Program Announcement

Department of Defense

Congressionally Directed Medical Research Programs

Neurofibromatosis Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-13-NFRP-IIRA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), **June 27, 2013**
- **Application Submission Deadline:** 11:59 p.m. ET, **July 11, 2013**
- **Peer Review: August 2013**
- **Programmatic Review: November 2013**

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Neurofibromatosis Research Program (NFRP) are being solicited by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The NFRP was initiated in 1996 to provide support for research of exceptional scientific merit that promotes the understanding, diagnosis, and treatment of neurofibromatosis (NF) including neurofibromatosis type 1 and type 2 and schwannomatosis. Appropriations for the NFRP from FY96 through FY12 totaled $242.85 million (M). The FY13 appropriation is $15M.

B. FY13 NFRP Vision and Areas of Emphasis

The vision of the FY13 NFRP is to decrease the clinical impact of NF. Toward this end, the NFRP seeks to: support innovative, high-impact research that will foster new directions for and address neglected issues in NF research; sponsor multidisciplinary and multi-institutional collaborations that will bring new perspectives to the field; 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.

Areas of Emphasis: The FY13 NFRP strongly encourages research applications that specifically address the critical needs of the NF community in one or more of the following Areas of Emphasis:

- Cognitive and social dysfunction in the setting of NF;
- Drug discovery for the treatment of NF;
- Heterogeneity of neurofibromas and other NF-related tumors using genomics, epigenetics, systems biology, or other similar approaches;
- Manifestations of NF post-adolescence;
- Novel disease markers such as imaging and proteomics of NF;
- Pain in the setting of NF.

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/resources/nfrpresources. Investigators are urged to leverage and contribute to these resources and include a sharing and distribution plan in the application for data and resources generated during the performance of the proposed research project. For more guidance on data sharing, refer to the General Application Instructions, Appendix 4, Section K.

C. Award Information

The NFRP Investigator-Initiated Research Award mechanism was first offered in FY96. Since then, 401 Investigator-Initiated Research Award applications have been received, and 104 have been recommended for funding.

The NFRP Investigator-Initiated Research Award supports innovative basic and clinically oriented research that will:

- Provide insight into the development of NF, or into particular lesions or abnormalities that occur as a result of NF;
- Result in substantial improvements over today's approach to the diagnosis and treatment of NF; and
- Have an impact on the quality of life of persons with NF.

Applications must include preliminary or published data that is relevant to NF and the proposed research project.

Optional Features: The IIRA mechanism allows for the inclusion of ***one of the following options***, which would allow the applicant to request additional funds as described in Section I.E., Funding. The NFRP reserves the right to fund an application at a lower level if the optional feature does not meet the eligibility criteria or intent of the mechanism.

Optional Qualified Collaborator: The FY13 NFRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic scientists and biotechnology/pharmaceutical industry scientists. Special consideration will be given to collaborations that bring new perspectives from other disciplines, or bring new investigators into the NF field. ***Although more than one collaborator may participate in the application only one can be named for this option.***

The Principal Investigator (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 biographical sketch (see Section II.C.3) and a letter of collaboration (see Section II.C.2) describing his/her involvement in the proposed research project. It should be clear that the success of the proposed research project depends on the complementary skills and contributions of both the PI and collaborator.

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

Optional Nested Postdoctoral Traineeship: The intent of the Nested Postdoctoral Traineeship is to enable doctoral degree graduates to either extend ongoing research related to NF or broaden the scope of their research to include work relevant to NF under the guidance of a designated mentor who is participating in the application. It is expected that the training will provide a valuable opportunity to further develop the experience necessary to advance the trainee's research career in NF.

A trainee is defined as a postdoctoral fellow with 5 years or less of postdoctoral experience at the application submission deadline. Eligible postdoctoral candidates must have successfully defended a doctoral thesis and completed all academic requirements at the application submission deadline.

The trainee must submit a transcript from all graduate institutions attended (see Section II.C.2) and a biographical sketch (see Section II.C.3). Additionally, the trainee must submit a training statement (see Section II.C.2) that will highlight how the mentor's record of accomplishment and the research environment will provide the necessary experience to advance the trainee's research career in NF.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the Congressionally Directed Medical Research Programs (CDMRP) eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/. PIs wishing to apply for funding for a clinical trial should utilize the FY13 NFRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-13-NFRP-CTA).

The CDMRP intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- PIs must be ***at or above*** the level of Assistant Professor (or equivalent).
- The Optional Qualified Collaborator must be ***at or above*** the level of Assistant Professor (or equivalent) and meets at least a 10% level of effort on the proposed research project.
- The Optional Nested Postdoctoral Trainee must have successfully defended a doctoral thesis and completed all academic requirements and have 5 years or less of postdoctoral experience at the time of application submission deadline.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **$525,000** plus indirect costs. If requesting an Optional Qualified Collaborator the maximum allowable direct costs for the entire period of performance are **$575,000** plus indirect

costs. If requesting an Optional Nested Postdoctoral Traineeship the maximum allowable direct costs for the entire period of performance are **$675,000** plus indirect costs.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- Applications requesting the higher level of funding that do not include or meet requirements for an Optional Qualified Collaborator **or** Optional Nested Postdoctoral Traineeship will have the budget reduced as appropriate.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply and are so noted in Section II.C.4. of the General Application Instructions.***

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (No clinical trials allowed)
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately $3.68M of the $15.00M FY13 appropriation to fund approximately 4 Investigator-Initiated Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

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

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-13-NFRP-IIRA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (https://cdmrp.org/).

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

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest – Tab 3**

  FY13 NFRP Integration Panel (IP) members (http://cdmrp.army.mil/nfrp/panels/panels13) should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the Area(s) of Emphasis under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. ***Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.***

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

  No additional documents are required.

C. Application Submission Content and Form

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The

application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

Grants.gov application package components: For the Investigator-Initiated Research Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

     Describe the proposed research project in detail using the outline below. ***The Project Narrative must include preliminary or published data that is relevant to NF and the proposed research project.***

     - **Background:** Present the ideas and reasoning behind the proposed research project. Cite relevant literature. Describe previous experience most pertinent to the proposed research project. Include relevant preliminary data.
     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
     - **Specific Aims:** Concisely explain the proposed research project's specific aims to be funded by this application. If the proposed research project is part of a larger study, present only tasks that this award would fund.
     - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific peer review. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan if appropriate for the research proposed. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Clearly describe the tissue or tumor type to be studied, where applicable (e.g., encapsulated versus diffuse plexiform neurofibroma). ***This award may not be used to conduct clinical trials.***

   - **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***

- References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed research project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must 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 proposed research project.
- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed research project.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Transcripts (required for Optional Nested Postdoctoral Traineeship): Include a copy of the trainee's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts.
- Data and Research Resources Sharing Plan (if applicable): Describe how data and resources generated during the performance of the proposed research project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers do not have access to the full application and therefore rely on the technical abstract for appropriate description of the proposed research project's key aspects. Clarity

and completeness within the space limits of the technical abstract are highly important.

- Background: Present the ideas and reasoning behind the proposed research project.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the proposed research project.
- Study Design: Briefly describe the study design including appropriate controls. If tumors or derived cell lines will be studied, the name and definition of the materials should be included (e.g., name of the cell or pathological classification of the tissue).
- Innovation: Briefly describe how the proposed research project is innovative.
- Impact: Briefly describe how the proposed research project will have an impact on NF research or patient care.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  Lay abstracts should be written using the outline below. The lay abstract is used by consumer reviewers along with other components of the application package.

  - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed research project.
    - Do not duplicate the technical abstract.
  - Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
  - What are the likely contributions of the proposed research project to advancing the field of NF research or patient care?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf." Identify the FY13 NFRP Area(s) of Emphasis that the application addresses, if applicable, and explain how the expected results of the proposed research project will make an original and important contribution to the goal of advancing NF research and/or its impact on patient care. Describe the potential clinical applications, benefits, and risks.

- **Attachment 7: Innovation Statement (one-page limit):** Upload as "Innovation.pdf." Summarize how the proposed research project 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 research project 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 treating NF.
  - 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 8: Statement of Collaboration (required if requesting an Optional Qualified Collaborator, two-page limit).** Upload as "Collaboration.pdf." The following components should be addressed:

  - The PI must identify the Optional Qualified Collaborator and address all criteria described above in Section I.C., Award Information.
  - In addition, the Optional Qualified Collaborator must describe how he/she will significantly contribute to the proposed research project such that it could not be accomplished without his/her involvement.
  - It should be clear that the success of the proposed research project depends on the complementary skills and contributions of both the PI and collaborator.

- **Attachment 9: Statement of Traineeship (required if requesting an Optional Nested Postdoctoral Traineeship; three-page limit)** Upload as "Traineeship.pdf." Identify the mentor. Describe the research training plan including a timeline, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Describe how the research being performed under the mentor's direction is relevant to NF. Describe the mentor's history of training other postdoctoral fellows. Specify how the mentor will assist in training the postdoctoral fellow for a career in NF research. Describe the laboratory's resources to demonstrate the adequacy of support for the trainee's project.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. ***Note: Some of the items in this attachment may be made available for programmatic review.***

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

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

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, United States Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the Department of Defense (DoD) and NFRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and

evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

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

   - **Research Strategy and Feasibility**
     - 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 proposed research project.
     - How well the PI identifies potential problems and addresses alternative approaches.
     - If the application includes an Optional Qualified Collaborator, how well the nature and extent of the collaboration supports the research project.
   - **Impact**
     - How well the applicant addresses one or more of the NFRP Areas of Emphasis, if applicable, and/or a critical problem in NF research or patient care.
     - How well the proposed research will, if successful, make an original and important contribution toward the goal of advancing NF research and/or its impact on patient care.
   - **Personnel**
     - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the proposed research project.
     - How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed research project.
     - Optional Qualified Collaborator (if applicable)
       - Whether the collaborator's experience, expertise, and involvement represents a significant contribution to the proposed research project such that it could not be accomplished without his/her involvement.
       - Whether the collaborator meets the criteria for an Optional Qualified Collaborator as verified by the Statement of Collaboration.

- Optional Nested Postdoctoral Trainee applicants (if applicable):
  - How well the qualifications of the Nested Postdoctoral Trainee will add to the proposed research project.
  - How the Nested Postdoctoral Trainee will benefit from participation in the proposed research project.

- **Innovation**
  - To what extent the proposed research is innovative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
  - How well the proposed research represents more than an incremental advance upon published data.

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

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity

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

2. **Programmatic Review:** To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

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

   b. **Relevance to the mission of the DoD and FY13 NFRP, as evidenced by the following:**
      - Adherence to the intent of the award mechanism
      - Program portfolio composition, with consideration of the FY13 Areas of Emphasis
      - Programmatic relevance
      - Relative impact and innovation

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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

IV. 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:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- A FY13 NFRP Integration Panel (IP) 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 document. A list of the FY13 NFRP IP members can be found at http://cdmrp.army.mil/nfrp/panels/panels13.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

D. Award Transfers

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

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload Statement of Collaboration (Collaboration.pdf) as Attachment 8 (if applicable).	
	Upload Statement of Traineeship (Traineeship.pdf) as Attachment 9 (if applicable).	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	