

2024 Tennessee CFAR Developmental Core Awards Funding Opportunity Announcement (FOA)

The Tennessee Center for AIDS Research (CFAR) requests applications for 2024 CFAR Developmental Core Awards. These awards are intended to support studies for short periods (~1 year) to develop preliminary data for highly competitive extramural research applications.

The highest priority of this program is to support:

- **New investigators who do not yet have existing independent (i.e., R01 or equivalent) HIV research funding from the NIH. Early career faculty and recipients of mentored training grants (e.g. K awards) are highly encouraged to apply. Post-doctoral fellows may also apply with a letter from the Department Chair or Division Chief committing to a faculty appointment. For the NIH definition of New Investigator see http://grants.nih.gov/grants/new_investigators/#definition.**

This program may also support:

- **Established investigators who are new to HIV research and have not previously received independent research awards such as an R01 in HIV/AIDS.**
- **Feasibility studies.**
- **Emerging research opportunities.**
- **HIV research activities of newly recruited faculty.**

Letter of Intent Deadline is February 1, 2024 (send to tn-cfar@vumc.org). A letter of intent is strongly encouraged but not required.

Application Deadline is March 1, 2024 (Applications should be submitted directly to tn-cfar@vumc.org with a request for confirmation of receipt)

After receipt of a LOI, participants will be placed in contact with the CFAR Data Sciences Core to discuss study design, analysis plans, and feasibility.

Applications are encouraged from any research discipline (clinical, translational, community, basic science, epidemiology, etc.). **The CFAR will ensure that early-stage investigators develop and maintain mentoring with established investigators so that they may acquire the skills necessary for a career in HIV research.**

See Section IV for application components and templates.

RESPONSIVENESS:

Applications that are most responsive to this FOA will meet at least one of the following criteria, as appropriate for the science being proposed:

- **Have a high likelihood of leading to a strong extramural peer-reviewed grant application; This criterion is required for CFAR Research Project Awards, and is encouraged for CFAR Mission Awards (award types are defined below).**

- Involve cross-institutional collaboration between investigators and/or trainees at Vanderbilt, Meharry Medical College, the Tennessee Department of Health, and/or Nashville CARES.
- Applicant has not previously received a CFAR Research Project Award (see CATEGORIES OF SUPPORT below.)

HIGH PRIORITY TOPICS FOR NIH RESEARCH FUNDING:

Applications should address a High Priority Topic for NIH support using AIDS-designated funds (Details available at [NOT-OD-20-018](https://www.oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf) and at https://www.oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf.)

ADDITIONAL CONSIDERATIONS:

- Applications are encouraged to include meaningful community engagement.
- Awards cannot support clinical research studies that include randomization to one or more low-risk interventions to evaluate effects on biomedical or behavioral outcomes (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-106.html>).
- **After submission of a LOI, each applicant will be contacted by the CFAR Data Sciences Core to discuss study design, analysis plans, and feasibility.**
- Before submitting an application, all applicants are encouraged to discuss their project with a Community Engaged Research investigator and/or relevant community stakeholder group to identify opportunities for community engagement.

WHO MAY APPLY:

An applicant may be junior faculty member (Instructor or Assistant Professor), a post-doctoral fellow about to join the faculty (with letter from the Department Chair or Division Chief stating planned faculty appointment), or an established investigator (i.e., Associate or Full Professor) at Vanderbilt or Meharry Medical College who is new to HIV research. We encourage applications from women, minority, and LGBTQI individuals. Recipients of mentored training grants (e.g. K awards or VA CDA awards) are encouraged to apply.

Employees of the Tennessee Department of Health or Nashville CARES may also apply, preferably in partnership with one or more Vanderbilt or Meharry faculty members.

Applications may include members of the community in partnership with one or more Vanderbilt or Meharry faculty members, and input from, or engagement with, members of the community during project development is highly encouraged. The Developmental Core can assist with identifying community partners as needed.

CONTACT:

All potential applicants should contact the CFAR early in the proposal planning process for guidance on making the application most responsive to this FOA. This will include how to best leverage available CFAR Core services, and how to connect with the Data Sciences Core, Community Engaged Research investigator, and/or community stakeholders. For further information and questions, please contact: tn-cfar@vumc.org or Heather Burgess (heather.burgess@vumc.org) at 615-343-7408

I. CATEGORIES OF SUPPORT

CFAR Research Project Awards

Up to \$50,000 direct cost per award for a duration of 12 months. Funding will begin on May 1, 2024 and will end on April 30, 2025. The likelihood of leading to a new funded NIH research grant application will be weighed heavily when evaluating CFAR Research Project applications. Because this award is concurrent with the final year of the current CFAR grand cycle, no cost extensions will not be available and feasibility of completing the proposed study within one year will be a review criterion.

The proposal must be for a new project or idea distinct from any currently funded project. Salary support can only be requested for faculty who are not tenured, and as is allowed based on other support the applicant may receive. Equipment requests are not allowed under this category.

CFAR Mission Awards

Up to \$20,000 per award for a duration of 12 months. Funding will begin on May 1, 2024 and will end on April 30, 2025. The likelihood of leading to a new funded NIH research grant application is encouraged but will not be weighed as heavily when evaluating CFAR Mission applications. Because this award is concurrent with the final year of the current CFAR grand cycle, no-cost extensions will not be available, and the feasibility of completing the proposed study within one year will be a review criterion.

Mission awards are intended to support applications that align with the specific aims of the Tennessee CFAR. These include creating new opportunities for HIV clinical/translational research at Meharry and between Meharry and Vanderbilt investigators, supporting junior investigator career development, and working toward developing a new emphasis on HIV-focused community-engaged research (CEnR). This also includes collaborative work between Meharry, Vanderbilt, the Tennessee Department of Health, and/or Nashville CARES that does not fall under the scope of a Research Project Award.

II. LETTER OF INTENT (due February 1, 2024)

A letter of intent is very strongly encouraged but not required. The letter should include a provisional title, a brief description of your anticipated project, how you fit eligibility criteria (see below), the program for which you are applying (Research Project or Mission award), 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, and to link you with the Data Science Core to discuss the study design and analysis plan of your proposal. Therefore, expect to be contacted soon after submission of your Letter of Intent. Full applications will be due March 1, 2024. In the Letter of Intent, explicitly indicate which NIH Priority Topic(s) the project will address (List of priorities for NIH support using AIDS-designated funds available at [NOT-OD-20-018](#) and on this [webpage](#).)

III. GENERAL POLICIES

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

A. Eligibility

Principal investigator must be a Faculty member of Meharry Medical College or Vanderbilt. 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 such from their Department chair or Division chief. Employees of the Tennessee Department of Health or Nashville CARES may also apply, preferably in partnership with one or more Vanderbilt or Meharry faculty members.

B. Funding Dates

The start date for all funded applications will be May 1, 2024 (at earliest, pending compliance with necessary approvals) and continue for 12 months. Because this award is concurrent with the final year of the current CFAR grand cycle, no-cost extensions (NCE) will not be available, and all funding will end on April 30, 2025.

C. Review Process

Applications will be reviewed internally by a panel of faculty chosen by CFAR leadership. Expertise relevant to all applications will be solicited, and the review is modeled on a standard NIH study section. Written critiques will be provided to the applicant upon completion of the review and ranking of the application. This will be useful for subsequent applications for extramural funding.

Studies that include research activities above minimal risk or involve vulnerable populations, or contain an international component, require an additional review by the CFAR Program at NIH. Developmental Core Awards cannot support clinical trials.

All funding decisions are final. However, unfunded applicants are encouraged to engage with the Developmental Core to improve their applications for a subsequent cycle.

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 from the Developmental Core 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 Tennessee CFAR upon notification of acceptance.

Support from CFAR MUST be acknowledged when findings are reported, published or publicity is given to the work. Acknowledgement such as the following is required: "This work was funded in part [or entirely] by a 201[X] Developmental Core award from the NIH-funded Tennessee Center for AIDS Research (P30 AI110527)".

F. Grants

The CFAR 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 this contribution and assist and provide support as needed.

G. Annual CFAR Retreat

The Developmental Core hosts an annual retreat where awardees receive constructive feedback on project design, conduct, and data interpretation. Both project and mission awardees are expected to present a brief overview (<10 minutes) in (1) the award year and (2) the following year. Awardees for this cycle should expect to present at the Developmental Core Retreat in August 2024 and August 2025. The tentative date for the 2024 retreat is Tuesday, August 20nd from noon to 5pm.

H. Dissemination of Research Findings

All applications should include a lay public health statement of <=10 lines describing in plain language how the research proposal will further our understanding of HIV and/or improve the health of persons with HIV (this document is for community dissemination and not considered in application scoring).

Mission Awards align with the specific priorities of the TN-CFAR and may be of particular interest to the community. At the completion of the Mission Award, the investigator will prepare a lay summary of research findings for dissemination (one-half to full page).

The DC leadership strongly encourages both Research Project and Mission awardees to accept any invitations to present research findings to HIV service organizations in Nashville after project completion.

I. Patents

Awards are made with the understanding that the CFAR will receive written notification of the filing of a patent application for any discovery made based on work funded by these grants.

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 Tennessee CFAR.

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 Tennessee CFAR 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 Tennessee 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 Tennessee CFAR as the source of data and will request pre-release review of any presentations or publications by the Tennessee 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 TENNESSEE CENTER FOR AIDS RESEARCH DEVELOPMENTAL AWARDS

A. Application Sections:

The maximum Research Plan length is 5 pages (excluding references); the sections of the Research Plan are described below. Applications that exceed the page limitation will be returned to the applicant. The face page (Form Page 1) and budget template (Form Page 4) are from the standard PHS 398 Grant Application packet, which may be found on the web at:

<http://grants.nih.gov/grants/funding/phs398/phs398.html>. 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). **Applicants are encouraged to engage their institutional grants office to prepare the PHS 398 face page and budget form.** Appended materials will not be accepted or considered as part of the application. A Conflict of Interest Statement is not required.

A complete application packet should include the following:

1. PHS 398 face page
2. Research Plan (5 pages, excluding references)
3. A brief paragraph describing how the application is relevant to HIV/AIDS and the priorities for NIH support using AIDS-designated funds (available at [NOT-OD-20-018](#) and on this [webpage](#)). This paragraph should be a separate page, but may duplicate text in the Research Plan.
4. A lay public health statement of ≤ 10 lines describing in plain language how the research proposal will further our understanding of HIV and/or improve the health of persons with HIV (this document is for community dissemination and not considered in application scoring).
5. NIH biosketches from PI(s) and all co-investigators

6. PHS 398 budget (limited to one year of funding)
7. Letters of Support from collaborators essential to the success of the proposed project
8. 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 and intent to provide a faculty position (if not already held) before the start of the award.
9. If applicable, include the CFAR International Checklist or Clinical Checklist if the study involves above minimal risk, vulnerable populations, or international research.
<https://www.niaid.nih.gov/research/cfar-research-project-guidelines> (please contact the Developmental Core with questions on these forms or whether proposed project could be funded by CFAR).

Content of Research Plan (limit to 5 pages for sections 1-5):

1. Specific Aims and Hypothesis

- Long-term objectives and goals
- Specific aims
- Hypothesis
- Explicit statement indicating which NIH Priority Topic(s) the project will address (List of priorities for NIH support using AIDS-designated funds available at [NOT-OD-20-018](#) and on this [webpage](#).)

2. Background and Significance

- Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field.
- This section should be very concise.

3. Preliminary Studies/Progress Report

- Preliminary data are not required for an application from a new investigator for a Pilot HIV/AIDS research project. 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).
- Preliminary data are required from an applicant who is not an NIH-defined new investigator.

4. Research Design and Methods

Describe the following:

- Research design conceptual or clinical framework, procedures, and analyses
- Data collection, analysis, interpretation, and sharing plan
- New methodology and its advantage over existing methodologies
- Novel concepts, approaches, tools, or technologies
- Potential difficulties and limitations
- Any hazardous procedures, situations, or materials and the precautions to be exercised

- Tentative sequence or timetable (i.e. schedule of events) for the project as well as inclusion/exclusion criteria.
- The feasibility of completing the proposed project within the 12-month funding period, including plans for obtaining any regulatory approvals (IRB, etc.) in advance. This is a new review criterion for 2024-2025 due to the final grant year of the parent CFAR award.

5. Sample Size Justification and Statistical Analysis Plan – THIS SECTION MUST BE COMPLETED

- Describe in detail your sample size justification and how the data will be collected, analyzed, and interpreted.
- May include, but is not limited to, the following: sample size, power analysis, statistical tests, description of statistical analysis including P-values and confidence intervals, and name of primary biostatistician who worked with the PI on the research plan (if any).

6. References (not included in 5 page limit)

7. Human subjects - as needed

8. Vertebrate animals - as needed

B. Budget:

All applications must include an itemized budget, utilizing the Initial Budget Period (Form Page 4) of the PHS 398 application forms available at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. The Developmental Core can assist with budget questions as needed. 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
- Patient costs
- Travel – A maximum of up to \$1,000 (U.S.) is permitted to attend a professional meeting in which research funded by this application is presented.
- Investigator salaries should be requested to reflect their % effort on the proposed project and the budget must be adequate to perform the project (e.g., include supply costs or indicate what other sources of support will be used),
- CFAR or other Core facility charges

2. Tennessee CFAR 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
- Studies involving new drugs, treatments, or devices, or off-label use of a licensed drug
- Clinical trials

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. The feasibility of completing the project within the 12-month funding period will be considered for the 2024-2025 application cycle (corresponding to the final year of the current CFAR parent award).

D. Reporting and Presenting Requirements:

After each 3 months of funding, awardees will be required to submit a brief written progress report to Tennessee CFAR. After 12 months of funding, awardees will be required to present study results at a Tennessee CFAR seminar.

E. Final Progress Report

A final written report is due 90 days after termination of the grant. This report 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.