, if applicable.

- **Areas of Emphasis:** Briefly describe how the proposed research is relevant to at least one of the FY24 NFRP Areas of Emphasis. If the proposed project does not address any of the FY24 NFRP Areas of Emphasis, provide a description to justify how the project will nevertheless significantly address a critical need in the field of NF research and/or patient care.

If the proposed research involves access to active-duty military and/or U.S. Department of Veterans Affairs (VA) patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.

- **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:** 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)*:** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **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.

- **DOD Data Management Plan:** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Inclusion Enrollment Plan *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

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

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

- **Attachment 3: Technical Abstract (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.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the scientific rationale behind the proposed research project.

  - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.

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

  - **Study Design:** Describe the study design, including appropriate controls.

- **Impact:** Briefly describe how the proposed research project will have short-term and/or long-term impact on NF research and/or patient care

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

  - Summarize the objectives and rationale for the proposed research.

  - Describe the ultimate applicability of the research.

    - What population will the research help, and how will it help them?

    - What are the potential applications, benefits, and risks of the anticipated outcomes?

    - What is the projected time it may take to achieve a patient-related outcome?

    - What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life?

    - 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 (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested Statement of Work (SOW) format and recommended strategies for assembling the SOW.

  - For the Early Investigator Research Award, refer to "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** State explicitly how the proposed research project addresses one or more of the FY24 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. Describe the anticipated outcomes (short-term gains) from the proposed research and how they will be used as a foundation for future research projects. Explain the anticipated long-term gains from the proposed research project,

including how the new understanding may ultimately contribute to the goal of advancing NF research and/or patient care. 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 7: Researcher Development Plan (one-page limit): Upload as "ResearchDev.pdf".**

  - Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed research project.

  - Indicate how the individualized Researcher Development Plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of NF, and effectively prepare them for a career as an independent NF researcher.

  - Describe how the Researcher Development Plan is supported by the environment and mentorship, including a description of ongoing NF research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI's primary institution (if applicable). If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the NF field. ***Do not reference or include members of the FY24 NFRP Programmatic Panel.***

- **Attachment 8: Eligibility Statement (one-page limit): Upload as "Eligibility.pdf**". Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official, to verify that the eligibility requirements have been met by the application submission deadline. The letter should provide the date (month/year) the PI completed/will complete requirements for their doctoral degree, and the date (month/year) the PI began/will begin postdoctoral research in the proposed setting.

- **Attachment 9: Data and Research Resources Sharing Plan (two-page limit): Upload as "DataResourceSharing.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, including animal models, tissue samples, methods, or other resources, specifically describe how the scientific community can obtain these resources. Describe how the data in the application follow the FAIR Data Principles for reproducible science found in "The FAIR Guiding Principles for scientific data management and stewardship." 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. ***Refer to the NFRP Research Resources Initiative paragraph at the end of Section II.A.1, FY24 NFRP Areas of Emphasis.***

- 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: Animal Research Plan (if applicable, three-page limit): Upload as AnimalResPlan.pdf.** When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.

  - Summarize the procedures to be conducted. Describe how the study will be controlled.

  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 11: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs.

Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".
- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

Additional Application Component

In addition to the complete application package, Early Investigator Research Award applications also require the following component:

- Confidential Letters of Recommendation
    - These should be from separate individuals as follows:
        - One from the Designated Mentor (**required**).
        - One from an independent researcher who has scientific knowledge and interaction with the PI (**required**).
        - One from a co-mentor (**applicable** if the Designated Mentor is a junior faculty member or if the PI will be utilizing resources at another institution to successfully complete the proposed project).
    - The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the pre-application. The PI will not be able to view the letters.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

II.D.5. Funding Restrictions

The maximum period of performance is **2** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$200,000**. 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 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 **2** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the NFRP EIRA.

Must not be requested for:

- Clinical trial costs
- Equipment
- Mentor salary

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Principal Investigator**
    - How the PI's experience, level of expertise, and record of accomplishment (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate the potential for a successful career as an NF researcher.
    - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in NF research.
    - To what extent the letters of recommendation from the mentor(s) and others support the PI's potential for a highly productive career as a NF researcher.
    - Whether the PI's proposed level of effort is appropriate for successful completion of the proposed work.
- **Mentor(s)**
    - Whether there is at least one mentor who is an established NF researcher, as evidenced by a demonstrated record of active funding and recent publications in NF research.
    - How the Designated Mentor's (and co-mentor's, if applicable) own experience in NF, and their research program and committed resources, support the ability to supervise the PI's research project.
    - To what extent the track record(s) of the mentor(s) in previously mentoring early-stage investigators indicates the potential for successful mentoring of the PI in NF research.
    - Whether the mentor letter(s) indicate(s) a high level of commitment to the PI's development as an NF researcher.
    - Whether the quality of the application suggests that the mentor(s) provided appropriate guidance in its preparation.
- **Research Project**
    - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, NF-relevant preliminary data (if included), and/or logical reasoning.
    - Whether the experimental design and the statistical plan, if applicable, are appropriate for the research proposed.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.

- How well the application acknowledges potential problems and addresses alternative approaches.

- If applicable, how well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.

- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- **Researcher Development Plan and Environment**

  - How well the application has outlined an individualized plan that will enable the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.

  - How well the individualized Researcher Development Plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in NF research, and effectively prepare the PI for a career as an independent NF researcher.

  - To what extent the scientific environment at the primary institution (and collaborating institution(s), if applicable) is appropriate for the proposed research and career development activities, including professional interaction with established NF researchers.

  - To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements and/or intellectual property plans as applicable).

  - 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.

- **Impact**

  - **To what extent:**

    - The anticipated outcomes (short-term gains) will make an important contribution toward the goal of advancing NF research and/or patient care.

    - The anticipated long-term gains will contribute to the goal of advancing NF research and/or patient care.

    - 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.

- How well the proposed research project addresses one or more of the FY24 NFRP Areas of Emphasis or a critical problem in NF research and/or patient care.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **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.
- **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 priorities of the Defense Health Program and FY24 NFRP, as evidenced by the following:

- Adherence to the intent of the funding opportunity ***(If the language of this criteria is changed, consider including matching language in Section II.A.1.)***
- Program portfolio composition
- Relative impact
- Relative innovation and/or military benefit
- Programmatic relevance to the FY24 NFRP Areas of Emphasis

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.

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the NFRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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 7, Section F, for general information on organization or PI changes.

II.F.3. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the OHARO prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

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

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 $10.0M are required to provide information to SAM 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 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission:

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

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

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 NFRP Programmatic Panel members can be found at https://cdmrp.health.mil/nfrp/panels/panels24***.
- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, 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).
- 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.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.

- The PI does not meet the eligibility criteria.
- The applicant fails to demonstrate access to the relevant study population or resources.

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. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Researcher Development Plan- Attachment 7, upload as "ResearchDev.pdf".	☐
Eligibility Statement – Attachment 8, upload as "Eligibility.pdf".	☐
Data and Research Resources Sharing Plan – Attachment 9, upload as **"**DataResourceSharing.pdf**"**	☐
Animal Research Plan – Attachment 10, upload as "AnimalResPlan.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐
Additional Application Components	
Confidential Letters of Recommendation	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
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
EIRA	Early Investigator Research Award
ET	Eastern Time
FAD	Funding Authorization Document
FAIR	Findable, Accessible, Interoperable, and Reusable
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NF1	Neurofibromatosis Type 1
NF2	Neurofibromatosis Type 2
NFRP	Neurofibromatosis Research Program
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
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	U.S. Department of Veterans Affairs