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

RFA issued: Late December, 2019
Letter of intent survey due: January 21, 2020
Pre-submission meetings: late January
Tentative application due date: February 17, 2020
Awards announcement expected: March 2020
Earliest start date: April 1, 2020 (dependent on funding)

Funding Opportunity Description
The Third Coast CFAR (an NIH P30) is now under review for a renewal for 5 more years starting April 2020. Planning is starting now in anticipation of renewal funds being available for new Pilot Awards in spring 2020.

Third Coast Center for AIDS Research (TC-CFAR) pilot awards are intended for key preliminary studies in HIV-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 high/medium research priorities (NOT-OD-15-137) with preference given to topics in high priority categories. The Third Coast CFAR is particularly interested in supporting more new research focused on co-morbidities that may occur with higher incidence in people living with HIV, particularly if proposed by cross-disciplinary research teams. Review criteria value projects that are trans-disciplinary and that will be competitive for NIH funding using pilot results.

Funds Available
- 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.
- Funding is contingent on the Third Coast CFAR receiving NIH funding for 4/1/20. We anticipate knowing if funding will be available by January 2020.

Duration of Support
The project period is one year starting as early as 4/1/20. Investigators are required to have all regulatory approvals (IRB, IACUC, etc) in place for the project start date.

Eligibility
The Principal Investigator (PI) (or co-PIs) on the application must be a new investigator (never PI on an R01-equivalent NIH grant) or new to HIV (never PI on R01-equivalent NIH grant for HIV). The corresponding PI must also be a TC-CFAR faculty member. Full TC-CFAR faculty membership is available to any faculty or staff person at Northwestern University (NU), University of Chicago (UC), and Lurie Children’s Hospital of Chicago (LCHC), who is allowed to apply for NIH grants as a principal investigator at their institution. All investigators must be a member of the TC-CFAR, either as a full (if at NU or UC) or affiliate (if at another institution) member (register here - (http://www.thirdcoastcfar.org/membership/)). New investigators are required, and new to HIV investigators are strongly encouraged, to include an established HIV researcher as a mentor on the application.

Investigators previously funded in this program may apply for a pilot award to continue with a second year of funding for an existing pilot. Permission from one of the TC-CFAR Developmental Core directors is required. 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 written permission to apply (email is sufficient).

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.

**Project relevance to HIV**

Proposals must be related to HIV 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](https://grants.nih.gov/grants/guide/notice.htm?ny=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:
     - 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.
     - 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](https://grants.nih.gov/policy/clinical-trials/definition.htm). 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 grant submission to NIH.

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

1. **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](https://grants.nih.gov/grants/guide/notice.htm?ny=OD-15-137)?
2. **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?
3. **Transdisciplinary nature of the research**: Proposals that successfully bring more than one scientific discipline to bear on research questions of interest are encouraged.
4. **Special emphasis on Non-AIDS co-morbidities:** Projects focused on co-morbidities that may occur with higher incidence in people living with HIV are specifically encouraged.

Additional review criteria are per standard NIH research project review:

5. **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?

6. **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?

7. **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?

8. **Investigative team:** Is the PI a new investigator or an established investigator new to HIV research? Is an appropriate plan in place to provide mentoring? Is an appropriate plan in place for collaborative work across disciplines and organizations?

**Application and Submission Information**

**Letter of intent (LOI) survey is required, but non-binding.**

**Due January 21, 2020:** The LOI survey is required, but is not binding.

Letter of intent information will be collected in a survey format. Access the survey here: [https://redcap.nubic.northwestern.edu/redcap/surveys/?s=AXK4D8AJ94](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 ideas for project
- Identify the specific NIH HIV research priority bullet with which the project aligns
- Checklist to identify types of Third Coast CFAR resources that could be useful
- Checklist to identify types of regulatory approvals that will be needed

*Additional sections for upload of final application sections are not required for the LOI.*

**Mandatory pre-submission review meeting in late January TBD:**

All eligible applicants and their mentor(s) will be contacted to schedule a brief pre-submission meeting (in person or by video/teleconference) with the Third Coast CFAR developmental core leadership to review the LOI survey and 1) navigate the applicant to resources in the Third Coast CFAR and across the universities that could be incorporated into the project development, 2) assess alignment with NIH HIV research priorities, 3) and identify regulatory reviews that may be required.

**Applications due February 17, 2020 (tentative - dependent on NIH renewal timeline):**

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](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 ([https://redcap.nubic.northwestern.edu/redcap/surveys/?s=AXK4D8AJ94](https://redcap.nubic.northwestern.edu/redcap/surveys/?s=AXK4D8AJ94)) is the same as for the LOI survey. Use your "return code" to open your application that will contain all previously entered LOI information. Update information in the LOI survey portion of the application as required at the time of full application. At the end of the LOI sections are the sections for upload of your final application components. Click "submit" when all final components are loaded. Contact Fern Murdoch (see below) if you need your "return code".
Award announcement and project start dates:
Awards are expected to be announced by in March 2020 (tentative dependent on NIH renewal timeline). The earliest project start date is 4/1/20 and all regulatory requirements must be in place by the project start date. Applicants will be advised during the pre-submission meeting to address administrative requirements. Processes for the following should be initiated at the time of submission:

- IRB review and approval
- IACUC review and approval
- Conflict of Interest disclosures and management
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<tr>
<th>REQUIRED COMPONENTS FOR APPLICATION</th>
<th>FORMAT AND NOTES</th>
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<tr>
<td><strong>LOI Survey information</strong></td>
<td>Update if necessary</td>
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<tr>
<td><strong>Department/Unit Research Administrator</strong></td>
<td>Enter name and contact information</td>
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<td><strong>Written Permission to Apply</strong></td>
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<td>Required only for applicants who have previously received TC-CFAR pilot funding and are requesting a second year of funding. A TC-CFAR Developmental Core director can provide written permission (email sufficient).</td>
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<tr>
<td><strong>Introduction</strong></td>
<td>1 page limit No form</td>
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<td>Required 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.</td>
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<td><strong>Project Summary (Abstract)</strong></td>
<td>Limited to 30 lines No form</td>
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<td>The <strong>Project Summary</strong> is meant to serve as a succinct and accurate description of the proposed work when separated from the application</td>
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<td><strong>Specific Aims</strong></td>
<td>1 page limit No form</td>
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<td>State concisely the goals of the proposed research and summarize the expected outcome(s).</td>
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<td><strong>Research Strategy</strong></td>
<td>5 page limit No form</td>
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<td>Similar to an NIH R01-style application, include the following sections:</td>
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<td>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.</td>
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<td>2. Innovation: Explain how the work will shift current paradigms, or the use of novel technologies/methods, approaches, and theoretical concepts.</td>
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<td>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.</td>
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<tr>
<td><strong>Scope of Human Subjects Work</strong></td>
<td>1 page limit No form</td>
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<td>• Is this study exempt from federal regulations for Human Subjects Research? List exemption.</td>
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<td>• Does this study solely utilize the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects? 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.</td>
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<td>• 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.</td>
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- 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.
- Outline the status/plan for IRB review and the institution that will provide primary oversight. Identify all sites that will conduct HSR.

**Bibliography**
Include title and names of all authors. Follow same formatting and type size rules as for the research strategy.

**Plans for future NIH proposal submission**
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.
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.

**Detailed Budget for Direct Costs**
- 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.
- Publication costs are not permitted. If needed, these can be requested as a Core Subsidy Award at the time of acceptance by the journal.
- 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 Northwestern University indirect or F&A costs for the overall project. These will be calculated at the time of funding.

**Budget Justification**
- Provide a justification for each line item on the budget, including all items on a sub-contract budget.
- Specifically identify any core facilities that will be used and how costs were calculated.
- Include timeline for completion of regulatory review, experimental strategy, and data analysis

**Biosketch**
Provide for PIs, co-Is, Mentor and other key personnel

| New NIH Biosketch 5 page limit | Use NIH template |

**Mentor Letter**
New investigators must have a mentor with HIV research experience and a mentor is strongly suggested for established investigators new to HIV. 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.

| No form | |

**Letters of Support**
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.

| No form | upload one pdf file for all letters |

**Sub-recipient Commitment Package**
Work with the investigator at the sub-recipient site to complete this form. This form with the signature of an authorized official at the sub-recipient site is required for all institutions, other than Northwestern University, participating in this research project.

* https://osr.northwestern.edu/sites/osr/files/subcommitform_phs.pdf

| Use NU Form* | |

**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-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, 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 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:

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Email: f-murdoch@northwestern.edu