

FY2021 EHE CFAR/ARC Supplement Announcement

Purpose

The NIH invites eligible NIH CFARs and NIMH ARCs to submit administrative supplements in support of the [Ending the HIV Epidemic: A Plan for America \(EHE\) initiative](#). Eligible CFARs and ARCs must collaborate with partners in the [57 priority areas](#): community, local, county and state health departments, CBOs, and clinics funded by the CDC, HRSA, SAMHSA, or IHS. These implementation science research projects should be developed by the team of CFAR/ARC investigators and community and local partners to support the local ending the HIV epidemic plans. CFAR/ARC investigators are also encouraged to collaborate with researchers from historically black colleges and universities (HBCUs) in planning projects and in the formation of future implementation science in communities served by HBCUs. CFAR/ARC investigators must coordinate with the local EHE team to ensure the proposed project supports and informs local EHE plans.

Background

The role of the NIH, as a research platform in the EHE initiative, is to support **implementation science research** by addressing the **four key pillars** (Diagnose, Treat, Prevent, and Respond). Specifically, the NIH will support CFAR/ARC investigators to collaborate with local partners and HHS agencies to support local EHE plans.

Several critical principles should guide these efforts:

- The CFAR and ARC principle of **local control** must be emphasized in the collaborations with entities funded by the CDC, HRSA, and other implementing agencies, and/or local and state health departments.
- There must be **value added** for all members of the partnership, including representation of local community partners affected by HIV. This includes **communication** and **collaboration** with all partners in all phases of the project including planning/development, initiation, execution, and dissemination.
- Teams should examine any local policies that have created unintended structural barriers to HIV treatment and prevention and seek ways to transform these processes.
- It is encouraged that these projects include consideration of **creative, locally defined, and culturally sensitive** concepts that align with the local EHE plans. These concepts should differ substantially from conventional means of service delivery, especially conventional approaches that are not effectively addressing the diversity of needs in the highest burden communities. Proposals should consider innovative ways to enhance engagement efforts across community, health departments, and implementing partners and community-based and outreach approaches that remove or alleviate barriers to conventional prevention and treatment access.
- All projects should focus on the 50 priority areas as well as the 7 states with a substantial rural HIV burden. CFARs and ARCs may work with priority areas outside of their institution's immediate location, particularly if relationships have already been established, and/or these relationships can be strengthened by collective work that includes HBCUs.

EHE Topics

1. EHE Team-initiated Implementation Research

The Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA) have both released funding opportunities to support programs and services towards ending the HIV epidemic in America. This supplement topic provides the local academic and implementing partners an opportunity to collaborate and develop an implementation research project that aligns with and supports the needs identified by the local EHE team. It is expected that this project is consistent with the EHE activities and priorities funded by CDC ([PS20-2010](#)) and HRSA ([HRSA-20-078](#), [HRSA-20-91](#)) through their EHE initiatives.

Each eligible Center is allowed a maximum of one application for this topic. The maximum funding allowed per application is \$200,000 Direct Costs for up to 1 year. Priority will be given to meritorious applications for (a) new partnerships that were not funded in [previous CFAR/ARC EHE opportunities](#), particularly in geographic areas, settings, or populations not yet reached by current NIH EHE efforts, and (b) collaborations with HBCUs, particularly regarding racial inequities that continue in HIV prevention and treatment outcomes.

2. Planning projects to address social and structural determinants of HIV using an intersectional framework in partnership with community to enhance efforts toward Ending the HIV Epidemic in the United States

In the United States, HIV disproportionately affects certain populations due to health inequities, health disparities, and social and structural determinants of health. It is important that an intersectional approach be used to understand how social and structural inequalities produce systematic differences in health. Intersectionality theory assumes that people's social positions are shaped by interlocking systems of advantage or disadvantage, and privilege or oppression – and in this case the disparities are apparent in HIV prevention and treatment outcomes. Applying an intersectional framework to social determinants, sometimes referred to as intersectional insecurities, allows examination not only at the intersection of multiple marginalized positions, but also at the intersections of different social processes. Many communities substantially impacted by HIV face multiple insecurities such as economic inequality, race inequality, stigma and discrimination, unstable housing, lack of transportation, limited or uncertain access to food, and/or inadequate access to health services. In order to reach the goal of Ending the HIV Epidemic in the United States within 10 years, it is critical to apply an intersectional framework to understand how multiple disadvantages interact to produce differences in prevention and treatment efforts. These intersectional insecurities impact efforts in HIV testing and diagnosis, linkage to HIV care, access to antiretroviral treatment, HIV viral suppression, and use of PrEP to prevent HIV.

A critical step in ending the HIV epidemic in the United States is to develop strategies to address the impact of intersectional insecurities on HIV prevention and treatment efforts at the community level. This must be done in partnership with the community (i.e., people affected by HIV from priority populations, health departments, community-based organizations, health centers, etc.) with a whole-of-society approach. Investigators must engage marginalized populations and stakeholders in the research process to collectively build knowledge and understanding, to help distinguish between intersecting identities, insecurities, positions, processes, policies and practices, and to develop intervention strategies to promote health and

prompt change. This will enable a fuller understanding of how multiple intersectional insecurities adversely impact HIV outcomes. Each EHE project team (i.e., CFAR/ARC investigator(s), community partner(s), and implementing collaborator(s)) should propose research activities to determine a strategy to address multiple intersectional insecurities impacting their community, and map out potential interventions to deploy to address the EHE targets and reduce inequities in the identified EHE priority area(s). The application should clearly describe the partnership, including the roles and responsibilities within the EHE project team. Additionally, the proposed activities should clearly reflect the priorities of the community. **Each Center is allowed a maximum of two applications for this topic. The maximum funding allowed per application is \$200,000 Direct Costs for up to 1 year.**

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.
- b. Cover Letter Attachment – Citing this Supplement Announcement, a request for an Administrative Supplement, and the following information:
 - i. CFAR Principal Investigator and Supplement Project Director names
 - ii. EHE topic for this supplement request
 - iii. Project Title
 - iv. Total Cost amount of the requested supplement

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 human subjects Institutional Review Board (IRB) at the grantee institution. Name the document “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. NOTE: Studies involving [clinical trials](#) are not allowed.
- b. Project summary and narrative is that of the administrative supplement, not the parent grant.
- c. Any clinical studies deemed above minimal risk or involving vulnerable populations requires CFAR clinical approval.
- d. 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), 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 the Supplement PI and Senior/Key Personnel who are being added through this supplement 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. Please note the personal statement should be related to the CFAR supplement project.
 - b. NO other support. Complete and current “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 purpose of presenting data from this supplement award.
 - b. A statement regarding the expenditure of currently available unobligated grant funds of the parent grant will be required. Both CFARs and ARCs must include a description of the plans to spend remaining funds to demonstrate the need for additional 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 including the EHE pillar(s) addressed**, the anticipated contribution of the requested supplement, and how the project addresses the NIH HIV/AIDS Research Priorities ([NOT-20-018](#)).
 - b. **Specific Aims:** State concisely 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. Aims described in the proposed study should be feasible given the available time, funds, and resources to do the work.
 - c. The **research strategy** is limited to **six pages** and should include:

Background and rationale for the proposed application. The study/research question(s) should be clearly stated and describe the underlying barriers or gaps in research to be addressed. The proposed application must include a description of the activities proposed, 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 add value by addressing one or more of the four pillars of the EHE; 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.

Provide an **implementation logic model** and describe what aspects of the logic model are being studied and with emphasis on implementation barriers/facilitators (determinants), how implementation strategies will address these determinants, and

which implementation outcomes will be measured and expected to improve. Describe the **implementation science framework or model** utilized to support the logic model and to guide the study design and evaluation methods.

For the purposes of this funding opportunity: Implementation research is defined as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health. Implementation research therefore seeks to understand and change the behavior of practitioners and support staff, organizations, consumers and family members, and policymakers to improve the adoption, implementation, and sustainability of evidence-based health interventions and guidelines. In addition to changing behaviors, implementation research can also understand and evaluate how to modify internal/external policies or procedures, norms, or other social/structural factors that are impeding on implementing and sustaining intervention delivery.

Studies of implementation strategies should build knowledge both on the overall effectiveness of the implementation strategies (implementation outcomes), as well as "how and why" they work (implementation mechanisms).

Data on facilitators and barriers (implementation determinants) to program success, mechanisms of action, moderators and mediators of implementation strategies, and implementation outcomes will greatly aid decision-making on which strategies work for which interventions, in which settings, and for what populations. Applicants should therefore incorporate implementation science theories, models, and/or frameworks appropriate for implementation research to inform study hypotheses, measures, implementation outcomes, and health outcomes if able to be measured. Applicants must include a copy of the project **implementation logic model**.

Applicants must include and describe a **communication plan** with implementing and community partners during the project period, including dissemination of outcomes agreed to by all parties. It is expected that applicants will ensure that data coming out of these projects will support local efforts to guide decision-making on prevention, care, and treatment needs at the local level.

- d. **Letter(s) of Support**
Submit letters of support from all implementing and collaborating partners which describes their roles and responsibilities on the project and how this project supports the local EHE plan.
 - 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.

Eligibility

Eligible Centers that are currently funded (not in a no cost extension/bridge year) can submit applications for this announcement.

Budget and Funding Information

Funding for supplements will be supported by the NIH. The maximum funding allowed per application is described within each topic above.

Funding for administrative supplements to existing CFAR grants will be available for up to one year in FY2021.

For the CFARs, funds for these supplements will be provided to the Developmental Core.

Please note that the number of applications that will be funded for this administrative supplement announcement will be based on funding availability, alignment with the local EHE plans, addressing the goals of the EHE initiative including one or more pillars and collaboration with local partners, and program balance.

How to Apply

This is a one-time announcement. Application must be submitted electronically through grants.gov.

Do not send applications to the NIH Center for Scientific Review or CFAR Program Officers.

Applications must be submitted electronically on or before **April 19, 2021**. If an application is received after that date, it will be rejected without consideration.

At the time of submission, both CFAR and ARC Applicants are requested to send an email notification of applications submitted that includes the below information for each:

- a. Supplement PI Name
- b. EHE Topic
- c. Project Title
- d. Primary Pillar
- e. EHE geographic priority area(s) (name of the county, territory, or state)
- f. Implementing Partner (organization name and collaborator name)
- g. Community Partner (organization name and collaborator name)
- h. Study population
- i. Implementation Science Framework

This information will assist us in planning for the review.

Information should be sent to:

Annalise Schoonmaker
National Institute of Allergy and Infectious Disease
Telephone: 240-669-5577
Email: annalise.schoonmaker@nih.gov

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 applications, unless noted. Reviewers will also examine the appropriateness of the budget, in consideration of the research environment and the supplement request.

1. Degree that the application iterates a process to fully collaborate with the community and implementing partner, such that any future project reflects locally defined HIV prevention and treatment needs. Applications should reflect the partnership with stakeholders such as people affected by HIV from priority populations, health departments, community-based organizations, health centers, etc.
2. Evidence of meaningful engagement of communities affected by HIV in the planning and implementation of the project (e.g., in the project description, letters of support, budget).
3. Extent to which the proposed activities are likely to both advance science and enhance capacity for service delivery for one or more of the four pillars in the EHE initiative.
4. Appropriateness and feasibility of the proposed project to address the goals of the EHE initiative, including addressing the local EHE plans and diversity of needs in the target communities.
4. Utilization of existing resources (including CFAR/ARC Cores) and/or development of unique and appropriate expertise, technology, and resources at the CFAR/ARC institution(s) and other sites, as appropriate.
5. Degree to which the implementation strategies proposed in the application are likely to result in effective approaches that could inform best practices and whether the strategies are sustainable.
6. Innovation is particularly encouraged for approaches that circumvent barriers to conventional prevention and treatment access.
7. Choice of appropriate project PI, co-investigators, and collaborative local community and implementing partners (e.g., qualifications, demonstration of commitment to the activities, and experience).
8. Appropriateness of the budget, in consideration of the project described.
9. Feasibility to complete the project within the project period.

Allowable Costs

Funding may be requested for any category normally funded by a CFAR/ARC grant that is required to fulfill the goals of the proposed request and must be fully justified.

Schedule for Applications

<i>Announcement Release Date:</i>	<i>2/08/2021</i>
<i>Application Receipt Date:</i>	<i>4/19/2021</i>
<i>Review Date:</i>	<i>5/21/2021</i>
<i>Earliest Anticipated Award (Start) Date:</i>	<i>7/01/2021</i>

Terms of Award

A formal notification in the form of a Notice of Award (NoA) will be provided to the grantee organization. The NoA signed by the Grants Management Officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Reporting

Awardees of administrative supplements will be required to submit a progress report that should be included in the annual progress report of the parent grant. Progress reports should include a summary of the supplement projects, milestones met, and outcomes, including next steps.

The EHE initiative requires reporting on key indicators to measure progress. All projects funded under this announcement will be required to provide this information on a regular basis. This will be communicated via the program officer. The NIH staff will work with awardees to ensure proper reporting.

Award Criteria

The following will be considered in making awards:

- Relevance to EHE initiative, including support of local EHE plans and engagement with community and implementing partners;
- Scientific and technical merit of the proposed project as determined by NIH convened internal review panel;
- Funding availability and;
- Program balance.

Inquiries

Prospective applicants are encouraged to discuss their applications, including proposed collaborators, with the NIH contacts below.

CFARs

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National Institute of Allergy and Infectious Diseases
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ARCs

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