Guidelines for Vanderbilt-Meharry Center For AIDS Research (CFAR)
Developmental Core Awards

Funding Start Date: By June 30, 2006
Letter of Intent Deadline: Feb. 17; Application Deadline: March 17, 2006

The Vanderbilt-Meharry Center For AIDS Research (CFAR) is requesting applications for two different funding mechanisms. The funds are intended to stimulate the development of new ideas and research projects, and are not intended as a source of bridge funding. The CFAR is interested in funding research relevant to the HIV/AIDS epidemic and centered on a promising new concept, hypothesis or breakthrough.

Applicants are particularly encouraged to submit proposals on any aspect of the study of racial/ethnic or gender disparities in HIV infection including either clinical or laboratory based research proposals. These research proposals may include studies on differences in epidemiology, pathogenesis, outcomes, treatment complications, genomics, socio-economic factors, adherence, virology, immunology, or any other area relevant to HIV infection/disease. Utilization of CFAR core services, facilities, and expertise is encouraged.

Applications will be judged based upon the novelty of the proposal, rigor of the experimental plan, and likelihood of later competing for extramural funding from NIH with pilot data gained during period of this award.

An applicant may be junior faculty (Instructor or Assistant Professor), a post-doctoral fellow about to become junior faculty (with letter from Dept. chair or Div. chief stating that), or an established investigator at Vanderbilt or Meharry Medical College.

Proposals from “new investigators” will be given special consideration during review. “New investigators” are defined as per the NIH (http://grants.nih.gov/grants/new_investigators/#definition): Applicants who have not previously served as the principal investigators (PI) on any Public Health Service-supported research project other than a small grant (R03), an exploratory/developmental grant (R21), or certain research career awards directed to those beginning their research career (K01, K08, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K04) are not considered new investigators.

Women and minority applicants are encouraged.

Applications will be evaluated on scientific merit and on the likelihood that a project, if further developed, will be competitive for individual research project funding from NIH (R01). As part of the application, we request information about what federally funded award the applicant plans to pursue using data and results from a CFAR Developmental Core Award.

If you need further information or have any questions, please contact:

Laurie Lebo, PhD, CFAR Research and Program Manager at lauire.lebo@vanderbilt.edu
I. CATEGORIES OF SUPPORT

- Interdisciplinary HIV/AIDS Research Projects

Up to $50,000/year will be awarded for up to 2 years for projects involving two or more investigators from different disciplines. Collaboration is encouraged between investigators in any two different disciplines, but particularly between faculty in clinical and basic science departments. This includes established AIDS investigators, investigators new to the HIV field, and/or new investigators. Teams that include faculty at Meharry and Vanderbilt are encouraged. The goal is to enable subsequent submission of new grant applications to NIH.

The total amount available to the Developmental Core for equipment is limited and equipment requests are not encouraged. Proposals for new equipment will be considered under this category, only if essential for project and to be used by multiple investigators. The reasons for purchasing equipment must be compelling.

- New HIV/AIDS Research Pilot Projects

Up to $25,000/year will be awarded for up to 2 years for single investigator projects.

These grants are intended to enable investigators to perform key preliminary studies prior to submitting new grant applications. A proposal must be for a new project or idea that is distinct from any currently funded project. For established investigators, the proposal should represent a new area of research for that laboratory. Applicants may be established AIDS investigators, investigators new to the HIV field, and/or new investigators. Equipment requests are not allowed under this category.

II. LETTER OF INTENT (due FEBRUARY 17, 2006)

The letter should include a brief description of your anticipated project, how you fit eligibility criteria (see below), the award program for which you are applying (see below), and your contact information (include email address). Also include names of project co-investigator(s), collaborator(s), and/or mentor(s), as appropriate. The purpose of this brief letter is to allow CFAR to contact you with advice about preparing a competitive application. Therefore, expect to be contacted soon after submission of your letter of intent. Full applications will be due March 17, 2006 and require prior LOI submission.

III. GENERAL POLICIES

The following guidelines apply to each of the two funding categories:

A. Eligibility
For Interdisciplinary HIV/AIDS Research Project and New HIV/AIDS Research Pilot Projects:
Principal investigator must be a Faculty member of Meharry Medical College or Vanderbilt University. This includes any faculty level investigator including Research Associates and Instructors, as well as more senior faculty. A post-doctoral fellow about to become junior faculty may apply with an accompanying letter stating that from their Department chair or Division chief.

B. Funding Dates/Renewals

The start date for all funded applications is January 1. Funding will have a duration of no more than two years and cannot be renewed. The second year of funding is contingent upon receipt by December 1 of a progress report demonstrating that significant progress has been made and including a description of efforts being made to obtain external funding. Second year funding will be reduced or eliminated if efforts are not judged as having been adequate. Carry-forward from the first to second year requires justification at the time of renewal and approval from the CFAR Developmental Core Director.

C. Review Process

Applications will be reviewed internally. Written critiques will be provided to the applicant upon completion of review and ranking of the application. This will be useful for subsequent applications for external funding. All funding decisions are final.

D. Change of Institution/Transfers

Recipients may not transfer these awards to another institution or to another individual. Reallocations in the approved budget (beyond 10% of the total budget) require prior written approval before expenditure. Awardees are required to give 90 days notice of any change in Institution. Funds will be pro rated when an applicant leaves the Institution within any funding year.

E. Publications

A copy of any manuscripts or abstracts accepted for publication/presentation, which contains any results found using funds from a CFAR Developmental Core Award should be sent to the Vanderbilt-Meharry Center For AIDS Research upon notification of acceptance.

Support from the Vanderbilt-Meharry Center For AIDS Research must be acknowledged when findings are reported, published or publicity is given to the work. Acknowledgement such as “This research was funded in part [in its entirety] by a 200[X] [enter appropriate year of award] developmental core award from the Vanderbilt-Meharry Center for AIDS Research (CFAR), an NIH funded program #P30 AI 54999.” is suggested.
F. Extensions

Unfunded extensions beyond the approved funding period must be requested in writing, must be approved by the CFAR Developmental Core Director, and may not exceed three months.

G. Grants

The Vanderbilt-Meharry Center For AIDS Research should be notified of any intentions to submit grants containing any results found using funds from the Development Award, so that CFAR personnel can document, and assist and provide support as needed.

H. Patents

Awards are made with the understanding that the Vanderbilt-Meharry Center For AIDS Research will receive written notification of the filing of a patent application for any discovery made based on work funded by these grants.

I. Ownership of Equipment

Equipment purchased under a Vanderbilt-Meharry Center For AIDS Research Developmental Award is for the primary use of the Principal Investigator and his/her associates, and is the property of the PI’s Institution, either Vanderbilt or Meharry. Thus, equipment funded through this mechanism may not be moved to another institution.
J. **Cancellation/Termination**

If a grant recipient fails to comply with the terms and conditions of an award, funding will be terminated. In the event of cancellation/termination, unexpended funds must be returned to Vanderbilt-Meharry Center For AIDS Research Developmental Core.

If support for the proposed project is obtained from other sources, the recipient must notify the CFAR Developmental Core Director. Any funds awarded by this program will be withdrawn when funding is received for the same project from other sources, thus permitting Vanderbilt-Meharry Center For AIDS Research to invest in other research projects and investigators.

K. **Human Subjects**

All human subjects must give their prior, legally acceptable consent (if a minor, legally acceptable consent of a parent or legal guardian) to take part in any research project funded in whole or in part by this program. Institutional policy for human subjects must be followed and the procedures involved will be as stringent as those imposed by the NIH. Budgets will not be approved prior to receipt of the IRB approval letter, if needed.

L. **Laboratory Animals**

The Principal Investigator must follow standards for care of laboratory animals as prescribed in the DHHS Publication 85-23 (NIH). Budgets will not be approved prior to receipt of the IACUC approval letter, if needed.

M. **Data Sharing**

In accord with NIH policy, all primary research data generated with Vanderbilt Meharry CFAR support will be available for sharing no later than the acceptance for publication of the main findings from the final data set. Even if primary research data are stripped of all personal identifiers, it is possible for deductive disclosure of subjects with unusual characteristics. Therefore, in order to maintain privacy (per HIPAA), data and associated documentation will be available only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and to NOT identifying any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning all data after analyses are complete. The data sharing agreement will also require acknowledgement of the Vanderbilt Meharry CFAR as the source of data and will request pre-release review of any presentations or publications by the Vanderbilt Meharry CFAR PI (or the PI who generated the primary data). Agreement to provide financial support for itemized specific expenses of data sharing may also be required in the data sharing agreement.
IV. ADMINISTRATION OF VANDERBILT-MEHARRY CENTER FOR AIDS RESEARCH DEVELOPMENTAL AWARDS

A. Application Forms:

Please use a standard PHS 398 (Rev. 5/01) Grant Application packet, completing only pages 1-5 (omit page 3-Table of Contents). The format should broadly follow NIH guidelines (e.g., abstract, introduction, experimental plan, etc.), following the page limitations for the specific category of application as indicated below. Please note that page 1 (front page) does not need to be signed by a University official, only the Principal Investigator. On line 2 of the PHS 398 face page, please indicate the application category (i.e., Interdisciplinary HIV/AIDS Research Project or New HIV/AIDS Pilot Projects). The standard continuation page should be used for the scientific portion of the application (Research Plan). Applications that exceed the page limitation for each category will be returned to the applicant. References may be listed on additional pages. Appended materials will not be accepted or considered as part of the application.

Maximum Length of Research Plan Section is 6 pages.
Research Plan must include the following sections:

A. Specific aims
B. Background
C. Preliminary studies (in some cases, as explained immediately below)

Preliminary data are not required for an application from a new investigator for a Pilot HIV/AIDS research project. Lack of preliminary data cannot be used as a criticism negatively affecting scoring of a Pilot HIV/AIDS research project application from a new investigator. However, inclusion of preliminary data, when possible, will be considered a plus in scoring of a new investigator’s application. A new investigator is defined as per the NIH definition (above and http://grants.nih.gov/grants/new_investigators/#definition). Lack of preliminary data that is not well-justified can be used as a criticism negatively affecting scoring of any application for a Pilot HIV/AIDS research project that is not from an NIH-defined new investigator, at the discretion of the review panel.

Preliminary data will be required for any application for an Interdisciplinary HIV/AIDS research project.

D. Research design and methods
E. Human subjects--as needed
F. Vertebrate animals--as needed
G. Literature cited--as needed

PHS 398 application forms may be found on the web at: http://grants1.nih.gov/grants/funding/phs398/phs398.html#forms

A Conflict of Interest Statement is not required.
In addition to the PHS 398 Forms, please include:
- A paragraph describing how application is relevant to HIV/AIDS.
- For Interdisciplinary Project Applications, a paragraph explaining how application is interdisciplinary.
- Letters of support from collaborators essential to the success of the proposed project must accompany the application.
- For Vanderbilt PI’s, an internal Proposal Transmittal Form, signed by the Principal Investigator and Department Chair(s) of all participating departments should accompany the application packet. This can be found at: http://medschool.mc.vanderbilt.edu/oor/gm/index.php?GM=5
- Senior post-doctoral fellow or junior faculty applicants must provide a letter of departmental support outlining the commitment of the department to the applicant’s career.

Please deliver the original, and 7 hard copies of the completed application to A-2200 Medical Center North, Vanderbilt, as well as an electronic copy to Laurie Lebo (laurie.lebo@vanderbilt.edu) no later than 5:00 p.m. on the deadline date.

B. Budget:

All applications must include an itemized budget. Funds provided by this program may be expended only for purpose and in the amounts set forth in the budget, unless written consent from the CFAR Developmental Core Director is obtained prior to the expenditure. The grantee may reallocate funds from one expense category to another without the prior approval of the CFAR Developmental Core Director provided that the reallocation does not exceed 10% of the amount of the total direct costs.

If the amount of a grant award is less than the amount requested in the grant application, the grantee shall submit to the CFAR Developmental Core Director a revised itemized budget not exceeding the amount of the grant award. All funding requests must be made in U.S. dollars.

1. Allowable Costs:

- Supplies
- Animals
- Salaries of postdoctoral associates, graduate student assistants, and research assistants
- Equipment (Items that cost more than $1,000 typically will be awarded only in the first year and must be justified)
- Patient costs
- Travel – A maximum of up to $1,000 (U.S.) during the second year of the grant period is permitted to attend a professional meeting in which research funded by this application is presented.
- Investigator salaries (No more than 25% of any award may be used to support salary and fringe benefits for a PI or another investigator. The review panel and/or the Developmental Core Director may recommend that no investigator salary support be allowed for grants made for $25,000 per year or less; this is an option that requires approval of the CFAR PI. Clinical faculty who are principal investigators
are eligible for up to $25,000/year to offset required clinical duties, when justified by a letter from the departmental chair. PI salaries)
• CFAR or other Core facility charges

2. Vanderbilt-Meharry Center For AIDS Research Developmental Awards may **not** be used for any of the following:

• Renovation of physical facilities
• Telephone services
• Laboratory or office furniture
• Dues and membership in scientific societies or journal subscriptions
• Recruiting fees and relocation expenses
• Maintenance contracts
• Computer equipment that is not essential for the research project at hand
C. Review Criteria:

Impact and originality of idea, ability of PI to carry out award, the prospect of successfully applying for further funding, and scientific merit of research design, approach, and methodology. Proposals from junior investigators and faculty new to HIV research will be given special consideration in the review process. Proposals not judged as relevant to HIV/AIDS will not be reviewed.

D. Renewal for Second Year:

A second year of funding is not automatic and will be granted only after submission of a Progress Report documenting adequate progress towards the goals of the proposal. The report must include:

- Summary of accomplishments to date.
- Description of objectives for the next year.
- Financial report summarizing budget expenditures to date.
- Proposed budget for second year, only if changes are proposed.
- Publications (submitted or planned).
- Grant proposals (planned, pending or funded).

This report is due by December 1, 2004. A committee will review the progress report and if progress is viewed as adequate, funding will be renewed for a second year.

E. Reporting and Presenting Requirements:

In addition to the renewal progress report, a one-page summary of accomplishments to date will also be required on July 1 of each year. Awardees will also be required to present progress at a Developmental Core Seminar every 6 months. These mechanisms are intended to provide constructive assistance.

F. Final Progress Report

A final written report is due 90 days after termination of the grant. This report may be brief, but should detail major accomplishments and publications obtained as a result of the funding, and a list of new grants submitted as a result of this funding.