

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Neurofibromatosis Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-09-NFRP-IIRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Neurofibromatosis Research Program (NFRP) was established in fiscal year 1996 (FY96) to promote the understanding, diagnosis, and treatment of neurofibromatosis (NF). Appropriations for the NFRP from FY96 through FY08 totaled \$190.3 million (M). The FY09 appropriation is \$10M.

FY09 NFRP Vision: The vision of the FY09 NFRP is to find and fund the best research to decrease the clinical impact of NF. Toward this goal, 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,
- Foster the next generation of NF investigators,
- Promote translational and clinical studies to move promising ideas from bench to bedside,
- Develop a balanced portfolio of meritorious research related to all aspects of NF1, NF2, and Schwannomatosis.

NFRP Research Resources Initiative: Resources developed through NFRP funding that are available to the scientific community can be found at <http://cdmrp.army.mil/nfrp/nfrpresources.htm>. Investigators are urged to leverage and contribute to these resources. For more guidance on data sharing, refer to Application Instructions and General Information, Appendix 5.

B. Award Description

The NFRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY96. Since that time, 293 IIRA applications have been received, and 86 have been recommended for funding.

The NFRP IIRA supports basic and clinically oriented research that will:

- Provide insight into the development of NF and related diseases,
- Result in substantial improvements over today's approach to the diagnosis and treatment of NF and Schwannomatosis, and
- Enhance the quality of life of persons with those diseases.

Areas of Encouragement (*Revised for FY09*): The FY09 NFRP encourages research proposals that specifically address the critical needs of the NF community in the following areas:

- Complications of NF with high mortality such as neoplasms and cerebrovascular abnormalities;
- Complications of NF with high morbidity such as skeletal maladies, learning deficits, hormone-associated effects, and pain;
- Refinement and standardization of imaging techniques, molecular and cellular markers, and quality of life metrics for use in future clinical trials; and
- Translational research such as the development or preclinical testing of therapeutic agents for the treatment of NF.

Clinical trials are not allowed under this mechanism. Principal Investigators (PIs) wishing to apply for funding for a clinical trial should utilize the Clinical Trial Award mechanism.

Applications must include preliminary data originating from the PI, research team, or collaborator that is relevant to NF and the proposed project.

Optional Qualified Collaborator(s): The FY09 NFRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic scientists and biotechnology/pharmaceutical industry scientists. Collaborations that bring new perspectives from other disciplines or bring new investigators into the NF field are also strongly encouraged. Collaborations that meet the criteria below will qualify for a higher level of funding as described in Section I.D.

For the application to qualify for the higher level of funding, the PI must submit a Statement of Collaboration that clearly identifies the collaborating investigator and addresses how each of the criteria below are met. Additionally, the collaborator must provide a letter of collaboration describing his/her involvement in the proposed work. It should be clear that the success of the project depends on the unique skills and contributions of each partner.

- The collaborator(s) must significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
 - A proposed project in which the collaborator(s) merely supplies tissue samples or access to patients will not meet the intent and will not be qualified for the higher level of funding.
- Either the PI or the collaborator(s) must have NF research experience as demonstrated through publications and/or funding history.
- The collaborator(s) must be ***at or above*** the level of Assistant Professor (or equivalent).
- At least a 10% level of effort is required of the collaborator(s). Contribution of the collaborator should be reflected in the application's budget.

C. Eligibility

PIs must be *at or above* the level of Assistant Professor (or equivalent). Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable funding for the entire period of performance is **\$525,000** in direct costs (**\$675,000** in direct costs if requesting an Optional Qualified Collaborator).
 - Applications requesting the higher level of funding that do not include a qualified collaborator who meets all of the specified criteria will have their budget reduced as appropriate.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with your institution's negotiated rate agreement.

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs (No clinical trials allowed)
- Travel between collaborating institutions
- Travel to scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$4.6M of the \$10M FY09 NFRP appropriation to fund approximately five IIRA applications, depending on the quality and number received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

Pre-application Submission Deadline:	March 24, 2009
Application Submission Deadline:	April 14, 2009
Scientific Peer Review:	Summer, 2009
Programmatic Review:	Late Summer/Early Fall, 2009

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/), and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. Eastern time (ET) on the deadline date**. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

1. SF-424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- Attachment 1: Project Narrative (20-page limit)

Describe the proposed project in detail using the outline below. The project narrative must include preliminary data originating from the PI, research team, or collaborator that is relevant to NF and the proposed project.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. If the proposed work is part of a larger study, present only tasks that the Department of Defense award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials.*
- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms and Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publications and/or Patent Abstracts (five-document limit)
 - Letters of Institutional Support (two-page limit per letter)
 - Letters of Collaboration (if applicable, two-page limit per letter)

If applying for the higher level of funding, the collaborator(s) must provide a letter of collaboration describing his/her involvement in the proposed work. It

should be clear that the success of the project depends on the unique skills and contributions of each collaborator.

- Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract (one-page limit)
- Attachment 4: Public Abstract (one-page limit)
- Attachment 5: Statement of Work (SOW, three-page limit)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement (one-page limit)

Explain how the expected results of the study will make an original and important contribution to the goal of advancing NF research and its impact on patient care. Describe the potential clinical applications, benefits, and risks.

- Attachment 8: Innovation Statement (one-page limit)

Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.

Although not all-inclusive, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame the innovative features:

- Study concept: Investigation of a novel idea and/or research question.
- Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
- Novel method or technology: Development of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- Attachment 9: Statement of Collaboration (required if requesting higher level of funding)

If applying for the higher level of funding, the PI must submit a statement that identifies the collaborating investigator and addresses all criteria described in Section I.B. It should be clear that the success of the project depends on the unique skills and contributions of each partner.

- Attachment 10: Federal Agency Financial Plan (if applicable)
- Attachment 11-15: Subaward Detailed Budget and Justification (if applicable)

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support

- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

4. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess.htm>.

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in decreasing order of importance.

- **Research Strategy and Feasibility (preliminary data are required)**
 - How well the preliminary data and rationale supports the research project.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.

- If the application includes the Optional Qualified Collaborator, how well the nature of the collaboration supports the research project.
- **Impact**
 - How the project addresses a critical problem in NF and/or Schwannomatosis research or patient care.
 - How the project makes an original and important contribution to the goal of advancing research on the treatment of NF or on the quality of life of patients.
- **Personnel**
 - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
 - How the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
 - Optional Qualified Collaborator(s) (if applicable)
 - Whether the collaborator's experience, expertise, and involvement in the study significantly contributes to the project such that the proposed work could not be accomplished without his/her involvement.
 - Whether the collaborator(s) meets the criteria for an Optional Qualified Collaborator as verified by the Statement of Collaboration (i.e., the collaborator[s] possesses appropriate NF research experience if the PI does not; the collaborator[s] is at or above the level of Assistant Professor [or equivalent]; the collaborator[s] is contributing at least 10% level of effort).
- **Innovation**
 - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies.
 - How the proposed research represents more than an incremental advance upon published data.
 - How the potential gain justifies the perceived risk.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - How the quality and extent of institutional support are appropriate for the proposed research.

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program’s broad portfolio:

- Ratings and evaluations of the peer reviewers,
- Program portfolio balance,
- Programmatic relevance,
- Relative innovation and impact, and
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals, objectives, and areas of encouragement of the program.

Investigators are urged to view previously NFRP-funded proposals at <http://cdmrp.army.mil/search.aspx?program=NFRP> to aid in the development of applications that represent novel areas of research, as portfolio balance is an important consideration at programmatic review to ensure that gaps in the research are adequately addressed.

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur.

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by email from CDMRP with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at <http://cdmrp.army.mil/research.htm>.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this funding opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

B. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Website: <https://cdmrp.org>
Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the [Grants.gov](http://www.grants.gov) ([http://www.grants.gov/](http://www.grants.gov)) portal should be directed to the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.