Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

The Fiscal Year 2005 (FY05) Appropriation Bill was signed by President Bush on August 5, 2004. This program announcement is being released prior to the receipt of funds appropriated in the bill for this research program; funding of proposals received in response to this program announcement is contingent on the receipt of funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: Concept Award (CA).

B. Program Name: Department of Defense (DOD) FY05 Neurofibromatosis Research Program (NFRP).

C. Funding Opportunity Number: NF05-CA.

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-ZB-C (NF05-CA) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

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

Website:	https://cdmrp.org (User's Guide located in upper right corner of 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. The website contains all the information, forms, documents, and links needed to apply.

I. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use. For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4).[1] Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Concept Award is to fund the exploration of an initial concept or theory that could give rise to a testable hypothesis. These awards are to encourage the exploration of untested, high-risk questions relevant to NF1, NF2, and/or Schwannomatosis and are not intended to support the next step in an already established research project. Presentation of preliminary data is not consistent with the intent of this award mechanism.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately $1 million (M) is available to fund the FY05 NFRP Concept Awards.
- Depending on the number and quality of the applications, it is anticipated that 10 proposals will be funded.
- Funding for Concept Awards can be requested for a maximum of $100,000 inclusive of direct and indirect costs for a 1-year performance period.

[1] Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

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, nonprofit, public, and private organizations.

C. Cost Sharing: It is expected that institutions will cost share. Please see "Major Equipment" located in Subsection V.G.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 (HBCU/MI), 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/.

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 Date and Time: Deadline: February 22, 2005. 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/. Please see the Full Text of Program Announcement for details.

VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tier 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 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

The Fiscal Year 2005 (FY05) Appropriation Bill was signed by President Bush on August 5, 2004. This program announcement is being released prior to the receipt of funds appropriated in the bill for this research program; funding of proposals received in response to this program announcement is contingent on the receipt of funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: Concept Award (CA).

B. Program Name: Department of Defense (DOD) FY05 Neurofibromatosis Research Program (NFRP).

C. Funding Opportunity Number: NF05-CA.

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-ZB-C (NF05-CA) 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/ (User's Guide located in upper right corner of 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-ZB-A 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/. This website will contain all the information, forms, documents, and links needed to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

I. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use. For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4)[2]. Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

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 written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Concept 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 $155.3 million (M). The program history of the FY96-04 NFRP is shown in Table 1. The FY05 appropriation is $25M.

[2]Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

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

Program History	FY96-03	FY04
Congressional Appropriations for NFRP	$110.3M	$20M
Total Proposals Received	361	95
Total Proposals Funded	117	~21[1]
Concept Award Proposals Received	N/A	61
Concept Award Proposals Funded	N/A	~9[2]

[1]Includes two FY03 proposals funded with FY04 appropriations. Award negotiations will be finalized by September 2005.

[2] Award negotiations will be finalized by September 2005.

B. Program Objectives: The overall goal of the FY05 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).

The NFRP is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to NF and/or Schwannomatosis research. Scientific ventures that represent under-investigated avenues of research or novel applications of existing technologies are highly sought. Although the NFRP encourages risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

C. Award Mechanism Description: The intent of the Concept Award is to fund the exploration of an initial concept or theory that could give rise to a testable hypothesis. These awards provide investigators with the opportunity to pursue serendipitous observations; it is anticipated that research completed through a Concept Award may provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for future research. Presentation of preliminary data is not consistent with the intent of this award mechanism. Proposals must describe how the new concept or theory will enhance existing knowledge of NF1, NF2, and/or Schwannomatosis.

Concepts from complementary areas of science such as chemistry, biophysics, mathematics, engineering, etc., are encouraged as are research proposals involving consumer-scientist collaborations.

Because these awards are designed for preliminary investigations, projects involving human subjects or human anatomical substances will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

III. AWARD INFORMATION

Funding for Concept Awards can be requested for a maximum of $100,000 inclusive of both direct and indirect costs over a 1-year performance period. Projects requiring lower levels of funding also may be submitted. These funds can cover salary, expenses including research supplies, and travel to scientific/technical meetings. The amount allotted for this travel is $1,800 per year.

The nature of the NFRP does not allow for renewal of grants or supplementation of existing grants. Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately $1M to fund approximately 10 Concept Awards.

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, nonprofit, 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" in Subsection V.G.2.c.

D. Other Eligibility Criteria

1. Duplicate Submissions: Submission of the same research project to the FY05 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 on guidance from Executive Orders.[3] 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/spp under Minority Institutions.

[3]Executive Orders 12876, 12900, and 13021

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 rating.

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

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.
- Margins are less than 0.5 inch on any side.
- Principal Investigator (PI) and/or institution names are included in proposal body.
- Proposal body exceeds page limit.
- Proposal body is missing.
- Concept Award Cost Estimate is missing.
- Proposal is incomplete after the deadline.

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

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 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.
- **Proposal Contacts:** Contact information for both the PI and the Contract Representative is required to complete the proposal submission process.
- **Statement of Work (SOW) and Proposal Abstracts:** The SOW is entered as a separate data field. The technical and public abstracts are not required for Concept Award

submissions, but the appropriate data fields must be completed for final submission of the proposal. Please complete these fields by entering "Not Applicable for Concept Awards" in the appropriate data field(s).

- **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:

- **The Contract Representative's contact information profile must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA) Required Documents:** The institution'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 (or equivalent) must provide approval of all proposal components (Proposal Information, Proposal Contacts, SOW, Proposal, Budget Information, and regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. Eastern time February 22, 2005. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time 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/. The Proposal Information may be "Verified & Saved" for editing purposes until "Submit Final" for approval by their Sponsored Programs Office's (or equivalent) representative.

- **Letter of Intent:** A Letter of Intent is not required for this award mechanism.

C. Proposal Contacts: Proposal Contacts **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 institution. Proposal Contacts must be "Finalized" for approval by the applicant's Sponsored Programs Office's (or equivalent) representative.

D. 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 number of animal subjects projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

E. Proposal Abstracts: For the technical abstract and the public abstract, please enter "Not Applicable for Concept Awards." These entries are captured as separate data fields under the "SOW/Abstract" tab in the CDMRP eReceipt system and are required for final submission of your proposal.

F. Proposal

1. Format: All proposal components (proposal body, biographical sketches, publications, letters of support, etc.) must be converted into a single 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.

Please Note New Format Requirements

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

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inch in all directions.**

- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

Failure to adhere to the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to peer review.

- Color, Resolution, and Multimedia Objects: Not allowed for Concept Award submissions.
- Language: English.

2. Title/Referral Page: Not applicable for Concept Award submissions.

3. Table of Contents/Checklist: Not applicable for Concept Award submissions.

4. Proposal Relevance Statement: Not applicable for Concept Award submissions.

5. Main Body: Start section on a new page; one-page limit. The body of the proposal should consist only of text. No figures, tables, graphs, photographs, diagrams, chemical structures, pictures, cartoons, schematics, pictorials, or pathways will be accepted. It is the investigator's responsibility to clearly articulate how the proposed research is innovative and relevant to NF1, NF2, and/or Schwannomatosis research. Presentation of data from preliminary studies is not consistent with the intent of this award mechanism. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature. Investigators must clearly describe the innovation and feasibility of the concept being developed. **Due to the blinded nature of the review process (see Subsection VI.A), references to the PI or institution are prohibited and will be cause for administrative withdrawal of the proposal.**

Describe the proposed project using the outline provided below:

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

b. Rationale/Purpose: State the rationale for the proposed research.

c. Objectives: State concisely the project's specific aims and research strategy.

d. Feasibility/Plausibility: Provide sufficient detail of experimental design and/or methodology to support the feasibility and plausibility of the project.

e. Relevance: Provide a brief statement in nontechnical terms regarding the relevance of this work to NF1, NF2, and/or Schwannomatosis.

6. References: Start section on a new page. Cite relevant literature references (maximum five). List 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: Not required at the time of proposal submission.

G. Budget Information: Budget Information includes the one-page Concept Award Cost Estimate form. Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for the Concept Award is a maximum of $100,000 inclusive of both direct and indirect costs over a 1-year performance period. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for this travel is $1,800 per year.

2. Concept Award Cost Estimate Form Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. **Organizations must provide sufficient detail so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.** The Concept Award Cost Estimate form for your proposal must be uploaded as a PDF file, separate from the proposal.

Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31 (http://farsite.hill.af.mil), Contract Cost Principles and Procedures.
- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

The following section provides instructions for preparing the Concept Award 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.

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. 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 nonprofit recipients provide the equipment needed to support proposed research. In those rare cases in which specific additional equipment is approved for commercial and nonprofit 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 to scientific/technical meetings may not exceed $1,800 per year.

f. Other Direct Costs: 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.

g. 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.

h. 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 with a statement identifying whether the proposed rates are provisional or fixed.

H. 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.

Do not submit other regulatory documents (for example, documents supporting research exempt under 32 CFR 219.101(b)(4) or Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

I. USAMRAA Required 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.

J. Submission Date and Time: 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 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 February 22, 2005 deadline.

The timeline for the Concept Award is:

Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time February 22, 2005**
Peer Review:	April 2005
Programmatic Review:	July 2005
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after programmatic review
Award Start Date:	Anticipated between September 2005 and January 2006

K. 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/.

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.
- Proposal Contacts must be submitted prior to submission of the proposal. The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- 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 February 22, 2005 deadline.

- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Budget Information includes the Concept Award Cost Estimate 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.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: This will be a blinded review process; PI and institution names will not be provided during the review process.

The CDMRP uses a two-tier 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 on 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). This criteria rating ensures that each component is considered in peer review. Second, the overall proposal is given a global priority rating. Reviewers are asked to use the criteria ratings as a guide in determining the global priority rating. 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 ratings 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 Integration Panel (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. One of the functions of programmatic review is to maintain a broad portfolio of grants across all disciplines. 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 one-page Concept Award proposal. SOWs may also be reviewed.

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 on scientific excellence and program relevance.

B. Review Criteria

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

- **Innovation and Novelty of Concept:** Is the proposed concept innovative? Is the concept in the initial stage of development? Is the concept untested? If successful, will this concept give rise to a testable hypothesis? If successful, does this proposal hold the potential to make a significant impact? Are logical reasoning and a sound scientific rationale the basis for this proposal?
- **Feasibility/Plausibility:** Is the feasibility/plausibility supported by the conceptual framework and the study design? Is the methodology proposed appropriate to expanding the observation and providing data for a testable hypothesis or proof-of-principle for a nascent hypothesis? Is there a clear rationale for pursuing the observation? Are the aims based on logical reasoning?
- **Disease Relevance:** Does this study address a critical problem relevant to NF and/or Schwannomatosis research? What will be the effect of this study on the concepts or methods that drive these fields? To what extent will the project, if successful, lead to a better understanding of NF and/or Schwannomatosis and/or lessening the impact of these disorders?

Proposals will be evaluated, prioritized according to rating, and sent forward for programmatic review.

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 maintain 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-tier evaluation process is completed, every applicant will receive notification of the award status of his or her proposal. Peer review summary statements will not be provided to the applicants. Applicants can expect to be notified of the agency's decision in August 2005.

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, nonprofit research institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for an 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 (OMB 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.*

No changes in the institution will be allowed for Concept Awards.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the 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. In addition, both technical and public abstracts will be requested at this time.

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

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver 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 https://mrmc.detrick.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 https://mrmc.detrick.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 https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: Projects involving human subjects or specimens **will not be supported** through this mechanism unless they are exempt under 32 CFR 219.101(b)(4). For exempt projects, documents supporting the exempt status of a project will be requested at a later date. These documents shall include local Institutional Review Board (IRB) approval of the project stating the level of risk and the USAMRMC Office of Research Protections (ORP) (formerly Regulatory Compliance and Quality) Claim of Exemption form. **It is important to note that the DOD considers cell lines of human origin to be human anatomical substances.** All exempt projects, including those using human cell lines, are subject to ORP review and approval.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc.

6. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use. For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

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 written approval from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

E. Reporting: All research awards will require the timely delivery of several reports during the research effort.

- **Research Progress Report Requirements:** All Concept Awards will require the timely delivery of an annual report for each year of the research effort. Each annual report must present a detailed summary of scientific issues and accomplishments for the previous year.
- **Fiscal Report Requirements:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research 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 used. 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, **the** 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.[4]), 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.

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

IX. ACRONYM LIST

CA	Concept Award
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
DOD	Department of Defense
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IP	Integration Panel
IRB	Institutional Review Board
M	Million
NFRP	Neurofibromatosis Research Program
OMB	Office of Management and Budget
ORP	Office of Research Protections (formerly Regulatory Compliance and Quality)
PDF	Portable Document Format
PI	Principal Investigator
SOW	Statement of Work
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code