Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

The Neurofibromatosis Research Program (NFRP) seeks to establish a consortium of exceptional investigators that will conceive, develop, and conduct collaborative pilot and Phase I and II clinical evaluations of promising new therapeutic agents or approaches for the management or treatment of neurofibromatosis type 1 (NF1). The consortium will consist of five to 10 participant member institutions with experience in developing and conducting clinical trials of innovative treatment approaches and multidisciplinary expertise in supporting NF1 clinical research. These institutions will be responsible jointly for proposing and conducting clinical evaluations of new treatment agents or approaches. The consortium will also have a single Operations Center responsible for providing operational and data management/analysis support to implement consortium protocols in a timely manner.

The Fiscal Year 2005 (FY05) NFRP is offering two separate award mechanisms to support the establishment of the necessary collaborations and development of the necessary resources for the consortium – the NF Consortium Development Site Award and the NF Consortium Development Operations Center Award. Proposals for the NF Consortium Development Site Award are being requested in this program announcement. Applicants selected through this award mechanism will be invited to join the consortium as participating member institutions. **Awardees shall collaborate with the recipient of the FY05 NF Consortium Development Operations Center Award to develop the full consortium and shall submit a proposal, clinical protocols, and associated clinical documents to the FY06 NF Consortium Award mechanism.** However, the FY06 NF Consortium Award will be open to all eligible consortia focused on NF1 clinical research. A maximum of $30,000, inclusive of direct and indirect costs, is available to each recipient of the FY05 NF Consortium Development Site Award (i.e., each consortium member institution) for expenses associated with the development of the consortium.

There is no guarantee that funds will be available for the FY06 NF Consortium Awards.

A. Title of Award: NF Consortium Development Site Award (NFCDSA).

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

C. Funding Opportunity Number: NF05-NFCDSA.

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

E. Agency Contact(s)

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

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-ZB-C (NF05-NFCDSA) 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: Funds from the NF Consortium Development Site Award may not be used to support laboratory or preclinical research. Moreover, investigators funded under this award mechanism may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals.

Applicants who are approved for funding for the NF Consortium Development Site Award will be required to attend a consortium planning meeting in the Baltimore-Washington, DC area at the beginning of the award period.

II. FUNDING OPPORTUNITY DESCRIPTION

The NFRP seeks to develop a major goal/product-driven consortium of leading investigators that will develop and conduct collaborative clinical studies aimed at decreasing the impact of NF1 and enhancing the quality of life of individuals with the disease. The consortium will consist of

outstanding clinical research institutions and an Operations Center to provide administrative, data management, and analytical support.

Two separate award mechanisms are being offered in FY05 to select consortium participants and fund the development of the consortium – the NF Consortium Development Site Award and the NF Consortium Development Operations Center Award . Proposals for the NF Consortium Development Site Award are being requested in this program announcement. This mechanism will be used to select exceptional NF1 clinical research institutions to join the consortium. A consortium member institution (or site) is defined as a for-profit, nonprofit, public, or private institution or organization in which all personnel, expertise, facilities, and resources dedicated to the consortium are contained in a single building, complex, or campus. Selected sites will develop the full consortium in collaboration with the Operations Center, which will be selected and funded through the NF Consortium Development Operations Center Award . The NF Consortium Development Site Award will provide support to member institutions to establish the necessary collaborations for the consortium and develop clinical protocols that will be conducted by participating investigators.

Recipients of the FY05 NF Consortium Development Site Award will be required to collaborate with one another and with the recipient of the FY05 NF Consortium Development Operations Center Award to submit a proposal, clinical protocols, and associated clinical documents to the FY06 NF Consortium Award mechanism.

Although there is also a critical need for improved treatments for NF2 and Schwannomatosis, the NFRP is focusing on the formation of an NF1 consortium in FY05 and FY06. However, the established consortium will have the option of expanding to encompass NF2- and Schwannomatosis-directed studies at the discretion of its Governing Body and the NFRP.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Funding for FY05 NF Consortium Development Site Awards can be requested for $30,000 for 1 year, inclusive of both direct and indirect costs.
- Up to $300,000 is available to fund the FY05 NF Consortium Development Site Awards.
- Depending on the number and quality of applications, it is anticipated that five to 10 proposals will be funded.
- Investigators funded under the NF Consortium Development Site Award mechanism will be required to collaborate with other investigators funded under this mechanism and with the recipient of the FY05 NF Consortium Development Operations Center Award to submit a proposal, clinical protocols, and associated clinical documents to the FY06 NF Consortium Award mechanism. However, the FY06 NF Consortium Award will be open to all eligible consortia focused on NF1 clinical research.
- The NFRP is anticipating funding the FY06 NF Consortium Award for up to $3M for site administration and $6M for scientific studies for 3 years, pending receipt of funds.

- **There is no guarantee that funds will be available for the NF Consortium Awards in FY06.**

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be independent investigators at the Assistant Professor level (or equivalent) or higher. The Principal Investigators (PIs) of submissions to the FY05 NF Consortium Development Operations Center Award are ineligible to submit proposals to the FY05 NF Consortium Development Site Award mechanism.

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. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs. For the NF Consortium Development Site Award, all personnel, expertise, facilities, and resources dedicated to the consortium must be contained in a single institutional building, complex, or campus.

C. Cost Sharing: It is expected that institutions will cost share. Please see "Major Equipment" under Subsection V.H.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: May 3, 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

A. Title of Award: Neurofibromatosis (NF) Consortium Development Site Award (NFCDSA).

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Neurofibromatosis Research Program (NFRP).

C. Funding Opportunity Number: NF05-NFCDSA.

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

E. Agency Contact(s)

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

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-ZB-C (NF05-NFCDSA) 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 (USAMRAA)
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: Funds from the NF Consortium Development Site Award may not be used to support laboratory or preclinical research. Moreover, investigators funded under this award mechanism may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals.

Applicants who are approved for funding for the NF Consortium Development Site Award will be required to attend a consortium planning meeting in the Baltimore-Washington, DC area at the beginning of the award period.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The NF Consortium Development Site Award is part of the DOD NFRP, which was established in FY96 to promote research directed toward decreasing the impact of 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.

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]
NF Consortium Development Site Award Proposals Received	N/A	N/A
NF Consortium Development Site Award Proposals Funded	N/A	N/A

[1]Includes two FY03 submissions funded with FY04 appropriations. 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).

C. Award Mechanism Description

1. General Information: The NFRP seeks to develop a major goal/product-driven consortium of exceptional investigators that will accelerate the clinical translation of basic NF1 research and ultimately decrease the overall impact of the disease. The consortium will conceive, develop, and conduct collaborative pilot and Phase I and II clinical evaluations of promising therapeutic agents or approaches for the prevention, diagnosis, management, or treatment of NF1. The consortium will consist of five to 10 participant member institutions with experience in developing and conducting clinical studies and multidisciplinary expertise in supporting NF1 clinical research. These institutions will be responsible jointly for proposing and conducting clinical evaluations of new treatment agents or approaches. The consortium will also have a single Operations Center responsible for providing operational and data management/analysis support to implement consortium protocols in a timely manner.

Two separate award mechanisms are being offered in FY05 to select consortium participants and fund the development of the consortium – the NF Consortium Development Site Award and the NF Consortium Development Operations Center Award. Proposals for the NF Consortium Development Site Award are being requested in this program announcement. This mechanism will be used to select exceptional NF1 clinical research institutions to join the consortium. A consortium member institution (or site) is defined as a for-profit, nonprofit, public, or private institution or organization in which all personnel, expertise, facilities, and resources dedicated to the consortium are contained in a single building, complex, or campus. Selected sites will develop the full consortium in collaboration with the Operations Center, which will be selected and funded through the NF Consortium Development Operations Center Award. The NF Consortium Development Site Award will provide support to member institutions to establish the necessary collaborations for the consortium and develop clinical protocols that will be conducted by participating investigators.

Recipients of the NF Consortium Development Site Award will be required to collaborate with one another and with the recipient of the NF Consortium Development Operations Center Award to submit a proposal, clinical protocols, and associated clinical documents to the FY06 NF Consortium Award mechanism. However, the FY06

NF Consortium Award will be open to all eligible consortia focused on NF1-relevant clinical research.

Although there is also a critical need for better treatments for NF2 and Schwannomatosis, the NFRP is focusing on the formation of an NF1 consortium in FY05 and FY06. However, the established consortium will have the option of expanding to encompass NF2- and Schwannomatosis-directed studies at the discretion of its Governing Body and the NFRP.

For planning purposes, please note that all DOD-funded research involving human subjects, human anatomical substances, and/or cadavers must be reviewed and approved by the USAMRMC Human Subjects Research Review Board (HSRRB) in addition to local Institutional Review Boards (IRBs). All protocols must 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. However, as stated previously, funds from the NF Consortium Development Site Award may not be used to support research involving human subjects, human anatomical substances, and/or cadavers.

2. Responsibilities of Consortium Member Institutions: Specific responsibilities of the consortium sites include:

- Full participation in the consortium, including protocol development, participant accrual for consortium studies, meeting attendance, and adherence to the consortium's operating procedures;
- Service as Protocol Chairs, who are responsible for protocol development and study monitoring;
- Service on consortium scientific committees (e.g., pathology, radiology, and neurodevelopment);
- Implementation of the consortium's core data collection methodology and strategies;
- Compliance with quality assurance and quality control procedures, as appropriate, including:
    - Pathology: Submission of appropriate materials to allow verification of pathologic diagnosis,
    - Therapeutics: Submission of appropriate data to allow determination of protocol compliance in dose administration and dosage modification,
    - Neurosurgery: Submission of appropriate information to allow review of protocol-specified neurosurgical procedures,
    - Imaging: Submission of appropriate imaging studies to allow central review, and
    - Participation in the on-site monitoring program to be established by the Operations Center;

- Implementation of procedures established by the Operations Center for ensuring compliance with Food and Drug Administration (FDA) requirements for investigational agents, as appropriate;
- Implementation of procedures established by the Operations Center to meet the institutional IRB and HSRRB requirements for the conduct of clinical studies and the protection of human subjects;
- Acquisition and submission of protocol-specified tumor specimens, biological fluids, and relevant clinical data to the appropriate laboratories for testing or storage;
- Serving as a resource for the conduct of protocol-specified laboratory projects (such as tumor biology studies);
- Participation in consortium procedures for the timely publication of major findings;
- Appropriate use of discretionary funds awarded by the Operations Center to conduct laboratory studies accompanying consortium clinical protocols;
- Submission of annual progress reports to the NFRP that describe activities, accomplishments, and plans for the coming year; and
- Additional responsibilities based on recommendations and guidance from the consortium Governing Body.

Recipients of the FY05 NF Consortium Development Site Award will be required to collaborate with one another and with the recipient of the FY05 NF Consortium Development Operations Center Award to prepare a proposal, clinical protocols, and associated clinical documents for submission to the FY06 NF Consortium Award mechanism.

3. Proposal Requirements: (See Subsection V.F.5 for complete details.) All proposals for the NF Consortium Development Site Award must include:

- Descriptions of the applicant's commitment to and experience in NF1 clinical research;
- Evidence of multidisciplinary clinical and/or laboratory expertise **within the applicant institution** that could serve as the basis for the development of clinical protocols by the consortium;
- Demonstration of adequate resources and expertise for specimen collection and processing;
- Demonstration of adequate resources and expertise for data management and maintenance of data security/confidentiality;
- Evidence of institutional commitment to using facilities and resources in the conduct of consortium studies as required. Documentation of willingness to resolve intellectual and material property issues should also be provided;
- Description of the NF1 population and documentation of ability to enroll at least 10-12 evaluable individuals with NF1 per year into consortium-sponsored studies;

- A named institutional clinical coordinator who will interact with the clinical coordinators at other consortium sites and at the Operations Center to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites;
- A plan for addressing human subjects protection requirements as outlined by the HSRRB at https://cdmrp.org/Program_Announcements_and_Forms under "Regulatory Document Forms"; and
- A proposed NF1-relevant clinical study congruent with the goals of the NFRP.

Following the award of funds, the NFRP will coordinate a meeting with the Principal Investigators (PIs) of the funded NF Consortium Development Site Award and NF Consortium Development Operations Center Award proposals to initiate discussions of the operational features of the consortium and the clinical studies that the consortium will pursue. It is expected that thereafter the PIs will collaborate to develop and prepare the NF Consortium Award proposal, clinical protocols, and associated clinical documents for submission in FY06 without the involvement of the NFRP.

The purpose of the NF Consortium Development Site Award is not to obtain preliminary data or to conduct studies to support the rationale for the proposed clinical studies; therefore, funds may not be used to support laboratory or preclinical research. However, funds from this award may be used to:

- Support consortium-related meetings, teleconferences, and travel among participating investigators;
- Develop consortium clinical protocols and associated clinical documents;
- Plan and write sections of the FY06 NF Consortium Award proposal; and
- Furnish salary support during the development of the consortium and clinical protocols.

Additionally, sites may collaborate with one another and with the Operations Center to:

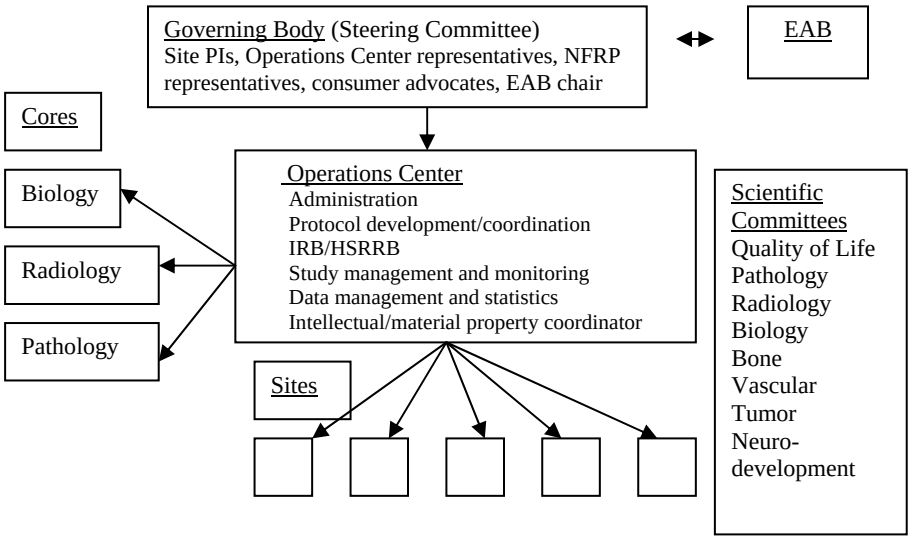
- Develop and implement data management, real-time communication, and/or administration plans for the consortium;
- Reimburse institutions for costs associated with conducting the IRB review of the clinical protocols and informed consent/assent forms;
- Provide other costs directly associated with planning and developing the consortium;
- Coordinate informed consent/assent forms and other IRB and/or HSRRB issues between different institutions;
- Resolve intellectual property and material rights among institutions;
- Adapt databases and other methods of data dissemination for public availability;
- Develop definitive statistical plans; and
- Develop sources and obtain letters affirming intervention supply or availability.

The NF Consortium Development Site Award will provide a maximum of $30,000, inclusive of direct and indirect costs, to each consortium member institution for expenses associated with the development of the consortium. Additionally, the Operations Center shall collaborate with the participant member institutions to develop the consortium and shall provide up to $500,000 in supplementary funds to assist and support the various sites.

4. FY06 NF Consortium Award Proposal Requirements: The FY06 NF Consortium Award will be open to all eligible consortia focused on NF1-relevant clinical research. However, there is no guarantee that funds will be available for the NF Consortium Award in FY06.

All FY06 NF Consortium Award proposals will be expected to include:

- Descriptions of the consortium organizational structure, including operational features, communications plans, and standard operating procedures. The organizational structure should include the following key features (see diagram):
  - A Governing Body that determines which studies the consortium will pursue. The Governing Body shall include PIs from all sites, Operations Center representatives, NFRP representatives, and consumer advocates,
  - An External Advisory Board (EAB) for scientific review, oversight, and data monitoring. The EAB chair shall be a member of the Governing Body,
  - Pro bono scientific committees that provide input on study feasibility and design, and
  - Core facilities that provide scientific support;



- A draft charter and by-laws for the consortium;
- Evidence of institutional commitment(s) to the consortium;
- A prioritized list of clinical studies to be conducted by the consortium;

- Description(s) of the NF1 population(s) and documentation of ability to enroll sufficient evaluable participants in consortium-sponsored studies;
- Clinical protocols (Manual of Operations and Procedures) and associated clinical documents that include HSRRB-prescribed content;
- Internal scientific and local IRB review documents for the clinical protocols and informed consent/assent form(s) that indicate the level of review achieved prior to submission of the NF Consortium Award. Indicate the highest possible level of review within the participating institutions before submission of a proposal;
- A document addressing human subjects protection requirements as outlined by the HSRRB at https://cdmrp.org/Program_Announcements_and_Forms under "Regulatory Document Forms";
- Descriptions of procedures for ensuring compliance with FDA requirements for investigational agents, as appropriate;
- A named clinical coordinator at the Operations Center who will guide the clinical protocols through the IRB, HSRRB, and other regulatory approval processes; coordinate activities among consortium clinical research sites; and coordinate participant accrual;
- A comprehensive data management plan, including:
  - A discussion of the overall approach to data collection and management,
  - A statistical plan that includes sample size calculations, methods to monitor quality and consistency of data collection, and methods to measure outcomes,
  - A plan for real-time data transfer, and
  - Data security measures;
- Descriptions of quality control, quality assurance, and study monitoring procedures;
- Descriptions of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies. Include a specimen handling and distribution plan agreed upon by all institutions in the consortium;
- A plan for public dissemination of data generated by consortium-sponsored studies that addresses all relevant privacy issues;
- An intellectual and material property plan agreed upon by all participating institutions. A coordinator at the Operations Center responsible for managing and resolving intellectual and material property issues among consortium institutions must be named in the proposal; and
- Plans for recruiting additional participant member institutions and identifying additional clinical research/trial opportunities.

Full guidance regarding the format and content of the FY06 NF Consortium Award proposal will be provided in the FY06 NF Consortium Award Program Announcement.

III. AWARD INFORMATION

Up to $300,000 is available to fund an anticipated five to 10 proposals for a 1-year performance period. Funding for FY05 NF Consortium Development Site Awards can be requested for $30,000 for 1 year, inclusive of both direct and indirect costs. **Recipients of the FY05 NF Consortium Development Site Award will be required to collaborate with one another and with the recipient of the FY05 NF Consortium Development Operations Center Award to prepare a proposal, clinical protocols, and associated clinical documents for submission to the FY06 NF Consortium Award mechanism.** As part of this collaboration, the recipient of the NF Consortium Development Operations Center Award shall provide up to $500,000 in supplementary funds to assist and support the various sites.

Funds from the NF Consortium Development Site Award can cover administrative support including salary, consortium meetings and related travel among participating investigators, teleconferences, and other costs directly associated with planning and developing the consortium and clinical protocols. Applicants must budget for travel to a consortium planning meeting in the Baltimore-Washington, DC area at the beginning of the award period.

All applicants must provide evidence of sufficient institutional support and commitment for the proposed studies. Consideration of cost sharing with other funding sources is encouraged. The nature of this award mechanism does not allow for renewal of grants or supplementation of existing grants with DOD funds.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be independent investigators at the Assistant Professor level (or equivalent) or higher. The PIs of submissions to the FY05 NF Consortium Development Operations Center Award are ineligible to submit proposals to the FY05 NF Consortium Development Site Award mechanism.

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, and companies. The USAMRMC is especially interested in receiving applications from HBCU/MI. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs. For the NF Consortium Development Site Award, all personnel, expertise, facilities, and resources dedicated to the consortium must be contained in a single institutional building, complex, or campus.

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under "Major Equipment" in Subsection V.H.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.[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 at http://cdmrp.army.mil/spp under Minority Institutions.

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

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.
- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed 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.

[1] Executive Orders 12876, 12900, and 13021

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 NF Consortium Development Site 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 NF Consortium Development Site 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.**
- **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 May 3, 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:** An electronic Letter of Intent should be submitted by April 5, 2005. To accomplish this, the applicant should complete Part 1 of the Proposal Information section at https://cdmrp.org, 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. 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;
- 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 NF Consortium Development Site 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: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files, but applicants should keep in mind that some reviewers work from black and white printed copies. Applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Language: English.

2. Title/Referral Page: No page limit. Complete the Title/Referral Page. Please note that all forms are available on the "Summary Tab" of eReceipt. 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 "NF Consortium Development Site Award."

f. Check the box next to "NEW proposal."

g. Keyword descriptive technical terms: Type in "Not applicable for NF Consortium Development Site Award submissions."

h. 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 that may have a conflict of interest in the 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. Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

4. Proposal Relevance Statement: Not applicable for NF Consortium Development Site Award submissions.

5. Main Body: Start section on a new page; 6-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. It is the responsibility of the investigator to clearly articulate the qualifications of the research team and institution to participate in the consortium.

Provide evidence that the research team and institution fulfill each of the following criteria for participation in the consortium:

- Commitment to and experience in NF1 clinical research:
  - Describe specific areas of research interest, including clinical manifestations (such as neurofibromas or cognitive deficits) and age range(s) (adult and/or pediatric),
  - Provide details of ongoing or completed NF1-relevant clinical studies, particularly Phase I clinical trials. Reference relevant publications and submit reprints with the proposal (see Subsection V.F.12);
- Institutional resources:
  - Provide evidence of expertise in the following disciplines **within the applicant institution**. Describe the experience of each department in the development and conduct of NF1 clinical studies:

Oncology	Neurosurgery
Dermatology	Plastic Surgery
Basic Research Science	Orthopedics
Neurology	Neuropsychology
Genetics	Ophthalmology
Radiology	Pediatrics
Pathology	Pain Management

As appropriate, describe any additional clinical and/or laboratory expertise that could serve as the basis for the development of clinical protocols by the consortium,

- Describe the resources and expertise available for the collection and processing of specimens from consortium-sponsored studies, and
- Describe the resources and expertise for data management and maintenance of data security/confidentiality;

- Participant recruitment and human subjects protection:
  - Describe the NF1 population (including size, age range, and clinical manifestations) and provide evidence of ability to enroll at least 10-12 evaluable individuals with NF1 per year into consortium-sponsored studies;
  - Provide evidence of commitment to entering eligible participants into consortium-sponsored studies and acknowledgment that the consortium studies have the highest priority,
  - Provide evidence of commitment to addressing quality of life issues for all participants enrolled in consortium studies, and
  - Provide a plan for addressing human subjects protection requirements as outlined by the HSRRB at https://cdmrp.org/Program_Announcements_and_Forms under "Regulatory Document Forms."

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

7. 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).

8. Biographical Sketches: Four-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 global 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.

9. 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.

10. 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 whether government-owned facilities or equipment are proposed for use.

11. 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 of willingness to resolve intellectual and material property issues with other institutions in the consortium. Documentation must be signed by an authorized senior official at the applicant institution.

Provide letters of commitment from senior leaders in each of the institutional departments listed in Subsection V.F.5.

Provide a letter of commitment from a senior administrator at the applicant's institution.

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.

12. 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.

G. Proposed Clinical Study: Three-page limit. Propose a new NF1-relevant clinical study for consideration by the full consortium. The proposed study will be evaluated at programmatic review as evidence of the applicant's overall capability to contribute to the research objectives of the consortium. However, the study itself will not be considered a major review criterion because consortium protocols will reflect the input and expertise of investigators from multiple institutions, including those at the Operations Center. (See Subsection VI.B for additional information on review criteria).

Include the following information:

- Background: Describe the rationale for conducting the study, as well as the study's relevance and applicability of findings;
- Objectives: Describe the purpose and goals of the study;
- Drug or device (if applicable): Describe the investigational drug or device to be used in the study. Include Investigational New Drug/Investigational Device Exemption number; sponsor; source, dose range, schedule, and administration; duration of treatment; and antidotes and treatments available;
- Study population: Describe the target population and the proposed sample size and provide estimates of accrual rates;
- Protocol design: Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology;
- Risks/benefits assessment: Describe risks and measures to be taken to minimize and/or eliminate risks. Describe the benefits to the subject;
- An estimate of the time required to complete the study; and
- Study endpoints.

H. Budget Information: Budget Information includes the one-page NF Consortium Development Site Award Cost Estimate form . Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for the NF Consortium Development Site Award can be requested for $30,000 for 1 year, inclusive of both direct and indirect costs. Direct costs can cover administrative support including salary, consortium meetings and related travel among participating investigators, teleconferences, and other costs directly associated with planning and developing the consortium and clinical protocols. Applicants must budget for travel to a consortium planning meeting in the Baltimore-Washington, DC area at the beginning of the award period. The recipients of the NF Consortium Development Site Awards shall collaborate with one another and with the recipient of the NF Consortium Development Operations Center Award to prepare a proposal, clinical protocols, and associated clinical documents for submission to the FY06 NF Consortium Award mechanism.

There is no guarantee that funds will be available for the NF Consortium Award in FY06.

2. NF Consortium Development Site 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 and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.** The NF Consortium Development Site 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 Indian 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 NF Consortium Development Site 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 consortium-related activities 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 in the consortium.

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 consortium are important factors in selecting proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on the consortium.

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. Categories in amounts less than $1,000 do not need to be itemized.

e. Travel Costs: Applicants must budget for travel to a consortium planning meeting in the Baltimore-Washington, DC area at the beginning of the award period.

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.

I. 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 (Research Involving Human Subjects and/or Anatomical Substances/Cadavers; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

J. 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.

K. 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 May 3, 2005 deadline.

The timeline for the NF Consortium Development Site Award is:

Online Letter of Intent:	Expected by **April 5, 2005**
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time May 3, 2005**
Peer Review:	August 2005
Programmatic Review:	October 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 December 2005 and March 2006

L. 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 May 3, 2005 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.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. 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 and 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). 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 proposal 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. 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 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 on scientific excellence and program relevance.

B. Review Criteria

1. Peer Review: NF Consortium Development Site Award proposals will be evaluated according to the following criteria:

- **PI and Personnel:** Do the PI and other key personnel have interest, training, experience, and competence in NF1 clinical research? Do the PI and other key personnel have the ability to substantially contribute to the design and conduct of consortium clinical studies? Is there a named institutional clinical coordinator to guide clinical protocols through the regulatory approval processes and interact with other consortium clinical coordinators? Are all participating personnel willing to commit adequate time, resources, and subjects to consortium studies?
- **Institutional Resources and Commitment:** Is there evidence of expertise in the following disciplines within the applicant institution – oncology, dermatology, basic research science, neurology, genetics, radiology, pathology, neurosurgery, plastic surgery, orthopedics, neuropsychology, ophthalmology, pediatrics, and pain management? Does the institution have the necessary resources and expertise for specimen collection and processing? Does the institution have the necessary resources and expertise for data management and maintaining security/confidentiality? Is there evidence of institutional commitment to the consortium? Is there evidence of willingness to resolve intellectual and material property issues with other institutions in the consortium?
- **Participant Recruitment and Human Subjects Protection:** Is there evidence of access to an appropriate and sufficiently large NF1 population? Is there a commitment to addressing quality of life issues for all participants involved in consortium studies? Are there plans for addressing HSRRB requirements for the protection of human subjects?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The Integration Panel (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;
- Innovation and potential impact of the proposed clinical study; and
- Unique clinical and/or laboratory expertise that could serve as the basis for the development of clinical protocols by the consortium.

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 and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in November 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*

Transferring the grant from the original institution will not be permitted for the NF Consortium Development Site Award.

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.

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. For planning purposes, please note that 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. Applicants who are approved for funding will be required to attend a consortium planning meeting in the Baltimore-Washington, DC area at the beginning of the award period.

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: (See Subsection V.I for information pertaining to the submission of human subjects and/or human anatomical substances or cadavers documents.) For planning purposes, please be advised that in addition to local IRB approval to conduct research involving human subjects and/or anatomical substances or cadavers, 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 Office of Research Protections (ORP) (formerly Regulatory Compliance and Quality). 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. Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-sponsored research. Title 10 United States Code 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

  Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained prior to the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in DOD-sponsored research unless the

research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators 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/cadavers. Use of these cell lines is subject to HSRRB 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. An informed consent form template can be located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

6. Award/Regulatory Approval: Funds from the NF Consortium Development Site Award may not be used to support laboratory or preclinical research. Moreover, investigators funded under this award mechanism may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals.

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

- **Research Progress Report Requirements:** 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.
- **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. [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
DOD	Department of Defense
EAB	External Advisory Board
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
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
MPEG	Moving Picture Experts Group
NFCDSA	Neurofibromatosis Consortium Development Site Award
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
WAV	Wave