Joint UNC-Duke CFAR PrEP Request for Applications

The objective of this RFA is to support emerging research regarding biomedical HIV prevention, particularly PrEP implementation, in North Carolina, by identifying: 1) mechanisms for strengthening the structural and social environment supporting PrEP use among key populations, and 2) innovative methods for engaging key populations in PrEP care.

Examples of responsive research topics include (but are not limited to):

- Exploring innovative approaches that address structural and societal barriers to PrEP service delivery in North Carolina
- Developing and assessing novel or alternative models of PrEP service delivery that promote linkage to and persistence in PrEP care and developing and assessing novel interventions on PrEP adherence
- Among PrEP prescribers and consumers, exploring perceptions of novel biomedical HIV prevention products in the pipeline and how these products might be implemented in practice

Proposals must align with NIH priorities. Applicants are also encouraged to give consideration to studies of populations currently underrepresented in PrEP care, including adolescents; persons who inject drugs; and Black and Latinx cisgender men, cisgender women, and transgender women who have sex with men.

General Information

- **Two co-PIs** required, one each from the UNC CFAR and Duke University
- $100,000 total funds available ($50,000 from each CFAR)
- Each PI will financially manage their CFAR’s half of the Award
- Involvement of CFAR Cores: applicability based on proposed research, across both CFARs as appropriate. A letter of support is required for all applications with a quantitative component from at least one CFAR Biostatistics Core, documenting that they provided a pre-submission statistical/informatics review of the proposal. Applicants with a qualitative application are also required to submit a letter of support documenting a pre-submission consultation with a Social and Behavioral Science Research Core.
- **Expected Project Outcomes:** Peer-review publication and use of findings to support independent NIH funding (i.e., R21, R01, and R01-equivalent awards) for each PI.
RFA Schedule

- Application Due Date: February 1, 2018
- Application Review: February 2018
- Projected Award Date: March 15, 2018
  - Actual start date will be contingent on IRB approvals and the date that the NIH issues clearance for the project, if applicable
- Period of Award: Award period is 12 months or less

Application Submission Process

Applications should contain the following components in order and be submitted as one complete PDF document.

1. The completed CFAR Small Grant Coversheet (available on the UNC CFAR Developmental Core RFP tab), which includes:
   - Applicant information
   - Duke applicants only: Duke departmental grants manager’s name, contact number, and signature
   - A project summary describing why this application is innovative and/or important

2. A current NIH Biosketch for all key personnel
   - NIH Notice
   - NIH biosketch sample, format, and instructions

3. Eligibility requirements
   - A faculty level position or equivalent is required to apply
   - Applicants on T32 grants are not eligible.
   - Applicants with a current K award must have NIH pre-approval.
   - Former CFAR Developmental Awardees are eligible; their applications will be judged in part by the success of their previous Award.
   - Applicants must be new or early stage investigators who have never received an R01 or R01-equivalent (R01, R23, R29, and R37) award in HIV/AIDS. Established investigators will only be considered if they are new to HIV research.
   - UNC CFAR PI must have an affiliation with UNC-Chapel Hill, FHI 360, RTI International, or a North Carolina-based historically black college or university (HBCU). Duke University PI must have an affiliation with Duke University.
   - New or early stage investigator applicants must be actively mentored by a senior investigator in the HIV field (i.e., someone with previous HIV-related independent R01-equivalent NIH funding). This must be evident in the application itself, including appropriate letters of support.
• Senior established investigators who are new to the HIV field must be consulting or collaborating with a senior HIV investigator. This must be evident in the application itself, including appropriate letters of support.
• Please contact Developmental Core leaders, Herman Staats (Duke) or Sallie Permar (Duke) or Kate MacQueen (UNC), to discuss your eligibility if you have questions.

4. Budget and Budget Justification on NIH 398 form pages. Applicants may request up to $100,000 in total direct costs for one year.
• Restrictions for Duke University affiliated applicants:
  o Travel must be specific to the funded project. Travel to attend a “General Scientific” meeting is NOT allowable. (Travel must be in support of project completion or presenting data from the CFAR project).
  o Sub awards for external collaborations are allowable, but must comply with Duke sub-award policies.
  o Projects that include an external collaboration, may incur a fee of 59% for the outgoing sub-award.
  o Research effort is allowed on the grant (no admin or clerical). Faculty effort must comply with primary department policy.

• Restrictions for UNC CFAR affiliated applicants:
  o Award funds may not be used to support UNC faculty or post-doc salary, conference travel, or food/drinks.
  o See FAQ on the UNC CFAR Developmental Core RFP page for guidance concerning indirect costs.

5. Research Proposal using the current NIH R03/R21 format (Specific Aims is limited to one page. Research Strategy is limited to six pages. Single-spaced 11 pt Arial font.) The Research Strategy should include sections to address Significance, Innovation and Approach.
• Project Leadership Plan, per NIH guidelines.
  • Define roles/areas of responsibility of each PI
  • Clearly outline what each institution’s fiscal responsibilities for the project will be, e.g., RA support at each institution, participant incentives, lab costs, etc. Each PI will then be responsible for managing the funds from their institution to meet their deliverables for the project.
  • Fiscal management will be according to each institution’s current post-Award management policies.
  • Any/all conflict resolution would be brought to the Core Leadership mentoring committees.
• Separate References section (not included in six-page limit)
• Separate Human Subjects section (not included in six-page limit)
The application must address issues related to Rigor and Reproducibility as described in NIH notice NOT-OD-16-011

6. All applications must include a separate document explaining how the proposed work is aligned with the NIH priorities. This document should include a plan outlining how the proposed work will lead to NIH funding, a timeline for seeking such funding, the NIH institute or center from which they anticipate seeking funding, and the type of grant they plan to pursue (maximum of one page, not part of six-page limit). This may include joint and/or separate future funding plans for the two PIs.

- Given that the CFAR will ultimately be judged on the success of its Awardees (defined by NIH as independent NIH funding), applications will be prioritized based on the alignment of proposals with NIH funding priorities.

7. All applicants using quantitative methods must have a letter of support from a CFAR Biostatistics Core documenting that it has provided a pre-submission statistical/informatics review of your proposal. Please email Dr. Cliburn Chan or Dr. Michael Hudgens to schedule a consult. All applicants using qualitative methods must have a letter of support from a CFAR Social and Behavioral Sciences Core documenting that it has provided a pre-submission review of your proposal. Please email Dr. Kathy Sikkema or Dr. Carol Golin.

8. Additional letters of support are strongly encouraged if applicable (e.g., to verify access to clinic populations, for collaborators, etc.), and a cover letter may be submitted if desired.

9. Involvement of Duke CFAR Cores in the proposed research is required when applicable. Use of UNC CFAR Cores is strongly encouraged when applicable.
   - Duke Immunology Core – Flow Cytometry, Cellular Cytotoxicity, Antibody Binding, etc.
   - Duke Clinical Core – Regulatory Support, Community Engagement, etc.
   - Duke Social and Behavioral Sciences Core – Consultation, Peer Review, etc.

Applications should be prepared as a single PDF file and emailed to:
upload.CFAR_Sm.wa5umi9g7e@u.box.com
Simply email your completed Application to the above address. You will receive a confirmation email stating that your upload was successful. If you do not receive a confirmation within a few minutes of submission, your application was not submitted, and you should try again.

Questions concerning the application or submission should be directed to Dr. Staats, Dr. Permar, Dr. MacQueen, or Cathy Emrick.
Funding Pre-Requisites

Projects Involving Clinical Trials: Projects involving clinical research (e.g., observational studies or sub-studies using existing data from an ongoing clinical trial) may be funded by the CFAR.

CFARs are unable to fund clinical trials. The NIH definition of a clinical trial is very broad. Some investigators conducting human subjects research may not be aware that NIH considers their study to be a clinical trial. For guidance, click here.

Applicants considering submission of proposals that might be considered clinical trials are strongly encouraged to seek advice from a CFAR Developmental Core Director (herman.staats@duke.edu or kmacqueen@fhi360.org) before submitting a proposal.

UNC applicants are also strongly encouraged to consult Tania Caravella, the UNC CFAR Regulatory Head, with any relevant questions during the application preparation process. We have found that such consultation often significantly strengthens proposals.

Start dates for funded awards involving clinical research entailing greater than minimal risk to the subjects will dependent on IRB approvals and the date that the NIH issues clearance for the project. The Duke CFAR Finance Administrator and/or UNC CFAR Developmental Core Manager will provide guidance to Awardees on the NIH clearance process.

Conditions of Award

- CFAR Developmental Core Awards provide funding for a one-year term. Any extension to the one-year term must be approved by the CFAR Developmental Cores. Leftover funds may not be used on other research.

- PIs will be required to submit a yearly progress report to both CFARs. Duke PI will present a poster presentation at the annual Duke CFAR Fall Scientific Retreat. UNC CFAR PI will present research progress and plans for follow up funding to UNC CFAR leadership approximately six months into the Award.

- PIs must acknowledge both UNC and Duke CFAR support (by grant numbers) in all publications and manuscripts derived from CFAR funding.

- Prior to funding, you must forward a copy of all Institutional Biohazard, Animal Care and IRB approvals to the appropriate CFAR Developmental Core. If the pilot involves human subjects and the institutional IRB Committee has deemed the study "more than minimal risk", PIs must submit an SOP plus the project must receive NIH clearance before funding is released, which will be coordinated by the CFAR Developmental Cores.
After being notified of an Award, all new/early stage investigator or junior faculty Awardees (i.e., Instructor or Assistant Professor) and established/senior researchers new to HIV/AIDS will be required to develop a CFAR Mentoring Plan that includes a core leadership person from each CFAR on the mentoring team.

Review Process

Applications will be reviewed by a CFAR Review Committee that will be comprised of highly-qualified scientific leaders with the Duke and UNC CFARs and will be appointed by CFAR leadership. If necessary, the Review Committee may request outside expertise to evaluate the scientific merit of a proposal.

The Committee will review the application based on the following criteria:

- **NIH HIV/AIDS Priority Areas**
- Overall scientific merit, level of innovation, relevance of the proposal to AIDS research, and ability of investigator
- Duke applicants only: Utilization of [Duke CFAR Cores](#)
- Specific and narrowly focused application with realistic goals
- Potential for generating independent funding
- Potential for drawing investigators from other fields into AIDS research
- Potential for developing new interactions between or among CFAR investigators
- Priority will be given to collaborative proposals that extend the scope of current CFAR activities across multiple participating laboratories/institutes. Collaborative proposals will be evaluated on the scientific merits of each individual component of the project, as well as the overall integration of the components.

Awardees will be notified in writing. All applications are subject to NIH approval and all applicants will receive a written review of their proposals, regardless of funding.

CFAR Funding Institutes

The CFAR program is co-funded by:

- National Institute of Allergy and Infectious Diseases (NIAID)
- [Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)](#)
- National Institute of Aging (NIA)
- National Institute on Drug Abuse (NIDA)
- National Cancer Institute (NCI)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Institute of Mental Health (NIMH)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Minority Health and Health Disparities (NIMHD)
The CFAR program emphasizes the importance of interdisciplinary collaboration, especially between basic and clinical investigators, translational research in which findings from the laboratory are brought to the clinic and vice versa, and an emphasis upon inclusion of minorities and of prevention and behavioral change research.