

Administrative Supplements to Support Planning Activities at Existing NIH HIV/AIDS Centers to Address the “Ending the HIV Epidemic: A Plan for America” Initiative

Purpose

The National Institutes of Health (NIH) invites currently funded and eligible NIH Centers for AIDS Research (CFAR) and National Institutes of Mental Health HIV/AIDS Research Centers (ARCs) to submit up to **three** administrative supplements per Center in support of the [Ending the HIV Epidemic: A Plan for America \(EtHE\)](#) initiative. Broadly speaking, the EtHE initiative focuses on four key pillars that together can end the HIV epidemic in the United States (U.S.): [Diagnose, Treat, Protect, and Respond](#).

Eligible CFARs and ARCs must collaborate with partners in specific jurisdictions: local, county and state health departments and community-based organizations (CBOs) funded by the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), or the Indian Health Service (IHS), as a preliminary step in developing approaches to fulfill the goals of the U.S. Department of Health and Human Services’ (HHS) 2020 EtHE initiative. These planning projects will provide CFAR/ARC investigators an opportunity to collaborate and establish partnerships to develop approaches to address high priority gaps in one or more of the four pillars of the EtHE initiative. The proposal must also be locally relevant in one or more of the identified [highest burden areas in the nation](#). It is expected that by the end of the planning project the team of CFAR/ARC investigators and local partners will have identified and designed a targeted implementation science research project that will support the local ending the HIV epidemic plans. The NIH intends to provide additional funding opportunities in subsequent fiscal years to support meritorious targeted implementation science research projects.

Background

In 2019, we have the tools to end the HIV epidemic. The EtHE initiative will leverage critical scientific advances in HIV prevention, diagnosis, treatment, and care through the successful programs, resources, and infrastructure of the CDC, NIH, HRSA, and IHS. The EtHE initiative, coordinated by the HHS Office of the Assistant Secretary of Health, will focus on the four pillars – Diagnose, Treat, Protect, and Respond - that are the key strategies to the EtHE initiative that together can end the HIV epidemic in the U.S. Success of the EtHE initiative will depend on trusted partnerships among local and state health departments, communities, and research institutions. HHS has proposed to address this ongoing public health crisis with the goals of first reducing numbers of incident infections in the United States by 75% within 5 years, and then by 90% within 10 years.

New HIV diagnoses are geographically highly concentrated, in specific areas where the initial phase of the planned three-phase 10-year EtHE initiative will focus. Surveillance data from CDC for 2016 and 2017 indicate that the top 50% of new diagnoses occurred in 48 counties, Washington, D.C., and San Juan, Puerto Rico. These 50 jurisdictions are all heavily urbanized, but HIV also affects parts of rural America, especially in the South. To inform efforts unique to ending the HIV epidemic in rural America, the initial phase of the EtHE initiative will also focus on 7 states with a substantial rural HIV burden, defined as having reported at least 75 cases in rural areas of the state that comprised 10% or more of the state’s total HIV diagnoses. All of these areas reflect the unbalanced demography of HIV in America, namely that HIV disproportionately affects African-American men and women (particularly African-American MSM), Latino MSM, transgender individuals, and people living in the South. The South overall

has the highest rates of new HIV diagnoses, people living with HIV, and HIV-related deaths of any U.S. region.

The role of the NIH, as a research platform in the EtHE initiative, is to support **implementation science research** by addressing the **four key pillars** (Diagnose, Treat, Protect, and Respond). Specifically, the NIH will support CFAR/ARC investigators to collaborate with local partners and HHS agencies. The planning project teams should identify locally relevant opportunities and needs to create plans for future projects to address one or more of the four key pillars in the following areas:

- Develop, test, and implement innovations in HIV testing, that could include advancements in approaches and technologies that will work for diverse populations. **(Diagnose)**
- Implement and evaluate approaches to expedite more timely linkage to HIV care and earlier treatment initiation for persons diagnosed with HIV, along with recommendations to communities for implementation of evidence-based strategies to improve adherence and retention in care. **(Treat)**
- Integrate pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) care delivery into sexually transmitted infection (STI) or sexual health clinics, family planning services, mental health and substance use treatment, community organizations, and other settings where persons at high risk for HIV infection could be identified. **(Protect)**
- Implement and evaluate systems to rapidly detect and respond to emerging clusters of HIV infection to further reduce new transmissions through biomedical and behavioral interventions that target the sexual and substance use networks where outbreaks are occurring. **(Respond)**

Several critical principles should guide these efforts:

- In all proposed collaborations and projects, teams should examine any local policies that have created unintended structural barriers to HIV treatment and prevention and seek ways to transform these processes.
- All projects should focus on the 50 jurisdictions as well as the rural areas of the 7 states with a heavy HIV burden. CFARs and ARCs may work with jurisdictions outside of their institution's location, particularly if relationships have already been established.
- It is encouraged that these planning projects include consideration of **creative, locally-defined** concepts. 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, and community-based and outreach approaches that remove barriers to conventional prevention and treatment access.
- 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.

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
- EtHE pillar(s) addressed
- Amount of the requested supplement
- 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 EtHE 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 EtHE 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; 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 add value by addressing one or more of the four pillars of the EtHE; 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.
- c. **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.

- d. **Biographical Sketch** for all new Senior/Key Personnel and for mentors. Use the new biosketch format in [MS Word](#). Please note the personal statement should be related to the CFAR supplement project.
- e. **Human Subjects documentation** (if applicable). Include a current Human Subjects/Institutional Review Board (IRB), 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.
- f. Further NIH-initiated administrative actions and approvals for any clinical studies deemed above minimal risk or involving vulnerable populations may be required.
- g. **PHS 398 Checklist Form** [MS Word](#) [PDF](#)
 - i. TYPE OF APPLICATION. Check REVISION box and enter your CFAR/ARC grant number;
 - ii. Applicants must state that all federal citations for PHS grants will be met (e.g., human subjects, data sharing, etc.)
- h. 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.
- i. NO resource page (unless there are new resources that will be used for this request)
- j. NO appendices
- k. Submit **letters of support from all collaborating partner(s)** which describes their role(s) on the planning project.

Eligibility

Eligible Centers that are currently funded (not in a no cost extension) can submit a maximum of **three** applications for this announcement.

All faculty, including early stage investigators are eligible to be the supplement PI. The integration of early stage faculty and fellows with other CFAR/ARC investigators and local partners is encouraged to advance these planning projects within the context of a team building approach.

Budget and Funding Information

Funding for supplements will be supported by the NIH. The maximum funding allowed per application is **\$100,000 Direct Costs**. Funding for administrative supplements to existing CFAR/ARC grants will be available for up to one year in FY2019.

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, scientific merit, addressing the goals of the EtHE 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 08, 2019**. 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:

Elaine Wong, M.S.
National Institute of Allergy and Infectious Disease
Telephone: 240-627-3100
Email: elaine.wong@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)) EtHE] [2019]. Example: “XYZ CFAR/ARC – Smith Respond_Protect EtHE 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 EtHE initiative by an internal NIH review group convened by the NIH CFAR Steering Committee and NIMH staff 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 EtHE initiative;
3. Appropriateness and feasibility of the proposed planning project to address the goals of the EtHE initiative, including addressing the 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 proposed activities are likely to result in an innovative implementation science project; innovation is particularly encouraged for approaches that circumvent barriers to conventional prevention and treatment access;
6. Choice of appropriate project PI, co-investigators, and collaborative local partners (e.g., qualifications, demonstration of commitment to the activities, and experience);
7. Appropriateness of the budget, in consideration of the project described;
8. Feasibility to complete the project within the FY19 project period (e.g., this will range between 8-12 months depending on the parent CFAR/ARC grant).

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

Announcement Release Date: **3/04/19**

Application Receipt Date: **5/08/19**

Review Date:

6/18/19

Earliest Anticipated Award (Start) Date:

7/8/19

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 EtHE 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 defined in the Terms of Award. The NIH staff will work with awardees to ensure proper reporting.

Award Criteria

The following will be considered in making awards:

- Relevance to EtHE initiative, including addressing one or more key pillars;
- Scientific and technical merit of the proposed project as determined by a NIH-convened internal review panel;
- Funding availability and;
- Program balance.

Inquiries

For inquiries related to this announcement, please contact:

CFARs

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