



Pilot Awards for HIV Research

Q & A Session:	February 5, 2025
LOI survey due:	February 19, 2025
Applications due:	Mach 31, 2025
Earliest start date:	June 1, 2025

Funding Opportunity Description

The Third Coast Center for AIDS Research (TC CFAR) pilot award program prepares faculty to successfully compete for HIV research funding from the NIH that will accelerate efforts to end the HIV epidemic. Applications from all disciplines in HIV science are welcome. Pilot awardees generate preliminary data, build collaborations, and gain experience that will ultimately lead to a first R01 or equivalent award in HIV. Early stage and new investigators, as well as R01-funded investigators from other fields who are expanding their work to include HIV, are encouraged to apply.

Growing and supporting the pool of faculty leading high impact HIV research in Chicago is the TC CFAR Developmental Core's primary mission. Core leadership invites interested investigators and their mentors to reach out with questions at any point in the application process. Applicants are encouraged to utilize services and resources offered by the center's three scientific cores to support proposals and funded awards. Learn more about CFAR core services. The Developmental Core intends to call for pilot award applications again in late 2025.

Eligibility

- Scientific focus. The TC CFAR supports HIV research from every discipline across the translational spectrum and especially encourages new cross-disciplinary collaborations. Pilot projects must directly address NIH priorities for HIV research (See strategic goals 1-3, as described in <u>NOT-24-060</u>) and faculty awardees must have a clear plan to eventually lead investigator-initiated HIV research funded by the NIH. The pilot program is not an appropriate pathway toward future research funding from other federal agencies or private entities.
- Applicants. The PI on the application must be an <u>early stage or new investigator</u> (i.e., not yet PI on an R01-equivalent NIH grant) or an established PI from another field who is new to HIV (i.e., history of R01-equivalent funding outside of HIV research). The PI must be a <u>TC CFAR faculty member</u>, which means they hold a PI-eligible appointment at Northwestern University, the University of Chicago, Rush University, or the University of Illinois at Chicago. Multiple PI proposals are allowed as long as the PIs are from different institutions. Each MPI must meet all eligibility criteria for the award. Investigators currently on a K award or preparing for one are encouraged to pursue pilot funding as long as the project is distinct from the research activities of the K award.
- **Mentors.** New investigators are required to include an established HIV researcher (i.e., PI of an R01equivalent grant in HIV) as primary mentor on the application. The Developmental Core will expect the mentor to support the mentee and interact with the Core throughout the application process, including confirmation that the mentor approved the full pilot application before submission. Mentors are also expected to support the project throughout its planning and execution phase. Primary mentors on pilot awards must be faculty at a TC CFAR institution; secondary mentors from external universities are allowed. R01-funded PIs who are new to HIV are strongly encouraged to include an HIV mentor on the

application who can help ensure the project is responsive to NIH priorities for HIV and leverages CFAR resources. The Developmental Core can help identify appropriate mentors before the LOI due date.

Funds Available and Application Timelines

- Direct costs are \$60,000 for single PI awards and \$80,000 for MPI awards. Smaller budgets may be awarded commensurate with the proposed study.
- Awards will be made from the TC CFAR P30 grant and/or institutional commitments.
- Funding is contingent upon NIH support for the TC CFAR, which is expected to continue through 2029. Applications will be prioritized for funding once the CFAR has received its NoA (anticipated May 2025).
- The maximum project period is one year. Proposals for shorter projects are encouraged.
- Regulatory approvals or exemption determinations from the designated IRB or IACUC offices must be in place before an application will be prioritized for funding. Proposals must include documentation that the applicant has started any required approval processes.

Review Criteria

The primary criteria for evaluation of the application are scientific merit and the concomitant likelihood that the pilot project will lead to an HIV grant submission to NIH. All required components of the application may affect the overall impact score. Reviewers will use a standardized scoring system, the <u>modified NIH peer review</u> <u>framework</u>, and additional criteria specific to this competition:

- Competitiveness for NIH HIV funding. Does the work align with the priorities for HIV research as described in <u>NOT-24-060</u>? Will the preliminary data increase the probability of obtaining HIV funding from NIH?
- **Plan for mentorship and career development**. Do the applicant and mentor provide clear plans that support the awardee/s eventual goal of leading investigator-initiated NIH grants in HIV research?
- **Feasibility.** Can the project be completed within the proposed timeline? Is the awardee leveraging appropriate local resources and expertise?
- **Transdisciplinary nature of the research**. Proposals that successfully bring more than one scientific discipline to bear on research questions of interest are encouraged.

Required Letter of Intent Phase

Pilot RFA Q & A Session

The Developmental Core will organize an online meeting on **Wednesday, February 5, from 3:30 p.m. – 4:30 p.m.** to answer questions about the spring 2025 pilot award competition. <u>Register here</u>. Potential applicants and their mentors are strongly encouraged to join, though participation is optional. A recording of the meeting will be available upon request.

Letter of Intent Survey

Preliminary information about the proposed project will be collected via a Letter of Intent (LOI) survey. Responses are required, but not binding, and are due on **February 19, 2025.** <u>https://is.gd/ThirdCoastCFAR_PilotApp</u>_Requested information will include:

- Name, position, role, and contact information for key personnel
- A 1-page draft of the aims and study design /approach
- Checklist to identify types of regulatory approvals that will be needed

REDCap will generate a unique link and return code for each LOI. Applicants should save their unique information as it will be needed to submit the final proposal.

Feedback and Permission to Apply

The Developmental Core will respond to LOIs by March 3. The primary purposes of this administrative process are to confirm that the proposal is responsive to the RFA and to make sure the applicant is fully

aware of all resources available to them and applicable regulatory requirements. The Core will advise on a project start date that is realistic given the complexities and timelines of subcontract set up. The communication from the Core will not include detailed feedback on the proposed approach. Applicants and their mentors are encouraged to contact the Core with their questions before the LOI deadline.

Full Application Due March 31, 2025

The application is an abbreviated NIH R01-style format. Use the CFAR or NIH forms as indicated in the table below. NIH forms can be downloaded from http://grants.nih.gov/grants/funding/phs398/phs398.html. Proposals are expected to use NIH formatting standards (single-spaced, 0.5 inch margin minimum, Arial, Helvetica, Palatino Linotype, or Georgia typeface in black in at least 11 point size).

Applicants will submit final proposals through REDCap, using the unique link and return code generated during the LOI survey phase. Information in the LOI survey portion of the application should be updated as needed. Applicants and their mentors should set clear internal timelines for the mentor to provide feedback on the proposal and sign off on the final version.

Full proposals must be time-stamped by REDCap by 11:59 p.m. March 31, 2025.

REQUIRED COMPONENTS FOR FULL APPLICATION	FORMAT AND NOTES
LOI Survey information	Update as needed
Introduction	
Required in some cases:	1 page limit
 When submitting a revision of a previously unfunded project. Respond to critiques from the prior submission and explain changes that have been made to improve the proposal. 	No form
 When the PI has already had a CFAR pilot award. Provide an update on NIH submissions resulting from the first pilot award and explain how a new award will prepare the PI for a competitive application to the NIH. 	
 When the PI is requesting a second year of funding for an ongoing pilot award. Explain why the current award will not yield results needed for an application to the NIH. Explain how additional funds will make the subsequent application to the NIH exceptionally strong. 	
Project Summary / Abstract	
Serves as a succinct and accurate description of the proposed work when separated from the application.	Limited to 30 lines No form
Project Narrative	
Use plain language understandable by a general audience to describe how the work will contribute to knowledge that will enhance health.	3 sentence limit No form
Specific Aims	1 page limit
State concisely the goals of the proposed research and summarize the expected outcome(s).	No form

Resea	rch Strategy	
Simila	r to an NIH R01-style application, include the following sections:	
•	Significance: Explain the importance of the research, the scientific premise, and gaps in current knowledge. You may include preliminary data, if available (not required), in this section or the approach section.	
•	Innovation: Explain how the work will shift current paradigms, or the use of novel technologies/methods, approaches, and theoretical concepts.	5 page limit
•	Approach: Describe the overall strategy to achieve the specific aims. Describe the experimental design and methods in sufficient detail to allow the reviewers to see how you will achieve robust and unbiased results. Discuss potential problems and alternative strategies. Include a table with a timeline by month for key activities, demonstrating feasibility of the proposed worked within a 1-year (or less) project period.	No form

Bibliography Include title and names of all authors. Follow same formatting and type size rules as for the research strategy.	No limit No form
Biosketches	
Biosketches are required for the PI and mentor. Include biosketches for other investigators only if they play a key role on the project.	Use NIH template
Multiple PI Leadership Plan	
Proposals with multiple PIs must clearly describe the specific roles and responsibilities of each investigator. Address processes for communication and decision making, allocation of	1 page limit
resources, data sharing, conflict resolution, and intellectual property (if needed). Be sure to designate the contact MPI, who will be the point person for reporting to the Developmental Core.	No form
Mentorship Plan and Letter of Support	
The letter from the primary mentor for the pilot award should serve as a clear plan for the type of guidance and support they will provide throughout the project as well as future applications to the NIH. The letter should also confirm that the mentor reviewed and endorses the final version of the full pilot proposal. Support from optional secondary mentors may be described in the primary mentor's letter.	
Plans for future NIH proposal submission	
Explain how this pilot project will add value to plans for future NIH proposals, citing the specific RFAs or Program Announcements and targeted date for submission. If the applicant	1 page limit
has previously received CFAR funding (e.g., pilot, supplement, or other mechanism), provide information on any NIH grant submissions to date, and explain how this new proposal for additional funding will support a successful NIH grant submission in the future. Pilot awards with two MPIs should lead to an application to NIH with the same MPIs.	No form
Regulatory Approvals	
Upload a screenshot that confirms any necessary approvals or exemption determinations from an IRB or IACUC have been requested. Final approvals or exemption determinations must be sent to the <u>Developmental Core</u> before an application will be prioritized for funding.	No form
Human Subjects Section	
Upload a single Word document that describes plans to work with human participants / subjects. Refer to <u>NIH guidance</u> so that all questions are thoroughly addressed.	No limit <u>Use CFAR form</u>

Detailed Budget for Direct Costs	
• Direct costs are limited to \$60,000 for single PI projects and \$80,000 for MPI projects.	
 In the budget workbook, provide a separate sheet for each institution's budget. Use federally-negotiated rates for fringe benefits and F&A. All subcontracts will be issued by Northwestern, as NIAID does not allow third tier subcontracts. 	Use CFAR budget workbook
 Allowable expenses include salary and fringe benefits for the research team, supplies, participant incentives, assays, consultants/service agreements, and core services. Identify all services to be purchased from core facilities and provide the name of the facility. 	
 Salary for the mentor should not be included unless they have an additional role on the project. 	
 Investigators on K awards may be restricted from accepting salary. 	
 Salary may be requested for a graduate student or postdoctoral scientist with a clear justification of the work they will do on the project. Training and tuition can be included as direct costs per the relevant institution's policy. 	
• Travel and equipment are not allowed unless essential for execution of the research.	
• Publication costs are not permitted. When allowable, use a service agreement rather than a subcontract, to support partners that are not conducting human subjects research for the project. Contact Justin Schmandt to discuss this option.	
Budget Justification	
• Provide a separate budget justification for each institution that will receive funds. Describe and justify each line item on the budget.	No limit <u>Use CFAR form</u>
Other Letters of Support	
Other letters of support may be included. They are strongly suggested when the applicant plans to use data, specimens, or services that are not widely available. Proposals that rely on participation from a community partner are required to include a letter signed by an authorized official, confirming the organization's intent to contribute to the project.	No limit No form
Appendices	
Appendices are permitted but not required. Applicants may include study instruments, draft interview guides, or consent forms in their submission. Note that reviewers are not required to read appendices; all information required for the peer review process must be contained within designated sections of the pilot application.	No limit No form

Post Award Timelines and Requirements

NIH CFAR Program Requirements for Pilot Awardees

- 1. Investigators awarded funding will be required to provide an interim report on the progress of their study and a final report detailing the outcome of their project. Specific due dates for reports will be provided in the Notice of Award and are chosen to support preparation of Third Coast CFAR reports to NIH and advisory boards.
- 2. In order to evaluate the long-term outcomes of the program, and in accordance with NIH reporting requirements for the Third Coast CFAR, brief, non-narrative annual reports will be solicited from the PI for five years following the completion of their project indicating:
 - a. The number of subsequent grant applications

- b. The funding outcome of these applications
- c. Any publications or presentations that may have been based on the pilot grant
- 3. Awardees are expected to present their work at CFAR events, upon invitation.
- 4. Awardees must agree to credit the Third Coast Center for AIDS Research in any publication or applications that result from awards. For example: "This *[insert: abstract /publication/ presentation/ grant proposal]* was (partially) supported by a pilot award from the Third Coast Center for AIDS Research (CFAR), an NIH-funded center (P30AI117943), with co-funding from the following Institutes and Centers: NICHD, NIA, NIDCR, NINR, NHLBI, NICHD, NIDA, NIDDK, NIMHD, NIMH, NCI, NIAID, FIC, and OAR. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."
- 5. All publications that benefit from support provided by the Third Coast CFAR must comply with the NIH Public Access Policy.
- 6. Awardees must provide, and agree to allow, information about research awarded under this program, subsequent awards, and publications to be posted on the Third Coast CFAR website.
- 7. Management of the award will be the responsibility of the PI's department or unit.

Administrative Responsibilities of the Pilot Principal Investigator's Department/Unit

The Third Coast CFAR functions as the sponsor for pilot awards and will work with Northwestern University's Sponsored Research office and relevant offices at the University of Chicago, Rush University, and the University of Illinois at Chicago to set up a funding mechanism for the pilot award PI. The award recipient is responsible for working with the research administration within their department/division/unit to manage this award. Management includes procurement, expense reports, deployment of unit personnel on this project, communication with other departments/units to assure proper deployment of personnel on this project, reconciliation of general ledger reports and expenditures, tracking of budget balances, and other activities in support of completion of project aims.

Award Announcement and Project Timelines

Awards are expected to be announced by late May. The earliest project start date is June 1, 2025. The processes below must be initiated by the time of submission and must be fully in place for an application to be prioritized for funding:

- IRB review and approval
- IACUC review and approval
- Conflict of Interest disclosures and management

At the time of the award, the Developmental Core and pilot PI will agree on the appropriate start date for the pilot project. They will take into consideration the timelines for potential subcontracts and other sources of funding to be put into place. Due to the nature of managing NIH funding, the TC CFAR is unlikely to approve no cost extensions. Requests with significant justification will be considered on a case-by-case basis and must be made at least 90 days before the end of the project period.

Developmental Core Contact Information

It is the mission of the Developmental Core to provide strong support for new investigators and established investigators new to HIV research. Please contact us with questions or requests for assistance at any point in the application process. Messages may be directed to the Developmental Core leader/s best suited to respond, based on their institutional affiliation or scientific focus.

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