CFAR Supplement Announcement – FY2023

NIAID invites supplemental applications from currently funded CFARs to the four areas of interest listed below. **CFARs who are submitting a competitive renewal application in 2023 may only apply to Topic #4.** Each active CFAR can submit a maximum of **two** supplement applications for topics #1-3. Two applications can be in the same topic area. Each CFAR can submit a maximum of **one** supplement application for the CDEIPI topic (Topic #4).

Purpose and Scientific Areas of Interest

The purpose of this administrative supplement opportunity is to **support innovative research projects (#1-3) and pathway programs for URM/BIPOC trainees (#4)** that address key gaps in HIV/AIDS and will advance the field. This opportunity should build research capacity and be consistent with the recent NIH HIV/AIDS research priorities (NOT-OD-20-018).

Research involving populations experiencing health disparities is encouraged (African Americans, Latinos/Hispanics, American Indians and Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, less privileged socioeconomic groups, underserved rural populations, and sexual and gender minorities).

1. **Formative, intervention, and implementation research to explore delivery of long-acting PrEP in populations who may benefit**

   The recently updated United States Public Health Service (USPHS) PrEP recommendations include support for the efficacy and use of long-acting PrEP, but there are multi-level barriers ~~that are being~~ reported in the field where implementation is being attempted, including systemic issues such as reimbursement and provider decision-making, optimal settings for delivery, and how best to reach the persons who could benefit most from this scientific advance. It is also critical to rapidly advance studies that will help to ensure that long-acting PrEP becomes accessible to all those who could benefit.

   This topic encourages research ranging from qualitative/quantitative formative inquiries with populations of interest, through intervention/implementation research where a setting has been identified and an approach for the long-acting PrEP delivery merits testing. The applicant should justify the selection of the key population and describe the strategies that will be interrogated or tested in the study – and in some cases, the innovations that will be deployed to overcome the specific barriers for the selected group (e.g., youth, rural populations, persons living with mental illness, persons who use substances, homeless, persons currently on oral PrEP regimens).

   Research topics may include, but are not limited to:
   - Studies to explore barriers to or facilitators of screening and therapeutic practices for HIV-associated chronic diseases in the implementation of long-acting PrEP among healthcare providers, including testing innovations to increase screen/therapy where appropriate
   - Studies that assess the accessibility, uptake, and consistent use of long-acting PrEP, which could include intervention and implementation studies in a variety of settings and populations
   - Formative research to understand the impact long-acting PrEP on patients presenting with co-morbid heart, lung, blood, and sleep (HLBS) disorders
   - Studies examining long-acting PrEP in the aging population with HIV
   - Impact of long-acting PrEP on oral health and oral transmission of HIV
   - Implementation of long-acting PrEP among persons with substance use disorder and/or mental illness

- Novel approaches to integrating long-acting PrEP with long-acting agents from opioid treatment
- Evaluation of stigma as a barrier to long-acting PrEP

Supplement awards are for one year with maximum funding per application of up to **$150,000** Direct Costs, not including third party indirect costs.

2. HIV and co-morbidities: Identification of mechanisms and strategies for optimal care that also reduce disparities

Integration of prevention and/or care for HIV and its co-morbidities needs further multidisciplinary attention (e.g., epidemiological, clinical, services research). When feasible, such research should address social determinants of health that can contribute to the health disparities in PWH and associated co-morbidities. Co-morbidities can include a wide range of health issues, including but not limited to behavioral health, oral and dental health, other infectious diseases, and non-communicable diseases.

Research topics may include, but are not limited to:

- Studies that evaluate the impact of community- and provider-related stigma on the development and exacerbation of co-morbidities in PWH
- Studies that identify deficiencies in the delivery of proven-effective treatment interventions
- Studies to address barriers at multiple levels (e.g., community, provider, patient) that impede the scale-up and implementation of preventive care of co-morbidities
- Research that informs novel ways to integrate multiple treatment and/or prevention services that are intended to address co-morbidities among PWH
- Strategies to enroll more cis- and trans- gender women in HIV cure research-related clinical studies

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3. Community-led research topic

Community healthcare workers, researchers, and advocates have been integral partners in the fight against HIV from the beginning of the epidemic. Many of the groundbreaking science advances, uptake of prevention and treatment modalities, and participation in cure research were possible because of the support of community members. Although researchers from academia and pharmaceutical organizations value the input of community members, there remains little opportunity for community-based researchers to be funded to lead and conduct research, particularly from conventional sources such as federal agencies. However, there is increasing appreciation for the capacity of community members and organizations to initiate studies or to have parity in leading, directing, and funding of studies addressing the interests of their organization and the populations they serve. The goals of this supplemental topic are to promote equitable research partnerships between community-based researchers and CFAR investigators by providing supplements to support studies that address the needs outlined by the community and include a strong community component where a community member will co-lead the project.

Research topics may include, but are not limited to:

- Understanding, developing, and deploying innovative strategies for community engagement, research literacy, and communication related to HIV cure research
- Developing and testing strategies for community engagement, research literacy, and

communication related to treatment interventions for co-morbidities and/or HIV cure
- Developing and testing strategies to address food, housing, or economic insecurity on HIV prevention, care, and treatment
- Mechanistic studies that examine biological mechanisms of HIV
- Developing and testing novel healthcare models for PWH and multiple chronic conditions and/or co-morbidities
- Developing and delivering innovative education and outreach strategies to increase the diversity of clinical study participants
- Studies that inform novel methods of community-based outreach to people who use drugs for providing HIV testing, prevention and/or care
- Addressing stigma as a barrier and developing appropriate interventions

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4. CFAR Diversity, Equity, and Inclusion Pathway Initiative

The overarching goal of the CFAR Diversity, Equity, and Inclusion Pathway Initiative (CDEIPI) is to increase the number of Underrepresented Minorities (URM)/Black, Indigenous, and People of Color (BIPOC) trainees who engage in HIV science and help develop pathways for successful careers in science and medicine. This will be achieved through supporting the development of new programs and the enhancement of existing programs within the CFAR network in partnership with Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs) throughout the United States.

The HIV research field would greatly benefit from a heterogeneous scientific workforce that is more reflective of communities at highest risk of HIV. This topic is in response to this critical need and aligned with the NIH's interest in diversity and the mission of the NIH UNITE Initiative affirming NIH's commitment to addressing structural racism in the biomedical research enterprise.

We encourage CDEIPI applicants to consider new mentoring opportunities in their proposal. Peer to peer mentoring has been shown to be a fundamental aspect of personal and career development. Peers are uniquely able to relate to one another's experiences and help each other navigate career pathways and problem-solve. Additionally, *peer* mentoring, specifically, can be more accessible and approachable for underrepresented groups. Opportunities to discuss the challenges faced builds awareness of the impact of systemic inequities and empowers young people to identify the ways in which they can overcome these challenges.

Applications to this topic can propose a one-year pathway program to either:
1. Continue and build on the established framework from the FY22 CDEIPI supplement project or,
2. Develop a new program and/or bring in new collaborators such as new or additional HBCU/MSI partners

New for FY23 proposals:
- One full page of progress from the FY21 and/or FY22 CDEIPI supplement projects should be provided. This discussion should include added value, lessons learned, identifying challenges/barriers, impact, and innovation of the previous project periods.
- All CDEIPI programs should propose how peer to peer mentoring will be established and maintained. Peer mentoring groups should have a multi-level approach (i.e., high school and undergraduate, undergraduate, and graduate, etc.)

- Ideas to maintain engagement along the pathway and throughout a scholar's career. Some examples include professional networks, newsletters, social media groups, etc.

- Inter-CFAR CDEIPI collaborations should also be explored to further support and connect scholars to opportunities who may be in a transition phase between academic levels

- Evaluation tools that can be broadly utilized within the CDEIPI program and beyond the CFAR network

- Institutional letter indicating support for costs associated with supporting CDEIPI scholars (e.g., workshops for academic and career development, supplies, travel, program evaluation, and other program-related expenses.)

Respecting the CFAR principle of local control, each participating CFAR and its collaborating HBCU/MSI partner(s) will bring their unique set of innovative ideas, existing programs, expertise, location, partnerships, and funding capacity to this initiative. Accordingly, CFARs should engage HBCU/MSI partners in the development of proposals based on identified areas of need. Each CFAR may submit a creative and innovative proposal outlining how they will utilize supplemental funds to support training and mentoring activities for "CFAR Scholars" in at least two of the four training levels: high school, undergraduate, graduate (masters, doctoral or medical) students, and post-doctoral trainees. CFARs wishing to propose partnerships with alternative institutions or organizations that serve URM populations or programs that focus on one training level may request permission to do so from the NIH CFAR Program Officers. Proposed FY23 supplement projects are not limited to what was proposed in FY22 but would need to provide rationale for significant changes in direction and/or new collaborators.

Integration with existing local programs, leveraging existing partnerships or creating new partnerships with HBCUs and other MSIs, developing cross-cadre mentoring programs and a commitment to using existing developmental pilot award funds to support URM/BIPOC ESIs as a fifth component of this initiative are strongly encouraged. For CFARs that do not have a pre-existing relationship with an HBCU or MSI, the CDEIPI CC and the NIH can help facilitate this connectivity during proposal development. Individual CFARs may propose that their home institutions provide complementary support for their local initiatives.

Each CFAR will designate two investigators (preferably with demonstrated expertise in URM/BIPOC training programs) to serve as project leads for their CFARs, one as the point of contact with the CDIEPI Program Core and one as the point of contact with the CDEIPI Evaluation Core.

Supplement awards are for one year with maximum funding per application of up to **$100,000** Direct Costs, not including third party indirect costs.

Eligibility

Currently funded CFARs can submit applications for this announcement. CFARs submitting a competitive renewal application in 2023 may only apply to Topic #4.

Project leaders for all scientific areas of interest (Topics #1-3) are restricted to early career investigators who have never received an R01-equivalent, P-series or U-series research grants, and established investigators new to HIV. Post-doctoral fellows are eligible to apply if they will assume a

faculty position by the time the supplement project and funding begins. For Topics #1-3, studies that are a continuation of previously funded CFAR supplements or funded NIH applications that do not address new specific aims are not eligible for funding under this announcement. Additionally, a proposed supplement application that is linked to a proposed application not yet funded is not eligible for funding under this announcement.

Established investigators can be the project leaders for the CDEIPI and inter-CFAR meeting topics (Topics #4).

Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are especially encouraged to apply for NIH support.

PLEASE NOTE THAT THE FOLLOWING INSTRUCTIONS ARE ONLY FOR THE FINAL FULL APPLICATION TO NIH. IF YOUR CONCEPT PROPOSAL IS SELECTED TO BE DEVELOPED INTO A FULL PROPOSAL, YOU WOULD FOLLOW THE INSTRUCTIONS BELOW. THESE ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

Application Instructions

Requests submitted in response to this opportunity must follow instructions outlined in PA-20-272. Administrative supplement requests must be submitted through Grants.gov using electronic submission processes (NOT-OD-20-128). Follow all instructions in the SF424 (R&R) Application Guide to ensure all appropriate required and optional forms are completed, with the following additional guidance:

1) **SF424 R&R Cover Form:**
    a. Select “Revision” in the “Type of Application” field.

2) **R&R Other Project Information Form:**
    a. If applicable to the supplement activities, attach PDF documents in the “Other Attachments” field indicating that the proposed research experience was approved by the human subjects Institutional Review Board (IRB) at the recipient’s institution. Name the documents “IRB Documentation.pdf”. Adherence to the NIH policy for including women and minorities in clinical studies must also be ensured, if additional human subjects’ involvement is planned for the supplement. All appropriate IRB approvals must be in place prior to Notice of Award.
    b. Project summary and narrative is that of the administrative supplement, not the parent grant.
    c. NO Facilities and Other Resources page (unless there are new resources that will be used for this request)

3) **Project/Performance Site Location(s) form**: Include the primary site where the proposed supplement activities will be performed. If a portion of the proposed supplement activities will be performed at any other site(s), including HBCU and/or MSI sites, identify the locations in the fields provided.

4) **Sr/Key Person Profile (Expanded) form**: List the PD/PI as the first person (regardless of their role on the supplement activities), include Supplement PI and any other Senior/Key Personnel who are being added through this supplement, or for whom additional funds are being requested through this supplement; include a biographical sketch for each.
    a. **Biographical Sketch** for all new Senior/Key Personnel and for mentors. Please note

the personal statement should be related to the CFAR supplement project.

b. NO Other Support. Complete and up to date "other support" information will be requested as part of Just-in-Time information collection.

5) **Budget forms (e.g., R&R Budget, PHS 398 Training Budget)**:
   a. **Budget** for the supplement with a justification that details the items requested, including Facilities and Administrative costs and a justification for all personnel and their role(s) in this project. Note the budget should be **appropriate for the work proposed** in the supplement request. If funding for travel to a scientific meeting is included, it must be for the CDEIPI scholar and must be within scope of the supplement award.
      i. If applicable, subcontract budgets should be included in the proposal for collaborating HBCUs and/or MSIs.
   b. **Other costs** for CDEIPI scholars can include costs for workshops for academic and career development (e.g., problem-solving, communication, time management, and grant-writing), supplies, travel, program evaluation, and other program-related expenses. Expenses must be well justified and cannot duplicate items generally available at the applicant institution.
   c. A statement regarding the plan for expenditure of currently available unobligated grant funds of the parent CFAR award will be requested during the supplement Just-in-Time (JIT) process. The recipient will need to demonstrate the need for the additional supplemental funds.

6) **Research Plan form (e.g., PHS 398 Research Plan form, PHS 398 Research Training Program Plan):**
   a. An **introduction** that clearly states the **scope of the overall request,** the anticipated contribution of the requested supplement, and how the project addresses the NIH HIV/AIDS Research Priorities (NOT-15-137). **Limit one page.**
   b. Specific aims page must concisely state the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved. **Limit one page.**
   c. The **research strategy** should include the background and rationale for the proposed application; a description of the activities to be undertaken, and roles of key staff; expected outcome of these activities; expected follow-up plan upon completion of the supplement; a description of how the supplement and follow-up plan are expected to achieve this outcome ("value-added"); and plans to monitor and evaluate the ability of the activities to achieve the outcome. Most importantly, applicants must clearly indicate how the proposed activities outlined in the supplement requests are expected to lead to development of the stated goals. Mentorship and collaborations must be explained.
      i. CDEIPI: One page progress from the FY21/FY22 CDEIPI projects **(not included in the six-page limit)**
      ii. **Topic #3:** Development of the research plan should be an equal partnership between the supplement PI and the community member.

      Limit six pages.
   d. Letter(s) of Support
      i. Submit a letter(s) of collaboration endorsing the proposed request from all substantial participants.
      ii. Submit a letter of support from the institution indicating support for costs associated with CDEIPI scholars.
      iii. If applicable, please include letters of support or approvals for projects requiring access to data, samples, tissues, cutting edge technologies or etc. Include evidence to support the feasibility of enrollment, including descriptions

of prior experiences and yield from research efforts employing similar referral sources and/or strategies for projects involving recruitment of participants.

iv. For transitioning post-doctoral fellows, please include a letter from your institution confirming the transition to a faculty position that includes the start date.

e. No appendices

7) **PHS Human Subjects and Clinical Trials Information form**: If new recruitment or use of an additional existing dataset or resource is proposed in the supplement application, the Study Record should be revised and new Inclusion Enrollment Reports created, as well as other required sections, as appropriate for supplemental activities. NOTE: Studies involving clinical trials are not allowed.

Review Considerations

Upon receipt, applications will be reviewed by the CFAR Program Officers for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to this announcement, the application will be returned without review.

Applications that are complete and responsive to the announcement will be evaluated for scientific and technical merit, and alignment with the NIH HIV/AIDS research priorities by an internal NIH review group convened by the NIAID in accordance with standard NIH review procedures.

Review Criteria

The following criteria apply to all scientific applications, unless noted. Reviewers will also examine the appropriateness of the budget, in consideration of the research environment and the supplement request.

All Topics:

1. Evidence that the proposed project will enhance new multidisciplinary collaborations and exert a sustained, powerful influence on HIV/AIDS research;
2. Extent to which the supplement will address scientific gaps and/or development of new strategies which include a variety of scientific disciplines;
3. Adequacy that the strategy, methodology, and analyses are well reasoned and appropriate to accomplish the specific aims;
4. Utilization of existing resources (including CFAR Cores) and/or development of unique and appropriate expertise, technology, and resources at the CFAR institution(s) and other sites, as appropriate;
5. Degree of innovation in project selection and experimental design;
6. Quality and appropriateness of mentorship and collaboration for the research project;
7. Choice of appropriate project PI and co-investigators (e.g., scientific qualifications, commitment, and experience), as well as the collaborations with other institutions, if applicable;
8. Appropriateness of the budget, in consideration of the research environment, for the scientific projects and cores;
9. Feasibility to complete the project within the FY2023 project period (e.g., this will range between 8-12 months depending on the parent CFAR grant).

Additional Criteria for Topic #4 (CDEIPI):

1. Progress made in the last supplemental project periods and rationale for any changes in direction;
2. Extent to which proposed activities leverage existing partnerships or create new partnerships with HBCUs, other MSIs, or alternative institutions or organizations that serve URM populations, and evidence of meaningful engagement of partners in the planning and implementation of the project (e.g., as co-investigators, in the project description, letters of support, budget);
3. Appropriateness and feasibility of the proposed project to address the goals of the CDEIPI, and degree to which strategies proposed in the application are likely to result in effective approaches that could inform best practices and are sustainable;
4. Extent to which proposals clearly operationalize program activities and metrics, and provide primary outcomes of interest;
5. Criteria which the CFAR will use to evaluate the success of its CDEIPI projects;
6. Appropriateness of how CDEIPI funds will be used to support training and mentoring activities for “CFAR Scholars”;
7. Evidence of institutional commitment and support to foster sustainability and engagement of CDEIPI scholars.