Request for Applications

Pilot Awards for Research on HIV and HIV-related Comorbidities

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RFA issued:	June 2, 2021
LOI survey due:	September 22, 2021
Pre-submission meeting:	September 27, 2021
Applications due:	October 25, 2021
Earliest start date:	January 2022

Funding Opportunity Description

The Third Coast Center for AIDS Research (CFAR) solicits applications for Pilot Awards to begin in early 2022. CFAR pilot awards are intended for preliminary studies in HIV-related basic, clinical, social or behavioral research that will lead to new NIH grant submissions. The proposed research project must **align** with NIH priorities for HIV research (NOT-OD-20-018). For the upcoming award cycle, the Third Coast CFAR will give special but not exclusive priority to research focused on non-AIDS comorbidities that occur with higher incidence in people living with HIV, including but not limited to: COVID-19, cardiovascular diseases, sleep disorders, non-AIDS defining cancer, TB, HCV, diabetes, and depression. Review criteria value projects that are trans-disciplinary and that will be competitive for NIH funding using pilot results. Proposals must outline a new project that is distinct from any currently funded research. Collaborations on non-AIDS comorbidities between HIV researchers and researchers in other (non-HIV) fields are encouraged. Please contact the developmental core leadership if there is need for identifying potential collaborators.

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 upon NIH support for the Third Coast CFAR P30 grant, which is expected to continue until 2025.

Duration of Support

The project period is one year starting as early as January 1, 2022. 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 (i.e. never PI on an R01-equivalent NIH grant) or new to HIV research (i.e. never PI on R01-equivalent NIH grant for HIV). The corresponding PI must also be a Third Coast CFAR faculty member. Full CFAR faculty membership is available to any investigator at Northwestern University (NU), University of Chicago (UC), or Lurie Children's Hospital (LCH), **who is allowed to apply for NIH grants as a principal investigator at their institution**. All investigators listed on an application must be a member of the Third Coast CFAR, either as a full or affiliate member. Register for CFAR membership 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 project with written permission from the Developmental Core.

Administrative responsibilities for the pilot 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 pilot award 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 **align** with the priorities as defined by the NIH Office of AIDS Research and described in NOT-OD-20-018. For the upcoming cycle, the Third Coast CFAR will give special priority to research focused on comorbidities that occur with higher incidence in people living with HIV, including but not limited to: COVID-19, TB, HCV, diabetes, and depression.

Examples of research ALIGNED with the priority areas are listed below. The list is not ranked and is not all inclusive.

- Reduce incidence of HIV/AIDS, including develop safe, effective, practical, and affordable HIV vaccines, microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that improve adherence; and develop, test, and implement strategies to improve HIV testing and entry into prevention services.
- Research focused at fundamental scientific questions with a clear or credible link to HIV/AIDS to understand the mechanisms of HIV transmission and acquisition, virus/host cell interactions and pathogenesis, and the structure and dynamics of HIV proteins to prevent ART drug resistance; immune dysfunction and persistent 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.
- Next generation HIV therapies with better safety and ease of use including develop and test HIV treatments that are less toxic with fewer side effects and complications, longer acting, easier to take and adhere to than current regimens.
- Long-term treatment or prevention strategies for HIV-relevant coinfections and comorbid conditions across the lifespan
- Effective socio-behavioral interventions to achieve uptake of HIV prevention and treatment strategies and reduce health disparities.
- Implementation research designed to ensure biomedical and other prevention and treatment strategies, are initiated as soon as possible, increased retention and engagement in treatment services, and maintenance of optimal prevention and treatment responses are achieved.
- Research toward a cure including development of novel approaches and strategies to study viral persistence, latency, reactivation, and eradication; identify and eliminate viral reservoirs that could lead toward a cure or long-term remission.
- Research training of the multidisciplinary workforce required to conduct High Priority HIV/AIDS or HIV/AIDS-related research.
- Research that includes people (or biological specimens from people) who with HIV, are HIV exposed, and/or are at elevated risk for HIV infection as part of a broader sample or as a comparative cohort.

- Research that examines health and social issues, such as other infectious or non-infectious conditions and substance use or mental health disorders, clearly linked with HIV. (transmission/acquisition, pathogenesis, morbidity and mortality, stigma) in populations or settings with high HIV prevalence or incidence.
- Research that meaningfully includes HIV/AIDS (or SIV) outcomes/endpoints.
- Development of innovative technologies, such as sensitive assays, biomarkers, and imaging methods, coupled with cutting-edge studies of biology, virology, pharmacology, and immunology to advance durable and scalable prevention, treatment and cure in people with HIV.

Regulatory compliance

Regulatory approvals must be provided to the Developmental Core 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, as defined by the NIH, are not eligible for CFAR funding. Utilize the NIH's decision tool to confirm that your project is not considered 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 grant submission to NIH.

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

- Alignment with NIH's priorities for HIV research. Does the work align with the priorities for HIV research as described in NOT-OD-20-018?
- 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?
- Transdisciplinary nature of the research: Proposals that successfully bring more than one scientific discipline to bear on research questions of interest are encouraged.
- Special emphasis on HIV-related comorbidities: Projects focused on comorbidities that may occur with higher incidence in people living with HIV will be given special priority for competitiveness during the review process. Collaborations between HIV researchers and researchers in other (non-HIV) fields are encouraged and could add merit to a proposal.

Additional review criteria are per standard NIH research project review:

- 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?
- 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?
- 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?
- 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 responses due September 22, 2021

LOI information will be collected via survey. Responses are required, but not binding. 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 on September 27, 2021

Each applicant and their mentor(s) will participate in a required pre-submission meeting with the developmental core leadership the afternoon of September 27. The specific time will be confirmed after submission of the LOI survey. The purpose of the meeting is to: 1) review the applicant's responses to the LOI survey; 2) navigate the applicant to resources in the Third Coast CFAR and across the universities that could be incorporated into the project development; 3) assess alignment with NIH HIV research priorities; and 4) identify regulatory reviews that may be required.

Applications due October 25, 2021

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 point size).

The application submission link (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 Justin Schmandt if you need your "return code". Applications are due by 11:59 p.m. on October 25, 2021.

Award announcement and project start dates

Awards are expected to be announced in late November. The earliest project start date is January 1, 2022. All regulatory approvals 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

REQUIRED COMPONENTS FOR APPLICATION	FORMAT AND NOTES
LOI Survey information	Update if necessary
Department/Unit Research Administrator Provide name and contact information.	No form
Written Permission to Apply Required only for applicants who have previously received CFAR pilot funding and are requesting a second year of funding. A CFAR Developmental Core director can provide written permission (email sufficient).	No form
Introduction 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.	1 page limit No form
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 State concisely the goals of the proposed research and summarize the expected outcome(s).	1 page limit No form
Research Strategy 1. Similar to an NIH R01-style application, include the following sections: 2. 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. 3. Innovation: Explain how the work will shift current paradigms, or the use of novel technologies/methods, approaches, and theoretical concepts. 4. 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

Scope of Human Subjects Work □ Is this study exempt from federal regulations for Human Subjects Research? List exemption. □ 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. □ 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 or gender non-conforming study participants will be enrolled. □ 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.	1 page limit 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
Plans for future NIH proposal submission Briefly explain how this pilot project will add value to plans for future NIH proposals, citing the specific RFA(s) and targeted date for submission. 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.	1 page limit No form

Detailed Budget for Direct Costs □ Allowable expenses include salary and fringe benefits for the research team, supplies, participant incentives, assays, 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 CFAR core services. Contact core directors or 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. □ 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. □ Provide a separate budget for each institution. □ Sites other than NU should list F&A costs. These costs do not count against the $50,000 limit. □ Do not include NU indirect or F&A costs for the overall project. These will be calculated at the time of funding. □ When feasible, use a service agreement to support partners that are not conducting human subjects research for the project. Contact Justin Schmandt to discuss this option.	Provide a separate budget for each institution Form Page 4
Budget Justification □ Describe and justify each line item on the budget. □ Identify any core facilities that will be used and how costs were calculated. □ Provide a separate budget justification for each institution that will receive funds.	No limit Use CFAR form
Biosketches Provide for PI, Co-PIs, Co-Investigators, Mentor, and other key personnel.	Use NIH template
Letters of Support New investigators must have a mentor with HIV research experience. 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 the CFAR for assistance in identifying a mentor.	No form

Appendices Appendices are permitted but not required. Applicants may include blank data collection forms, lists of interview questions, 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
Sub-recipient Commitment Form 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. * 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 CFAR by investigators.	Use NU form*

The application submission link is the same as for the LOI survey. Use your "return code" to open your application, which will contain all previously entered LOI information. 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 Justin Schmandt if you need your "return code".

Applications must be time-stamped by the system no later than 11:59 PM on October 25, 2021.

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 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.

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:

Justin Schmandt, MPH
Associate Director, Third Coast CFAR
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