

# Announcement of Federal Funding Opportunity

## Summary

### I. GENERAL INFORMATION

**A. Title of Award:** Clinical Trial Development Award (CTDA).

**B. Program Name:** Department of Defense (DOD) Fiscal Year 2003 (FY03) Neurofibromatosis Research Program (NFRP).

**C. Funding Opportunity Number:** DAMD17-NF03-CTDA.

**D. Agency Name:** US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

### E. Agency Contact(s)

**1. Questions related to the Program, proposal format, or required documentation** may be addressed to the CDMRP at:

Phone: 301-619-7079  
Fax: 301-619-7792  
E-mail: [cdmrp.pa@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (DAMD17-NF03-CTDA)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

**2. Questions related to electronic submission:** The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Website: <https://cdmrp.org/proposals> (the proposal submission website)  
E-mail: [help-proposals-cdmrp@cdmrp.org](mailto:help-proposals-cdmrp@cdmrp.org)

**F. Anticipated Instrument Type(s):** Grants/Cooperative Agreements.

**G. Catalog of Federal Domestic Assistance (CFDA) Number(s):** 12.420; Military Medical Research and Development.

**H. Website Address to Access Application Package:** Proposals must be submitted electronically at <https://cdmrp.org/proposals>. The website contains all the information, forms, documents, and links you will need to apply.

## II. FUNDING OPPORTUNITY DESCRIPTION

The intent of Clinical Trial Development Award is to provide support to establish the necessary collaborations and develop the necessary infrastructure, including a coordination core, for the foundation of a multi-institutional NF-related clinical trial. The goal of these awards is the development of clinical trials with the potential to have a major impact on the treatment of either neurofibromatosis 1 (NF1), NF2, or Schwannomatosis.

## III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately \$0.5 million (M) is available for this award mechanism.
- Funding for Clinical Trial Development Awards can be requested for \$150,000 for 1 year, inclusive of both direct and indirect costs.
- Depending on the number and quality of the applications, it is anticipated that approximately three proposals will be funded.

## IV. ELIGIBILITY INFORMATION

**A. Applicants:** Applicants from all academic levels are eligible to submit proposals.

**B. Institutions:** Eligible institutions include for-profit, non-profit, public, and private organizations. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

**C. Cost Sharing:** Not required.

**D. Other Eligibility Criteria:** Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

## V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

**A. Proposal Information:** Applicants are required to submit the Proposal Information prior to upload of the proposal. Complete the Proposal Information as described at <https://cdmrp.org/proposals>.

**B. Proposal Preparation:** All proposals must be converted into an electronic PDF (Portable Document Format) file for electronic proposal submission. Please see the Full Text of Program Announcement for details.

**C. Submission Dates and Times:** Deadline Date: August 20, 2003. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

**D. Electronic Submission Requirements: Electronic submission is required.** No paper copy submissions will be accepted. Proposals must be submitted electronically at <https://cdmrp.org/proposals>. Please see the Full Text of Program Announcement for details.

## **VI. PROPOSAL REVIEW INFORMATION**

Clinical Trial Development Award proposals will be scientifically and programmatically reviewed by the NFRP Integration Panel (IP), which is composed of scientific experts, clinicians, and consumer advocates. The IP will determine which proposals best fulfill the intent of the award mechanism.

## **VII. AWARD ADMINISTRATION INFORMATION**

**A. Award Notices and Administrative Requirements:** Details of award notification procedures and administrative requirements including Regulatory Compliance and Quality documents (Certificate of Environmental Compliance, and Safety Program Plan) can be found in the Full Text of Program Announcement.

**B. Reporting Requirements:** Annual reporting requirements apply.

## **VIII. OTHER INFORMATION**

Details pertaining to Disclosure of Proprietary Information outside the Government, Government Obligation, Information Service, Inquiry Panel Review, and Title to Inventions and Patents can be found in the Full Text of the Program Announcement.

# Full Text of Program Announcement

## I. GENERAL INFORMATION

**A. Title of Award:** Clinical Trial Development Award (CTDA).

**B. Program Name:** Department of Defense (DOD) Fiscal Year 2003 (FY03) Neurofibromatosis Research Program (NFRP).

**C. Funding Opportunity Number:** DAMD17-NF03-CTDA.

**D. Agency Name:** US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

### E. Agency Contact(s):

**1. Questions related to the Program, proposal format, or required documentation.** Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079  
Fax: 301-619-7792  
E-mail: [cdmrp.pa@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (DAMD17-NF03-CTDA)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

**2. Questions related to electronic submission:** Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Website: <https://cdmrp.org/proposals> (the proposal submission website)  
E-mail: [help-proposals-cdmrp@cdmrp.org](mailto:help-proposals-cdmrp@cdmrp.org)

**F. Anticipated Instrument Type(s):** The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

**Fax:** 301-619-2937  
**E-mail:** [q&a.baa@det.amedd.army.mil](mailto:q&a.baa@det.amedd.army.mil)  
**Mail:** Director  
US Army Medical Research Acquisition Activity  
ATTN: MCMR-AAA  
820 Chandler Street  
Fort Detrick, MD 21702-5014

**G. Catalog of Federal Domestic Assistance (CFDA) Number 12.420:** Military Medical Research and Development.

**H. Website to Access Application Package:** Proposals must be submitted electronically at <https://cdmrp.org/proposals>. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Section E.1 above.

## II. FUNDING OPPORTUNITY DESCRIPTION

**A. Program History:** The Clinical Trial Development Award is part of the DOD NFRP, which was established in FY96 to promote research directed toward decreasing the impact of neurofibromatosis (NF). Appropriations for the NFRP since FY96 total \$110.3 million (M). The program history of the FY96-02 NFRP is shown in Table 1. The FY03 appropriation is \$20M. The Clinical Trial Development Award is a new award mechanism for the NFRP and is being offered for the first time in FY03.

**Table 1: History of the DOD's Peer Reviewed NFRP**

<b>Program History</b>	<b>FY96-01</b>	<b>FY02<sup>1</sup></b>
Congressional Appropriations for NFRP	\$69.3M	\$21M
Total Proposals Received	223	76
Total Proposals Funded	85	~17

<sup>1</sup> Award negotiations will be finalized by September 2003.

**B. Program Objectives:** The overall goal of the FY03 NFRP is to develop effective therapies for NF1, NF2, and Schwannomatosis. Within this context, support for the training of NF researchers, the encouragement of established scientists in the field, and the attraction of new scientific expertise from other fields are essential to the NF community. Proposals to the NFRP are sought across all areas of laboratory, clinical, behavioral, and epidemiological research including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations may be submitted from any eligible institutional source. Proposals are encouraged from investigators working at Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

**C. Award Mechanism Description:** Due to the scope and magnitude of the NFRP Clinical Trial Awards, the Clinical Trial Development Award has been instituted to provide support to establish the necessary collaborations and develop the preliminary infrastructure, including a coordination core, which will provide the foundation for submission of a Clinical Trial Award proposal. The goal of these awards is the development of clinical trials with the potential to have a major impact on the treatment of NF1, NF2, or Schwannomatosis.

Plans should be included in the Clinical Trial Development Award submission for:

- Communication between the multiple collaborating institutions,
- Patient accrual including recruitment schedule,

- Real-time data transfer,
- The handling and distribution of specimen and imaging products, and
- Statistical analysis.

In addition, a plan must be in place to obtain the necessary Institutional Review Board (IRB) approvals for the proposed clinical trial for each institution.

**One product of the Clinical Trial Development Award will be the requirement to submit a NFRP Clinical Trial Award in FY04, pending receipt of funds by the NFRP.** Another product of this award mechanism will be a detailed clinical protocol or “Manual of Operations and Procedures” for the proposed clinical trial. This protocol should be submitted as part of the resulting application for the Clinical Trial Award in FY04.

### III. AWARD INFORMATION

Funding for the Clinical Trial Development Award in FY03 is up to \$150,000 per award inclusive of both direct and indirect costs for 1 year. These funds can cover administrative support including salary, meetings and related travel among participating investigators, database generation and software development, purchase of computers, design of web sites, teleconferences, and other costs directly associated with planning and developing the clinical trial. Travel costs may not exceed \$1,800 per year per investigator. *Funds may not be used to support laboratory research.*

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. Approximately \$0.5 million (M) is available to the NFRP for the Clinical Trial Development Awards. Depending on the number and quality of the applications, it is anticipated that approximately three proposals will be funded.

**Please note there is no guarantee that funds will be available for Clinical Trial Awards in FY04.**

### IV. ELIGIBILITY INFORMATION

**A. Applicants:** All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined below.

**B. Institutions:** Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

**C. Cost Sharing:** Cost sharing is not a requirement for this award.

#### D. Other Eligibility Criteria

**1. Duplicate Submissions:** Submission of the same research project to the FY03 NFRP under different award mechanisms or to other CDMRP programs is not allowed. This includes duplicate submissions under different award mechanisms by different Principal Investigators (PIs). The Government reserves the right to reject duplicative proposals.

**2. HBCU/MI:** A goal of the DOD is to allocate funds for the CDMRP's peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.<sup>1</sup> Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/funding/pdf/minfrp030703.pdf> under Minority Institutions.

**3. Administrative Compliance Issues:** Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a lower global priority score.

Failure to comply with any of the five items listed below will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Cost estimate is missing.
- Proposal is submitted after the deadline.
- Required administrative documentation is not included.

For any other sections of a proposal with a defined page limit, any pages over the specified limit will be removed from the proposal and not forwarded for peer review.

Unless specifically requested by the CDMRP, any material submitted after the submission deadline will not be forwarded for peer review.

## V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

**A. Proposal Components Summary:** This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.
- **Statement of Work (SOW):** The SOW is entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the "File Upload" tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the "File Upload" tab.

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<sup>1</sup>Executive Orders 12876, 12900, and 13021

- **Regulatory Compliance and Quality (RCQ) Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance Form are each uploaded as separate PDF files under the “File Upload” tab.

The Contract Representative (or equivalent) from the applicant’s institution is responsible for the following:

- **US Army Medical Research Acquisition Activity (USAMRAA) Documents:** The institute’s currently negotiated “Rate Agreement,” “Certifications and Assurances for Assistance Agreements” and the “Representations for Assistance Agreements” are to be uploaded as separate PDF files under the Contract Representative’s My Profile” tab.
- **Approval:** The Contract Representative must provide approval of all proposal components (Proposal Information, SOW, Proposal, Budget Information, and RCQ documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) August 20, 2003. Otherwise, the entire proposal will be considered to be a “LATE” submission and will not be forwarded for review.

**B. Proposal Information:** Applicants are required to submit the Proposal Information, Parts 1 and 2, (referred to in previous years as the “Proposal Cover Booklet”) prior to upload of the proposal and the budget information. Complete the Proposal Information as described in <https://cdmrp.org/proposals>. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** All applicants considering the submission of a proposal in response to this Program Announcement are expected to submit an electronic Letter of Intent no later than 4 weeks prior to the August 20, 2003 deadline. To accomplish this, the applicant should complete Part 1 of the Proposal Information section at <https://cdmrp.org/proposals>, then save the information by clicking on the “Save and Forward Letter of Intent” button. This information may be changed at any time until the applicant submits the final Proposal Information by clicking on the “Submit Final” button.

**C. SOW – 11,400-character limit, including spaces (approximately two pages):** The SOW is captured as a data field under the “SOW/Abstract” tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW or “cut and paste” it from a word processing application into the data field. Sample SOWs can be found at <https://cdmrp.org/samples.cfm>.

The SOW is a concise restatement of the proposal that outlines, step by step, how each of the major goals or objectives of the proposed activities will be accomplished during the timeline for which the USAMRMC will provide financial support.

As appropriate, the SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims),
- Identify the timeline and milestones for the work over the period of the proposed effort,
- Identify methods, and
- Identify products/deliverables for each phase of the project.



**D. Proposal Abstracts** – Abstracts are not required for the Clinical Trial Development Award application process, but the data fields must be completed for the final submission. Therefore, the applicant should type “N/A” into both abstract data fields.

## **E. Proposal**

**1. Format:** All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the “File Upload” tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files, but applicants should keep in mind that some reviewers work from black and white printed copies. Applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm).

**2. Title/Referral Page: No page limit.** Complete the Title/Referral Page, which can be downloaded at <https://cdmrp.org/programAnnouncements.cfm>. Complete each section as described:

- a. Proposal title (up to 160 characters).
- b. Proposal log number (this will be automatically provided when the Proposal Information is completed and saved).
- c. PI’s full name (first, middle initial, last).
- d. Submitting Institution.
- e. Award mechanism: Type in “Clinical Trial Development Award.”

- f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.
- g. Conflicts of interest: To avoid real and apparent conflicts of interest during the peer review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subcontractors. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and role(s) on the proposed project or perceived conflicts of interest.

**3. Table of Contents/Checklist: Start section on a new page.** Prepare a [Table of Contents/Checklist](#), with page numbers, using the form provided. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. If possible, provide headers throughout the proposal that include the PI's name (last name, first name, middle initial) and proposal log number (this will be automatically provided when the electronic Proposal Information is saved).

**4. Main Body: Start section on a new page; six-page limit inclusive of any figures, tables, graphs, and photographs.** It is the responsibility of the investigator to clearly articulate how the proposed plan for a clinical trial meets the intent of the mechanism. The proposal body should address the review criteria as outlined in Section VI-B of this program announcement and should include the following five parts:

- A description of the clinical trial proposed, and relevance of the trial for treating NF1, NF2, or Schwannomatosis.
- Management and communication plans for the Clinical Trial Development Award.
- Preliminary management and communication plans for submission to the Clinical Trial Award mechanism including logistics, real-time data transfer and management, handling and distribution of specimens and imaging products (as appropriate), and patient recruitment and accrual.
- A statistical plan for the proposed clinical trial.
- Key participants and their contributions (additional information on collaborators can be included in the Biographical Sketch section, see item 7 below).

**5. Abbreviations: Start section on a new page; one-page limit.** Provide a list of all acronyms, abbreviations, and symbols used.

**6. References: Start section on a new page; no page limit.** List all relevant references 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).

**7. Biographical Sketches: Three-page limit per individual.** Biographical sketches should be included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower priority scores. The [Biographical Sketch form](#) may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

**8. Administrative Documentation: No page limit.** Submit only material specifically requested or required in this program announcement. **This section is not for additional data, figures, or other similar information.** Unrequested material that is submitted may be construed as an attempt to gain a competitive advantage and will be removed; it may be grounds for administrative rejection of the proposal.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the submitted proposal.

The first item in this section must be a list of all the items included in the Administrative Documentation section.

- Provide letter(s) of support from any collaborating individuals or institutions.
- Provide letter(s) of commitment from institutions that will be participating in the clinical trial.

**F. Budget Information:** Budget Information includes the [CTDA Cost Estimate form](#). Budget Information is uploaded under the “File Upload” tab of the CDMRP eReceipt system.

**1. Funding Restrictions:** Funding for the Clinical Trial Development Award in FY03 is up to \$150,000 per award inclusive of both direct and indirect costs for 1 year. These funds can cover administrative support including salary, meetings and related travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning and developing the clinical trial. Travel costs may not exceed \$1,800 per year per investigator. *Funds may not be used to support laboratory research.*

**Please note there is no guarantee that funds will be available for Clinical Trial Awards in FY04.**

**2. Cost Estimate Form Instructions:** Budget is an important consideration in both scientific and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. The [CTDA Cost Estimate form](#) for your proposal must be uploaded as a PDF file, separate from the proposal.

The following section provides instructions for preparing the CTDA Cost Estimate form. All amounts entered should be in U.S. dollars.

**a. Personnel**

**i. Name:** Starting with the PI, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.

**ii. Role on Project:** Identify the role of each individual listed on the project. Describe his or her specific functions in the “Justification” section of the CTDA Cost Estimate form.

**iii. Type of Appointment (Months):** List the number of months per year reflected in an individual’s contractual appointment with the applicant organization. The DOD staff

assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent, note this with an asterisk (\*) and provide a full explanation in the “Justification” section of the Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

**iv. Annual Base Salary:** Enter the annual institutional base salary for each individual listed for the project.

**v. Percentage of Effort on Project:** The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

**vi. Salaries Requested:** Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual’s institutional base salary by the percentage of effort on the project.

**vii. Fringe Benefits:** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors. Documentation to support the fringe benefits should be provided.

**viii. Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.

**b. Consultant Costs:** Provide an itemized list of all consultant costs. In addition, regardless of whether funds are requested, provide the names and organizational affiliations of all consultants.

**c. Major Equipment:** It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.

**d. Travel Costs:** Travel costs may not exceed \$1,800 per year per investigator.

**e. Other Expenses:** Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

**f. Indirect Costs (overhead, general and administrative, and other):** The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

**g. Justification (third page of the Detailed Cost Estimate form):** Each item in the budget should be clearly justified under the “Justification” section of the CTDA Cost Estimate form.

**G. Regulatory Compliance and Quality Requirements:** Completed and signed copies of the “[Certificate of Environmental Compliance](#)” and “[Principal Investigator Safety Program Assurance Form](#)” must be uploaded under the “File Upload” tab of the CDMRP eReceipt system as separate PDF files.

**H. USAMRAA Documents:** A copy of the institution’s negotiated “Rate Agreement,” the “[Certifications and Assurances for Assistance Agreements](#)”, and the “[Representations for Assistance Agreements](#)” must be uploaded by the Contract Representative from the Sponsored Programs Office. These documents must be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab of the CDMRP eReceipt system.

**I. Submission Dates and Times:** Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution’s Sponsored Programs Office (or equivalent) by the deadline. If your proposal is submitted and approved electronically after the deadline, it will not be considered for review.

**The timeline for Clinical Trial Development Awards is:**

On-Line Letter of Intent:	As soon as possible but no later than July 23, 2003.
On-Line Proposal Information:	Prior to proposal submission.
<b>Proposal Submission/Approval Deadline:</b>	<b>5:00 p.m. Eastern time August 20, 2003.</b>
Proposal Review:	September 2003
Notification Letter:	Approximately 4 weeks after proposal review.
Award Start Date:	As early as November 2003.

**J. Electronic Submission Requirements:** Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at <https://cdmrp.org/proposals>.

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- **If final approval is not accomplished by the submission deadline, the proposal will be considered to be a “LATE” submission and will not be considered for review.**
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the CTDA Cost Estimate form. Budget Information must be uploaded under the “File Upload” tab of the CDMRP eReceipt system.

- The RCQ documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed PI Safety Program Assurance Form. These must be uploaded under the “File Upload” tab of the CDMRP eReceipt system.

## VI. PROPOSAL REVIEW INFORMATION

**A. Proposal Review and Selection Overview:** Clinical Trial Development Award proposals will be scientifically and programmatically reviewed by the NFRP Integration Panel (IP), which is composed of scientific experts, clinicians, and consumer advocates. The IP will determine which proposals best fulfill the intent of the award mechanism.

**B. Review Criteria:** Clinical Trial Development Award proposals will be evaluated according to the following criteria:

- **Clinical Relevance:** Does the applicant provide a clear scientific rationale for the proposed clinical trial? Does the proposed clinical trial address an important problem related to the treatment of NF, and is it likely to have a substantial clinical impact?
- **Trial Management:** Have the logistical aspects of the proposed clinical trial been appropriately addressed? Is there a plan for communication between the collaborating institutions? Is there a real-time data management plan? Is there a plan for the handling and distribution of specimens and imaging products? Is there an initial plan for patient accrual? Has the likelihood of subject attrition been addressed? Is the preliminary recruitment schedule reasonable?
- **Statistical Plan:** For the proposed clinical trial, is a clear statistical plan, including sample size projections and power analysis, outlined in the proposal? Is the appropriate statistical expertise represented on the research team?
- **Principal Investigator and Personnel:** Does the PI have expertise in NF? Are the PI and other scientific personnel appropriately trained and well suited to carry out this work? Is there representation from all the areas of expertise needed to conduct the clinical trial successfully?
- **Institutional Commitment:** Is there evidence of institutional commitment to the proposed clinical trial at each participating center?

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

## VII. AWARD ADMINISTRATION INFORMATION

**A. Award Notices:** After the evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency’s decision in October 2003.

**B. Administrative Requirements:** All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support. To be eligible for award, a prospective recipient should meet certain minimum standards

pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (Office of Management and Budget Circular A-110).

**Any change in the institution, the PI, and/or the SOW will require that the PI resubmit contact information.** Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

**C. Award Negotiation:** Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the proposed SOW and associated budgets may be required.

Note that the award start date will be determined during the negotiation process.

#### **D. Regulatory Compliance and Quality Review**

**1. Overview:** Concurrent with the USAMRAA negotiations, RCQ will review the Certificate of Environmental Compliance, and PI Safety Program Assurance form submitted with the proposal, as well as RCQ documents related to Research Involving Animal Use and Research Involving Human Subjects/Anatomical Substance Use submitted upon request to ensure that Army regulations are met.

**2. Certificate of Environmental Compliance:** The [Certificate of Environmental Compliance](#) should be submitted with the proposal. If multiple research sites/institutions are funded in your proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

**3. Safety Program Documents:** The [Principal Investigator Safety Assurance Form](#) should be submitted with the proposal.

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at <http://mrmc-www.army.mil/crprcqsohdfspan.asp>. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at <http://mrmc-www.army.mil/docs/rcq/FY02FSPAappendix.doc>.

If multiple research sites/institutions are funded in your proposal, then a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

**E. Reporting:** Reporting requirements consist of a report at the conclusion of the 1-year award that summarizes the goals and accomplishments during the year.

### **VIII. OTHER INFORMATION**

**A. Disclosure of Proprietary Information outside the Government:** By submission of a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further

disclosed or utilized. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding will not be subject to public release.

**B. Government Obligation:** Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

**C. Information Service:** Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. To the extent practical, all other sources should also be consulted for the same purpose.

**D. Inquiry Review Panel:** Applicants can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

**E. Title to Inventions and Patents:** In accordance with the Bayh-Dole Act (35 USC 200 et seq.<sup>2</sup>), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

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<sup>2</sup>Title 35, United States Code, Section 200 et seq.



## IX. ACRONYM LIST

AVI	Audio Video Interleave
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CTA	Clinical Trial Award
CTDA	Clinical Trial Development Award
DOD	Department of Defense
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IDEA	Idea Award
IIRA	Investigator-Initiated Research Award
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MPEG	Moving Picture Experts Group
NF	Neurofibromatosis
NFRP	Neurofibromatosis Research Program
NIA	New Investigator Award
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SOW	Statement of Work
TDA	Therapeutic Development Award
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave