Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

A. Title of Award: Clinical Trial Award (CTA)

B. Program Name: DOD FY04 Neurofibromatosis Research Program (NFRP).

C. Funding Opportunity Number: NF04-CTA.

D. Agency Name: 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
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-PLF (NF04-CTA)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website: https://cdmrp.org/proposals (the proposal submission website)
E-mail: 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.

I. Award/Regulatory Approval: Please note, each award mechanism has specific requirements regarding human subjects and animal use. Please see the full text of the Program Announcement for details pertaining to this award mechanism.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

II. FUNDING OPPORTUNITY DESCRIPTION

The goal of the Clinical Trial Award mechanism is to sponsor novel clinical research, specifically a Phase I or Phase II clinical trial that has the potential to substantially improve today's approach to the treatment and/or management of neurofibromatosis 1 (NF1), NF2, and/or Schwannomatosis.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately $3.0 million (M) is available for this award mechanism.
- Depending on the number and quality of applications, it is anticipated that approximately one to two proposals will be funded.
- Although there are no total dollar amount restrictions to these awards, programmatic priority will be given to smaller-scale, cost-efficient clinical trials. The NFRP is particularly interested in proposals for Phase I clinical trials that are less than $500,000. Funding for Phase I clinical trials can be requested for up to 3 years, whereas funding for Phase II clinical trials can be requested for up to 4 years.

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.

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations.

C. Cost Sharing: It is expected that institutions will cost share. Please see "Major Equipment" located in Subsection V.F.2.c of the Full Text of Program Announcement for details.

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: June 29, 2004. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institutional 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

The CDMRP uses a two-tiered review process for proposals: scientific peer review, followed by programmatic review. Details of both tiers of review can be found in the Full Text of Program Announcement.

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, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of Program Announcement.

B. Reporting Requirements: Annual reporting requirements apply.

Full Text of Program Announcement

I. GENERAL INFORMATION

A. Title of Award: Clinical Trial Award (CTA).

B. Program Name: DOD FY04 Neurofibromatosis Research Program (NFRP).

C. Funding Opportunity Number: NF04-CTA.

D. Agency Name: 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
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-PLF (NF04-CTA) 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 number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website:	https://cdmrp.org/proposals (the proposal submission website)
E-mail:	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:	qa.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 Subsection E.1 above.

I. Award/Regulatory Approval: Please note, each award mechanism has specific requirements regarding human subjects and animal use.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Clinical Trial Award is part of the DOD NFRP, which was established in Fiscal Year 1996 (FY96) to promote research directed toward decreasing the impact of neurofibromatosis (NF). Appropriations for the NFRP since FY96 total $130.3 million (M). The program history of the FY96-03 NFRP is shown in Table 1. The FY04 appropriation is $20M.

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

Program History	FY96-02	FY03
Congressional Appropriations for NFRP	$90.3M	$20M
Total Proposals Received	299	62
Total Proposals Funded	103	~13[1]
Clinical Trial Award Proposals Received	9	2
Clinical Trial Award Proposals Funded	2	0

[1] Award negotiations will be finalized by September 2004.

B. Program Objectives: The overall goal of the FY04 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 under-represented 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: The intent of Clinical Trial Awards is to sponsor patient-oriented research with the potential to have a major impact on the treatment and/or management of NF1, NF2, and/or Schwannomatosis. Clinical Trial Awards will support Phase I and Phase II clinical trials; separate discussions are provided below for each type of clinical trial. Applicants should clearly specify in their proposals for which type of Clinical Trial Award they are applying. The ultimate goal of the Clinical Trial Award mechanism is to sponsor novel clinical research that has the potential to substantially improve today's approach to the treatment and management of NF1, NF2, and/or Schwannomatosis. Participating institutions must be willing to resolve potential intellectual property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of the clinical trials. An intellectual property plan agreed upon by all participating institutions is required as part of the administrative documentation of this proposal (see V.E.14).

Please note that all Department of Defense (DOD)-funded research involving human subjects and/or human anatomical substances must be reviewed and approved by the Human Subjects Research Review Board (HSRRB) in addition to local Institutional Review Boards (IRBs). It is recommended that all protocols be prepared according to the guidelines provided in the document titled "Research Involving Human Subjects and/or Anatomical Substances," which can be found at https://cdmrp.org/programAnnouncements.cfm *under "Regulatory Document Forms." An HSRRB-approved template for clinical protocols also can be found at this site.*

All proposals for the Clinical Trial Award should include:

- The objective and rationale of the proposed clinical trial, including any preclinical science and preliminary clinical research relevant to the trial;
- The relevance of the proposed clinical trial to NF1, NF2, and/or Schwannomatosis;
- The proposed intervention(s) to be tested in the clinical trial, with a brief description, as appropriate, of its:
    a. Source,
    b. Investigational New Drug (IND) status,
    c. Availability of the substance in sufficient quantity under current Good Manufacturing Practice (cGMP) production. Applicants must provide evidence of the availability of the substance. If the substance is to be provided from industrial sources, evidence of a cost sharing plan also must be provided,
    d. Dosing and toxicity,
    e. Mechanisms of action, and
    f. Preclinical/clinical evidence of efficacy;
- The sample size for the clinical trial, a patient accrual/recruitment schedule including inclusion and exclusion criteria, and evidence of access to appropriate patient population(s);
- A clinical protocol, a Manual of Operations and Procedures (if available), and consent/assent form(s) that follows the HSRRB-prescribed format;
- Internal scientific and local IRB reviews for the clinical protocol and consent/assent form(s) at the highest level possible within the participating institutions, up to and including preliminary IRB approval if available at your institution;

- A plan for addressing human subjects protection requirements as outlined by the HSRRB at https://cdmrp.org/programAnnouncements.cfm under "Regulatory Document Forms";
- A clinical trial management plan, including a plan for ensuring the standardization of procedures across sites and among staff; and
- Evidence of institutional commitment(s) for the proposed clinical trial.

Phase I clinical trials should focus on determining the safety, toxicity, tolerability, and pharmacokinetics of new agents or treatment schedules in humans. It is expected that this award will allow the recipient the opportunity to obtain the data and experience necessary to conduct a Phase II clinical trial, if appropriate. Applicants for Phase I trials must include a clear scientific rationale for the trial as well as adequate preclinical supplemental data to support the feasibility of their hypotheses and approaches. Applicants must include a detailed plan for completing the Phase I trial during the award and a clear experimental and appropriately powered statistical plan to perform the clinical trial. Phase I applicants are encouraged to pursue correlative studies.

Phase II clinical trials should focus on defining the efficacy of new agents. Applicants for Phase II clinical trials must include Phase I or pilot clinical trial data, adequate preclinical supplemental data to support the feasibility of their hypotheses and approaches, and a detailed plan for completion of the Phase II clinical trial during the award. Applicants should include plans for communication and real-time data transfer between the collaborating institutions, as well as the handling and distribution of specimens and/or imaging products obtained during the study. *In addition, applicants also must include a clear experimental and appropriately powered statistical plan to perform the Phase II clinical trial.* Thus, the NFRP highly encourages applicants to consider applying for the Clinical Trial Development Award to properly develop the appropriate resources for a Phase II clinical trial. Applicants are encouraged to submit studies that further test the safety of a novel combination of agents before it is used on a larger number of patients in a Phase III clinical trial.

The Clinical Trial Award is not limited to therapeutic studies. Applicants also are encouraged to submit proposals focusing on the development of endpoints and tools for measuring outcomes. However, as noted above, a clinical trial must be conducted as part of the study.

III. AWARD INFORMATION

Although there are no total dollar amount restrictions to these awards, programmatic priority will be given to smaller-scale, cost-efficient clinical trials. The NFRP is particularly interested in proposals for Phase I clinical trials that are less than $500,000. Approximately $3.0M is available for this award mechanism.

Funding for Phase I clinical trials can be requested for up to 3 years, whereas funding for Phase II clinical trials can be requested for up to 4 years. Direct costs can cover salary, expenses including research supplies, and travel to scientific meetings. The amount for this travel may not exceed $1,800 per year per investigator.

Applicants must provide evidence of sufficient institutional support and commitment for the proposed studies, such as the provision of access to adequate laboratory facilities and equipment. Consideration of cost sharing with other funding sources and multi-institutional/multidisciplinary research collaborations is encouraged. Applicants are encouraged to use the existing infrastructures of the NFRP-funded NF1 and NF2 natural history studies as infrastructures for their proposed clinical trials.

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. Depending on the number and quality of the applications, it is anticipated that approximately one to two proposals will be funded.

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 HBCU/MI.

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under "Major Equipment" located in Subsection V.F.2.c.

D. Other Eligibility Criteria:

1. Duplicate Submissions: Submission of the same research project to the FY04 NFRP under different award mechanisms or to other CDMRP programs is discouraged. 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.[1] 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 under Minority Institutions at http://cdmrp.army.mil/funding/pdf/minfrp020604.pdf.

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.

The following will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete 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.

[1] Executive Orders 12876, 12900, and 13021

Unless specifically requested by the Government, 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 Principal Investigator (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) and Proposal Abstracts:** The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the "Required Files" tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the "Required Files" tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form are each uploaded as separate PDF files under the "Required Files" tab.

The Contract Representative or institutional official responsible for sponsored program administration (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 or institutional official responsible for sponsored program administration must provide approval of all proposal components (Proposal Information, SOW, Abstracts, Proposal, Budget Information, and Regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) June 29, 2004. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time June 29, 2004 deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, 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 (or equivalent) who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** An electronic Letter of Intent should be submitted by June 1, 2004. 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 research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services 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,
- Indicate the numbers of research subjects (animal or human) and/or anatomical samples projected or required for each task,
- Identify methods, and
- Identify outcomes, products, and deliverables for each phase of the project.

D. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important to both the peer and programmatic review process.

Programmatic review is based upon the Integration Panel's (IP's) review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work.

Each abstract must contain the title of the proposal and the name of the PI. Each abstract must be submitted as a data field under the "SOW/Abstracts" tab of the CDMRP eReceipt system. Applicants can either type in their abstracts, or "cut and paste" them from a word processing application into the respective data fields. Do not include figures or tables in either abstract. Spell out all Greek or other non-English letters.

Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Thus, proprietary or confidential information should not be included in the abstracts.

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective or hypothesis and its supporting rationale, specific aims of the study, study design, and significance of the proposed work to the Program's goals.

Use the outline below for preparing the structured technical abstract.

- Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State concisely the specific aims of the study.

- Study Design: Briefly describe the study design.
- Relevance: Provide a brief statement explaining the relevance of the proposed work to the Program's goals, for example, how the study will cure, prevent, or improve the detection or treatment of the disease.

2. Public Abstract: Sample public abstracts can be found at https://cdmrp.org/samples.cfm. The public abstract is intended to communicate the purpose of, and rationale for, the study to non-scientific audiences. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. It must be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. **The public abstract should not be a duplicate of the technical abstract**, but should describe the goals and objectives of the research project, and its relevance to the Program.

In addition to describing the project, the public abstract must answer the following questions:

(1) What will the ultimate applicability of the research be?
- What types of patients will it help and how?
- What are the potential clinical applications, benefits, and risks?
- What is the projected time it may take to achieve a consumer-related outcome?

(2) If the research is too basic for clinical applicability, what are the interim outcomes?
- What types of contributions will this study make to advance research?
- How will the research enhance this or other studies being conducted?

E. Proposal:

1. Format: All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the "Required Files" 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; however, these items must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since 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?prg=NFRP&prg_fy=2004. 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 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 review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subawardees. 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, if applicable, his or her role(s) on the proposed project.

3. Table of Contents/Checklist: Start section on a new page; one-page limit. Prepare a Table of Contents/Checklist, with page numbers. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page.

4. Proposal Relevance Statement: Start section on a new page; one-page limit. Applicants should state explicitly how the proposed work is relevant to NF research, and describe how the proposed research is pertinent to one or more critical issues of the disease.

5. Proposal Resubmission Statement (optional): Start section on a new page; two-page limit. Proposals that have been declined for funding in a previous year may be resubmitted to the NFRP. Resubmitted/revised proposals must meet all requirements for the Clinical Trial Award proposals described in this program announcement. Resubmitted/revised proposals should include a two-page section that addresses the issues identified in the peer review summary statement of the previously unfunded application. This section should address all aspects of the critique from the previous peer and programmatic reviews and should reference any new preliminary data included. A copy of the summary statement from the unfunded application also should be included and placed immediately after the resubmission statement.

Applicants should be aware that the year-to-year status of funding for the NFRP does not permit establishment of standing panels for scientific peer review. Therefore, the submission of a revised proposal does not guarantee funding or an improved global priority score.

6. Main Body: Start section on a new page; 50-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. Phase I and Phase II Clinical Trial Award applicants must submit promising and well-founded preliminary data relevant to NF and the proposed project. In addition, the inclusion of Phase I or pilot clinical trial data is required for Phase II clinical trial applicants.

Describe the proposed project using the general outline below:

a. Background: Describe the ideas and reasoning behind the proposed work and previous experience most pertinent to the proposal. Cite relevant literature references.

b. Rationale: State the purpose of the study and the expected results.

c. Objectives: State the specific aims of the study.

d. Preliminary Studies: A presentation of the studies that led to the proposed clinical trial is required. In addition, Phase II clinical trial applicants must provide Phase I or Pilot clinical trial data.

e. Description of the Clinical Protocol: Be sure to include a discussion of the following topics:

- Study design for the intervention(s) to be used.
- Potential biases in the research protocol and how they will be addressed.
- Clinical, behavioral, laboratory, and physiological tests and protocols.
- Patient recruitment, including (1) patient availability; (2) inclusion and exclusion criteria; (3) methods for recruiting, retention, and follow-up; (4) data to support recruitment/retention estimates; (5) patient assignment to experimental groups and methods of randomization (if any); and (6) study endpoints.
- Data management, including the (1) overall approach to data management; (2) a plan for real-time data transfer; (3) a statistical plan that includes sample size calculations and methods to monitor quality and consistency of the intervention(s) and data collection; and (4) data security measures.
- Methods for the handling, distribution, and analysis of specimens and/or imaging products (primary and secondary endpoints should be clearly defined and related to the power calculation).
- Any issues that may lead to concern for the welfare of human subjects and confidentiality, including a plan for addressing human subject protection requirements as outlined by the HSRRB at https://cdmrp.org/programAnnouncements/cfm under "Regulatory Document Forms";
- Internal scientific and local IRB reviews for the clinical protocol and consent/assent form(s) at the highest possible level within the participating institutions, up to and including preliminary IRB approval if available at the institution(s);
- A study organization and management plan, including a plan for communication among collaborating institutions, a plan for ensuring the standardization of procedures across sites and among staff, and an organizational chart and timetable.

Please note that the clinical protocol, Manual of Operations and Procedures, consent/assent forms, and any available IRB approvals also must be submitted (see Section V.E.12).

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

8. 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).

9. 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.

10. Existing/Pending Support: Start section on a new page; no page limit. List on a separate page the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel. If no support exists, state "none." Proposals submitted under this program announcement should not duplicate other funded research projects.

11. Facilities/Equipment Description: No page limit. Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate if Government-owned facilities or equipment are proposed for use.

12. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit. The first item in this section must be a list of all documents included in this section. Provide the following in this section of the proposal:

- Clinical protocol
- Manual of Operations and Procedures (if available)
- Consent/assent forms
- IRB approvals (if any)

13. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, the extra items will not be peer reviewed.

14. Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. **This section is not for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other relevant information needed to judge the proposal.** 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.

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

Provide letters of support from any collaborating individuals or institutions in this section of the proposal.

Provide documentation that the participating institutions have an intellectual property plan and are willing to resolve intellectual property issues.

Provide documentation of the availability of the substance to be used in the clinical trial. If the substance is to be provided from industrial sources, provide documentation of a cost sharing plan.

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.

F. Budget Information: Budget Information includes the Detailed Cost Estimate forms and Budget Justification. Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

1. Funding Restrictions: There are no total dollar amount restrictions to these awards. However, the NFRP is particularly interested in proposals for Phase I clinical trials that are less than $500,000.

Funding for Phase I clinical trials can be requested for up to 3 years, whereas funding for Phase II clinical trials can be requested for up to 4 years. Direct costs can cover salary, expenses including research supplies, costs for research-related injury medical costs (if applicable), and travel to scientific meetings. The amount for this travel may not exceed $1,800 per year per investigator.

2. Detailed Cost Estimate Forms and Justifications Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided for expenses in all categories. The Detailed Cost Estimate form and Justification for your proposal must be uploaded as a PDF file, separate from the proposal.

The following section provides instructions for preparing the Detailed 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 Detailed 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%, note this with an asterisk (*) and provide a

full explanation in the "Justification" section of the Detailed 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 for 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: 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. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed $5,000.

d. Materials, Supplies, and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than $1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

e. Travel Costs: Travel costs for scientific and technical meetings may not exceed $1,800 per year per investigator.

f. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

g. 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.

h. Subaward Costs: A description of services or materials that are to be awarded by subcontract or subgrant is required. For awards totaling $10,000 or more, provide the following specific information:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.

i. 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.

j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the "Justification" section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should equal the amount previously entered online in the Proposal Information https://cdmrp.org/proposals.

3. Justification (third page of the Detailed Cost Estimate form): Each item in the budget should be clearly justified under the "Justification" section of the Detailed Cost Estimate form.

G. Regulatory Requirements: Completed and signed copies of the "Certificate of Environmental Compliance" and "Principal Investigator Safety Program Assurance Form" must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files.

In addition, Regulatory Documents pertaining to research involving human subjects and/or human anatomical substances must be submitted within the body of the proposal (see section V.E.12). Any other Regulatory Documents should not be submitted with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

H. USAMRAA Documents: The most current version 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 (or equivalent). These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system prior to negotiations.

I. Submission Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institutional Sponsored Programs Office (or equivalent) by the deadline. If your proposal is either incomplete or not approved electronically before

the deadline, it will not be considered for review. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time June 29, 2004 deadline.

The timeline for Clinical Trial Awards is:

Online Letter of Intent:	Expected by **June 1, 2004**
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time June 29, 2004**
Peer Review:	July 2004.
Programmatic Review:	September 2004.
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review.
Notification Letter:	late September 2004
Award Start Date:	Between October 2004 and September 2005.

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 (or equivalent) must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time June 29, 2004 deadline.
- 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 Detailed Cost Estimate form and the Budget Justification form. Budget Information must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The Regulatory Documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the "Required Files" tab of the CDMRP eReceipt system. Please refer to Section V.E.12 for information regarding the submission of other Regulatory Documents required for this award.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview:

1. Process: The CDMRP uses a two-tiered review process for proposal evaluation. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit as well as overall program goals.

2. Peer Review: Peer review is conducted by panels organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals, based upon the review criteria published for each award mechanism.

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting scientific review administrator. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see below). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

3. Programmatic Review: The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the peer review summary statements and the proposal abstracts. SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

HBCU/MI proposals will be reviewed concurrently with all others in the same research area during scientific peer review, but may be evaluated separately during programmatic review. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI submissions will be based upon scientific excellence and program relevance.

B. Review Criteria:

1. Peer Review: Clinical Trial Award proposals will be evaluated according to the following criteria:

- **Trial Design:** Are the conceptual framework, design, methods, and analyses adequately developed and well integrated, including laboratory and other preclinical evidence, to support the clinical feasibility and promise of the approach? Does the applicant provide a clear scientific rationale for the trial? Have the logistical aspects of the proposed clinical trial been appropriately addressed (e.g., plans for communication, real-time data transfer, and standardization of procedures among collaborating institutions)? Have the availability of subjects for the clinical trial, the prospect of their participation, and the likelihood of subject attrition been addressed? Is the recruitment schedule reasonable? Have preliminary internal scientific and local IRB approval for the clinical protocol and consent/assent form(s) been obtained?
- **Clinical Relevance:** Does the study address an important problem related to the treatment of NF? If the aims of the proposal are achieved, are they likely to have a substantial clinical impact? *If the proposal involves the development of endpoints or tools for measuring outcomes,* are they relevant to the clinical management/treatment of NF?
- **Intervention:** Is the proposed intervention to be tested in the clinical trial adequately described and available? Is the intervention novel? Has the applicant provided evidence of the availability of the substance to be used in the clinical trial? If the substance is to be provided from industrial sources, has the applicant provided documentation of a cost sharing plan?
- **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 and clinical trials experience? Is the PI appropriately trained and well suited to carry out this work? Are the other scientific personnel well qualified to participate in the project? Is there representation from all the areas of expertise needed to conduct the clinical trial successfully?
- **Environment:** Is there evidence for an appropriate clinical setting and the availability of institutional resources to support the study at each participating center? Are there assurances that therapies to be used are available? Are letters of commitment included from participating centers? Is there evidence of an intellectual property management plan that is agreed upon by all participating centers?
- **Budget:** Is the budget appropriate for the research proposed? Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to structure the NFRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;

- Relative innovation; and
- Program portfolio balance.

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

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tiered 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 September 2004.

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 and DOD Grant and Agreement Regulations). Any organization requesting receipt of an award from this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.

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 Review:

1. Overview: Concurrent with the USAMRAA negotiations, the Office of Surety, Safety and Environmental will review the Certificate of Environmental Compliance, and Principal Investigator Safety Program Assurance form submitted with the proposal. The USAMRMC RCQ office will review 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 must 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 Program Assurance form must 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/crprcqsohdfsplan.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/FY02FSPAppendix.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.

4. Research Involving Animal Use: Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc.

5. Research Involving Human Subjects/Anatomical Substances: (See Sections V.G and V.J for information pertaining to the submission of human subjects and/or human anatomical substances documents.) In addition to local IRB approval to conduct research involving human subjects and/or anatomical substances, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the HSRRB, which is administered by the USAMRMC RCQ office. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. For example:

- Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects and/or anatomical substances can be found at http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf. An informed consent form template can be located at http://mrmc-www.army.mil/docs/rcq/consentform_template.pdf.

6. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or use of laboratory animals without express written approval from the applicable USAMRMC RCQ office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

E. Reporting: All research awards will require the timely delivery of several reports during the research effort. Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project.

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.[2]), 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.

F. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

[2]Title 35, United States Code, Section 200 et seq.

IX. ACRONYM LIST

AVI	Audio Video Interleave
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
cGMP	Current Good Manufacturing Practice
CTA	Clinical Trial Award
DOD	Department of Defense
FY	Fiscal Year
HBCU	Historically Black Colleges and Universities
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IND	Investigational New Drug
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MB	Megabyte
MPEG	Moving Picture Experts Group
NFRP	Neurofibromatosis Research Program
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SOW	Statement of Work
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave