

Limited 2-Year FY2020 EHE Implementation Science Supplement Opportunity: Open to FY19 CFAR/ARC EHE Awardees

Purpose

The NIH invites the 2019 EHE CFAR and ARC awarded teams at currently funded and 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 continue to collaborate with partners in the [57 jurisdictions](#): local, county and state health departments, CBOs, and clinics funded by the CDC, HRSA, SAMHSA, or IHS. CFAR/ARC investigators must coordinate with the local jurisdictional team to ensure the proposed project supports and informs jurisdictional plans.

These implementation science research projects should build on the progress and outcomes from the initial planning projects developed by the team of CFAR/ARC investigators and local partners to support the local ending the HIV epidemic plans with input from the local community. If a NIAID or NIMH Center team has not had enough formative work to merit a two-year supplement application, they should apply to topic 1 in the companion “One-Year FY2020 EHE CFAR/ARC Supplement Announcement.” Limited funds are available for projects requesting 2-year funding and projects without substantial formative work will not be prioritized.

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 jurisdictional 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 jurisdictional 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 continue to focus on the 50 jurisdictions as well as the 7 states with a substantial rural HIV burden.

Application Instructions

Requests submitted in response to this opportunity must use the [PHS 398 forms](#) (rev. 1/2018) and include the elements in the request packet as described below. Applicants must submit each application as an e-mail attachment, in one file, in PDF format; however, the signature of the institutional official must be clearly visible. Font size restrictions apply as designated within the PHS 398 instructions.

1) Cover Letter – Citing this Supplement Announcement, a request for an Administrative Supplement, and the following information:

- CFAR/ARC Principal Investigator and Supplement Project Director names
- Parent grant number and project title
- EHE pillar(s) addressed, indicating primary pillar
- Name of primary implementing partner, affiliated organization, and supporting federal agency
- Project jurisdiction
- Study population, if defined
- Amount of the requested supplement/year (up to 2)
- Name and title of the authorized institutional official
- Phone, email, and address information for the PI, the PD and the institutional official

The cover letter must be signed by the authorized organizational representative/institutional official.

2) PHS 398 Form Page 1 (Face page) ([MS Word](#) [PDF](#)) – Provide requested information as follows:

- The title of the project (Box 1) should be the title of the parent award and a descriptive title of the supplement application.
- The EHE pillar(s) addressed should be cited under title in Box 2, and the “yes” box should be checked.
- Enter name of CFAR/ARC PI and the name of the project director. (Example: Dr. Bill Jones (CFAR/ARC PI) and Dr. John Smith (Project Director)).
- The remaining items on the face page should be filled out in accordance with the PHS 398 application instructions.

3) PHS 398 Form page 2

Note: The project “summary” is that of the administrative supplement, not the parent grant. All other information requested on Form Page 2 should be provided.

4) A **brief proposal** describing the request (with parts 4a and 4b **not exceeding five pages** in total), should include:

- 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-15-137](#)).
- b. The **research project plan** should include the 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. Progress from the planning period should be discussed and how this informs the proposed project. Project teams are not limited to what was originally proposed but would need to provide rationale for significant changes in direction.

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.

- c. 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.
- d. 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 in order 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**.

- e. Applicants must include and describe a **communication plan** with collaborators 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.
- f. **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 or collaboration meeting is included, it must be for the purpose of the project described in this application.

For CFARs, a statement regarding the expenditure of currently available unobligated grant funds of the parent CFAR grant will be required. The CFAR must include a description of the plans to spend remaining funds in order to demonstrate the need for additional funds.

- g. **Biographical Sketch** for all new Senior/Key Personnel and for mentors. Use the biosketch format in [MS Word](#). Please note the personal statement should be related to the CFAR supplement project.
- h. **Human Subjects documentation** (if applicable). Include a current Human Subjects/Institutional Review Board (IRB) documentation, if applicable. Otherwise, this information will be required at time of funding. All appropriate IRB approvals must be in place prior to the initiation of a project. NOTE: Studies involving [clinical trials](#) are not allowed.
- i. Further NIH-initiated administrative actions and approvals for any clinical studies deemed above minimal risk or involving vulnerable populations may be required.
- j. **PHS 398 Checklist Form** [MS Word](#) [PDF](#)
 - TYPE OF APPLICATION. Check REVISION box and enter your CFAR/ARC grant number;
 - Applicants must state that all federal citations for PHS grants will be met (e.g., human subjects, data sharing, etc.)
- k. NO other support. This information will be required for all applications that will be funded. NIH will request complete and up to date “other support” information at an appropriate time after review.
- l. NO resource page (unless there are new resources that will be used for this request)
- m. NO appendices
- n. Submit **letters of support from all collaborating partner(s)** which describes their role(s) on the project and how this project supports the jurisdictional plan.

Eligibility

Eligible Centers that are currently funded (not in a no cost extension/bridge year) and that were previously funded for FY19 EHE supplements can submit a **maximum of two applications** to this announcement.

Budget and Funding Information

Funding for supplements will be supported by the NIH. The maximum funding allowed per application is **\$200,000 Direct Costs/year**. The project and budget periods must be within the currently approved project period for the existing parent award for up to a **maximum of 2 years**. If the parent grant has less than 2 years remaining at the time of anticipated award date, the project and budget period for this application cannot exceed the time remaining on the parent grant.

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 jurisdictional plans, addressing the goals of the EHE initiative including one or more pillars, and program balance.

How to Apply

This is a one-time announcement.

Do not send applications to the NIH Center for Scientific Review.

Applications must be signed by the authorized institutional official and submitted on or before **May 15, 2020**. If an application is received after that date, it will be returned to the applicant without review.

All CFAR and ARC applications should be emailed to:

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

For ARC applications, please also send a copy to: NIMHAdminSupplements@mail.nih.gov.

Applicants must submit each application electronically as an e-mail attachment in a single PDF file to the Program Officer; however, the signature of the institutional official must be clearly visible.

Files should be named [XYZ] CFAR/ARC – [Project PI Last Name] [(Indicate pillar(s)) EHE] [2019]. Example: “XYZ CFAR/ARC – Smith Respond_Protect EHE 2019.”

Review Considerations

Upon receipt, applications will be reviewed by the CFAR/ARC 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 AIDS research priorities and the EHE initiative by an internal NIH review group 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 implementing partner, such that any future project reflects locally-defined HIV prevention and treatment needs.
2. 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;
3. Appropriateness and feasibility of the proposed project to address the goals of the EHE initiative, including addressing the jurisdictional plan(s) 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;
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 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>03/18/2020</i>
<i>Application Receipt Date:</i>	<i>05/18/2020</i>
<i>Review Date:</i>	<i>06/19/2020</i>
<i>Earliest Anticipated Award (Start) Date:</i>	<i>07/01/2020</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 to 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 a jurisdictional plan;
- Scientific and technical merit of the proposed project as determined by a NIH-convened internal review panel;
- Funding availability and;
- Program balance.

Inquiries

Applicants are strongly encouraged to consult with the Scientific/Research Contact to discuss the potential supplement request prior to submission. For inquiries related to this announcement, please contact:

CFARs

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ARCs

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