



Third Coast Center for AIDS Research in Chicago Pilot Awards for HIV/AIDS Research

RFA issued: November 15, 2017

Required letter of intent survey due: January 10, 2018

Mandatory pre-submission review meeting: January 22, 2018

Applications due: February 28, 2018

Awards announcement expected: April 2018

Project start date: Variable

Funding Opportunity Description

[Third Coast Center for AIDS Research](#) (TC-CFAR) pilot awards are intended for key preliminary studies in HIV/AIDS-related basic, clinical, or behavioral research that will lead to new NIH grant submissions. A proposal must be for a new project that is distinct from any currently funded project. The proposed research project must align with NIH HIV/AIDS high/medium research priorities ([NOT-OD-15-137](#)) with preference given to topics in high priority categories. Teams that cross disciplines and include more than one Chicago institution are encouraged.

Funds Available and Duration of Support

Up to \$50,000 in direct costs are allowed and smaller budgets may be awarded. Indirect costs will be determined at the time of award. The number of awards will depend upon the availability of funds. Awards are for one year of support.

Investigators previously funded in this program may apply for a pilot award to continue with a second year of funding for an existing pilot or for a new project. A letter of eligibility from one of the TC-CFAR Developmental Core directors must be included with the application from an investigator previously funded by the Third Coast CFAR. Contact [John Schneider](#) at University of Chicago or [Richard D'Aquila](#) at Northwestern University to discuss your ideas and need for pilot funding and request the letter of eligibility. You will be asked to provide a written justification to include with the letter of eligibility that explains how additional pilot funding will lead to an NIH application.

Administrative responsibilities for the Principal Investigator's department/unit

The Third Coast CFAR functions as the sponsor for these pilot awards and will work with Northwestern University's Office of Sponsored Research to set up a funding mechanism for the PI. The award recipient is responsible for working with 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.

Eligibility

The Principal Investigator (PI) on the application must be a new investigator (never PI on an R01-equivalent NIH grant) or new to HIV/AIDS (never PI on R01-equivalent NIH grant for HIV/AIDS). The PI must also be a TC-CFAR faculty member. TC-CFAR faculty membership is available to any faculty or staff person at Northwestern University, University of Chicago, and Lurie Children's Hospital, **who is allowed to apply for NIH grants as a principal investigator at their institution**. Investigators who are not PI-eligible, as well as investigators at other academic and community organizations in the Chicago-area, may serve as a co-PI or co-Investigator (co-I) on these projects. All investigators must be TC-CFAR members (register here - (<http://www.thirdcoastcfar.org/membership/>)). New investigators are required, and new to HIV/AIDS investigators are strongly encouraged, to include an established HIV/AIDS researcher as a mentor on the application.

Project relevance to HIV/AIDS

Proposals must be related to HIV/AIDS and preference will be given to projects that align with high priority topics as defined by the NIH Office of AIDS Research and outlined in [NOT-OD-15-137](#). This notice designates topics as high, medium, or low priority for AIDS funding. Low priority topics usually cannot be funded. The high priority topics are:

1. Reducing Incidence of HIV/AIDS including: developing and testing promising vaccines, developing and testing microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that mitigate

adherence issues; and developing, testing, and implementing strategies to improve HIV testing and entry into prevention services.

2. Next generation of HIV therapies with better safety and ease of use including: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens. Additionally, implementation research to ensure initiation of treatment as soon as diagnosis has been made, retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses.
3. Research toward a cure including: developing novel approaches and strategies to identify and eliminate viral reservoirs that could lead toward a cure or lifelong remission of HIV infection, including studies of viral persistence, latency, reactivation, and eradication.
4. HIV-associated comorbidities, coinfections, and complications (must have focus on or inclusion of HIV) including: addressing the impact of HIV-associated comorbidities, including tuberculosis, malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.
5. Cross cutting areas: Basic research, health disparities, and training including:
 - a. Basic Research: understanding the basic biology of HIV transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and other fundamental issues that underpin the development of high priority HIV prevention, cure, co-morbidities, and treatment strategies.
 - b. Research to Reduce Health Disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.

Regulatory Compliance

Regulatory approvals must be complete before work with animals or human subjects can begin. Studies involving human subjects may be subject to additional NIH review prior to initiating the study. Clinical trials are not allowed and NIH has recently updated the definition of a clinical trial. You can find information here: <https://grants.nih.gov/policy/clinical-trials/definition.htm>. Please contact us if you have questions about how to determine if your study falls under the new definition of a clinical trial. If the project or any project-related activities will occur outside of the US, additional NIH review will be required. NIH reviews may delay the project start date.

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/AIDS grant submission to NIH.

Reviewers will use the NIH scoring system and a modified set of criteria listed below.

1. **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
2. **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
3. **Innovation:** Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
4. **Investigative team:** Is the PI a new investigator or an established investigator new to HIV/AIDS research? Is an appropriate plan in place to provide mentoring? Is an appropriate plan in place for collaborative work across disciplines and organizations?
5. **Transdisciplinary nature of the research:** Proposals that successfully bring more than one scientific discipline to bear on research questions of interest are encouraged.
6. **Alignment with Office of AIDS Research Priorities:** Does the work align research topics of high priority as designated by the OAR in NOT-OD-15-137?
7. **Competitiveness for NIH AIDS funding:** Is the pilot project targeted at development of an NIH grant proposal? Will completion of the pilot project increase the probability of obtaining AIDS funding from NIH?

Application and Submission Information

Letter of intent (LOI) is required, but non-binding. Due January 10, 2018:

Letter of intent information will be collected in a survey format.

Access the survey here: <https://redcap.nubic.northwestern.edu/redcap/surveys/?s=AXK4D8AJ94>

Requested information will include:

- Name, position, institution, contact information, and role on project for members of the research team
- Mentor: name, position, institution, contact information
- Planned title and brief (4-8 sentence) description of project
- Identify the specific NIH HIV/AIDS research priority bullet with which the project aligns
- Checklist to identify types of resources and regulatory approvals that will be needed

The TC-CFAR Developmental Core will review LOI surveys for eligibility, alignment with NIH HIV/AIDS research priorities, and resource needs. The LOI survey is required, but is not binding.

Mandatory pre-submission review meeting January 22, 2018 - time TBA between 2:00 - 5:00 pm:

Following LOI review, all eligible applicants will be contacted to schedule a 10-15 minute pre-submission review (in person or by video/teleconference). Applicants will meet individually with the Third Coast CFAR developmental core resource committee to review the LOI survey for alignment with NIH HIV/AIDS research priorities, identification of regulatory reviews that will be required, and link the project to needed resources and mentoring. Third Coast CFAR members of the committee are:

John Schneider, MD, Director, Developmental Core

Richard D'Aquila, MD, Director, Third Coast CFAR, and co-director Developmental Core

Brian Mustanski, PhD, Co-director, Third Coast CFAR

Patrick Janulis, PhD, Quantitative Methodologist

Fern Murdoch, PhD, Asst Director for University Interactions and Strategic Growth

Justin Schmandt, MPH, Asst Director for Community Interactions and External Communications

Application due February 28, 2018:

The application is an abbreviated NIH R01-style format and NIH forms are used as indicated in the table below. Forms can be downloaded from <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Applications 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 pt size).

The application submission link is the same as for the LOI survey. Use your "return code" to open your application that will contain all previously entered LOI information. After the pre-review additional fields will be displayed where you add your proposal. You must update information in the LOI survey portion of the application as required at the time of full application. Contact Fern Murdoch (see below) if you need your "return code".

Award announcement and project start dates:

Awards are expected to be announced in late April 2018. The project start date is dependent on the time needed for budget review, regulatory approvals, and execution of subcontract agreements with organizations outside Northwestern University. Applicants will be advised during the pre-submission meeting to address administrative requirements that could delay project start dates. Processes for the following should be initiated at the time of submission to avoid delays:

- IRB review and approval
- IACUC review and approval
- Conflict of Interest disclosures and management
- Commitment packages for sub-contracts for any organization other than Northwestern University.

REQUIRED COMPONENTS FOR APPLICATION	FORMAT & NOTES
LOI Survey information	Update if necessary
Department/Unit Research Administrator	Enter name and contact information
<p>Letter of Eligibility and Justification</p> <p>Required only for applicants who have previously received TC-CFAR pilot funding and are requesting a second year of funding or proposing a new project. A TC-CFAR Developmental Core director can provide letter after reviewing the written justification.</p>	No form
<p>Introduction</p> <p>Required only for applicants who are 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.</p>	1 page limit No form
<p>Final Project Summary (Abstract)</p> <p>The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application</p>	Limited to 30 lines No form
<p>Specific Aims</p> <p>State concisely the goals of the proposed research and summarize the expected outcome(s).</p>	1 page limit No form
<p>Research Strategy</p> <p>Similar to an NIH R01-style application, include the following sections:</p> <ol style="list-style-type: none"> 1. Significance: Explain the importance of the problem, the scientific premise, and gaps in current knowledge. You may include preliminary data, if available (not required), in this section or the approach section. 2. Innovation: Explain how the work will shift current paradigms, or the use of novel technologies/methods, approaches, and theoretical concepts. 3. 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. 	5 page limit No form
<p>Scope of Human Subjects Work</p> <p>An abbreviated version of the NIH <i>Protection of Human Subjects</i> section is required if the study includes human subjects work. Definitions and tools to determine if your study is considered human subjects research can be found here: https://humansubjects.nih.gov/</p> <ul style="list-style-type: none"> • Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant. State if children, pregnant women, prisoners, or transgender individuals will be included. • Provide a description of the recruitment plan and interaction with participants. • List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. • For studies involving human data or biological specimens, include a description of the source of the data/biospecimens; whether they will be collected specifically for this study or were collected for another purpose; what identifiers will be associated with the human specimens and data and who has access to subject identities; and the role(s) of providers of the data/biological specimens in the proposed research. • Outline plan for IRB review and institution that will provide primary oversight. 	1 page limit

<p>Bibliography</p> <p>Include title and names of all authors. Follow same formatting and type size rules as for the research strategy.</p>	<p>No limit No form</p>
<p>Plans for future NIH proposal submission</p> <p>Briefly explain how this pilot project will add value to plans for future NIH proposals. If a specific NIH submission date is planned, please cite the RFA and targeted date.</p> <p>If the applicant has previously received pilot funding, provide information on any NIH grant submissions to date, and explain how additional funding will support a successful NIH grant submission in the future.</p>	<p>1 page limit No form</p>
<p>Detailed Budget for Direct Costs</p> <ul style="list-style-type: none"> • Allowable expenses include salary and fringe benefits for the research team, supplies, patient incentives, assays, computer time, data analysis, and core services. Identify all services to be purchased from core facilities and provide the name of the facility. • Applicants are encouraged to utilize TC-CFAR core services. Contact core directors or the TC-CFAR assistant directors, Fern Murdoch and Justin Schmandt to confirm available services and generate an estimate of costs. • Salary for the mentor should generally not be included, unless they are doing work on the project. • Investigators on K-awards may be restricted from accepting salary. • It is not the purpose of these grants to provide support for training and graduate student stipends. Training and tuition cannot be supported. Salary may be requested for a graduate student or postdoctoral scientist with a clear justification of the work they will do on the project and who do not have salary supported on a training grant. • Travel and equipment are not allowed unless essential for execution of the research. • Sub-contracts are permitted. Use a second Form Page 4 to detail the sub-contract budget. Indirect or F&A costs should be listed on the sub-contract budget form, but do not count against the \$50,000 maximum budget. Add the direct costs of the sub-contract to the Budget form for the overall project. • Do not include indirect or F&A costs for the overall project. These will be calculated at the time of funding. 	<p>Use PHS 398 Form Page 4</p>
<p>Budget Justification</p> <ul style="list-style-type: none"> • Provide a justification for each line item on the Budget, including all items on a sub-contract budget. • Specifically identify any CFAR or other core facilities that will be used and how costs were calculated. 	<p>No limit No form</p>
<p>Biosketch</p> <p>Provide for PIs, co-Is, Mentor and other key personnel</p>	<p>New NIH Biosketch 5 page limit Use NIH template</p>
<p>Mentor Letter</p> <p>New investigators must have a mentor with HIV/AIDS research experience and a mentor is strongly suggested for established investigators new to HIV/AIDS. The letter from the mentor should describe the relationship between the mentor-mentee and the mentoring plan. Investigators may contact TC-CFAR for assistance in identifying a mentor.</p>	<p>No form</p>

<p>Letters of Support</p> <p>Letters providing specific information related to the research strategy - such as availability of reagents, or other resources - can be attached. If the PI is not currently eligible to serve as PI, but a change is expected prior to funding, a letter from the supervisor is needed.</p> <p>General letters of recommendation should not be included.</p>	<p>No form upload one pdf file for all letters</p>
<p>Sub-recipient Commitment Package</p> <p>Work with the investigator at the sub-recipient site to complete this form. Budget, F&A rate, and the signature of an authorized official at the sub-recipient site must be included.</p> <p><small>*http://www.northwestern.edu/coi/subrecipients/Subrecipient_Commitment_Form.doc</small></p>	<p>Use NU Form*</p>

Application Processing

A note regarding Office of Sponsored Research: This funding mechanism uses internal funding and does not require review or approval by an Office of Sponsored Research. Applications are submitted directly to the TC-CFAR by investigators.

The application submission link (TBA) is the same as for the LOI survey. Use your "return code" to open your application, which will contain all previously entered LOI information. You must update information in the LOI survey portion of the application as needed. After the pre-submission review additional fields will be displayed where you will add your proposal components. Contact Fern Murdoch (see below) if you need your "return code".

Applications must be time-stamped by the system no later than 11:59 PM on the receipt date(s) described above.

Obligations of the Pilot Award Recipient PI

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 TC-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 TC-CFAR, brief, non-narrative annual reports will be solicited from the PI for five years following the completion of their project indicating:
 - The number of subsequent grant applications
 - The funding outcome of these applications
 - Any publications or presentations that may have been based on the pilot grant
3. Awardees are expected to present their work at a TC-CFAR forum, 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), which is supported by the following NIH Co-Funding and Participating Institutes and centers: NICHD, NIAID, NIMHD, NIA, NIGMS, NIDDK, NIDA, NCI, NHLBI, NIMH, 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 TC-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 TC-CFAR website.
7. Management of the award will be the responsibility of the PI's department or unit.

Additional Information and Questions

It is the mission of the Developmental Core of the Third Coast Center for AIDS Research to provide strong support for new investigators and established investigators new to HIV/AIDS research. Please contact us with questions or requests for assistance at any point in the application process.

Requests for additional information and questions may be directed to:

Fern E. Murdoch, PhD

Assistant Director for University Interactions and Strategic Growth

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