

## One-Year FY2020 EHE CFAR/ARC Supplement Announcement

### Research Topics:

1. EHE Team-initiated Implementation Research
2. Reaching Cisgender Heterosexual Women with PrEP
3. Evaluating and Developing Data-Driven Messages and Communication Strategies for EHE

### 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 jurisdictions](#): 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 local partners to support the local ending the HIV epidemic plans with input from the local community. CFAR/ARC investigators must coordinate with the local jurisdictional team to ensure the proposed project supports and informs jurisdictional 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 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 focus on the 50 jurisdictions as well as the 7 states with a substantial rural HIV burden. CFARs and ARCs may work with jurisdictions outside of their institution's location, particularly if relationships have already been established.

## Research 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. Funding will support the EHE jurisdictions to meet the goals of EHE.

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 jurisdictional team. It is expected that this project is consistent with the jurisdictional activities and priorities funded by CDC ([PS20-2010](#)) and HRSA ([HRSA-20-078](#), [HRSA-20-91](#)) through their EHE initiatives.

This proposed one-year implementation research project can either build on the work from a NIH 2019 EHE supplemental planning project or can be a new project based on awareness of other priorities identified by the jurisdiction since the 2019 projects were funded. If a NIAID or NIMH Center team received a 2019 EHE supplement, and decides that they have done sufficient planning and formative work to merit a two-year supplement application, they should apply to the companion "Limited 2-Year FY2020 EHE Implementation Science Supplement Opportunity."

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**.

### 2. Reaching Cisgender Heterosexual Women with PrEP

(Note: In response to the 2019 NIH EHE call for supplement projects, a number of PrEP-focused applications were funded which focused on MSM and transgender women. However, few funded projects focused on cisgender heterosexual women. Therefore, this 2020 solicitation requests applications to meet the unique needs of cisgender heterosexual women, as they relate to EHE jurisdictional plans.)

Despite continued decline overall in HIV diagnoses for cisgender women in the United States, in 2017 more than 7,400 (19%) of all diagnoses were identified among cisgender women. Cisgender women of color are disproportionately vulnerable to HIV in some communities, and disproportionately represented among women living with HIV.

For cisgender heterosexual women, it can be more challenging for providers and patients/consumers to determine whether PrEP may be a relevant HIV prevention tool to consider, because in some cases factors that may increase risk of acquiring HIV are unknown (e.g., male partner HIV status, viral load status, or high risk behaviors). Moreover, even if women decide upon PrEP as an HIV prevention strategy, there may

be other multi-level social, structural, or system barriers present (e.g., stigma, discrimination, financial, ability to access HIV prevention services).

This supplement solicitation is intended to fund studies to determine how best to implement strategies to help cisgender heterosexual women learn about PrEP, decide if this HIV prevention tool is relevant for their lives, access PrEP care, and sustain PrEP use for as long as desired. Studies should focus on implementation strategies that address existing barriers most relevant to the local community's needs and also evaluate their effect on improving implementation outcomes. Focused research efforts are needed that provide meaningful, significant contributions to the prevention and susceptibility of HIV infection in cisgender heterosexual women living in the United States.

Applicants are encouraged to utilize a developmental perspective that addresses the substantial changes that occur for cis-gender heterosexual women across the lifespan, and tailor their approach/strategy appropriately, depending upon the age-range of potential participants.

Responsive studies may address, but are not limited to:

- Studies to determine how best to assist providers and consumers/patients to identify and counsel cisgender women who may be vulnerable to HIV regarding PrEP initiation.
- Studies to better understand the intersectional influence of factors from multiple levels (individual, partner, family, cultural, religious, health systems) that affect PrEP access, initiation, and sustained use).
- Studies to advance implementation of routine monitoring of PrEP adherence in EHE PrEP delivery settings, particularly settings that are accessed frequently by cis-gender women
- Studies of innovative strategies to scale up HIV prevention --including PrEP and other HIV prevention services -- in conjunction with mental health, substance use and sexual and reproductive health services; or implementation strategies for integrating PrEP services within other settings that serve women
- Studies to evaluate the effectiveness of moving towards a more comprehensive, normalizing sexual health approach for cis-gender women that includes HIV testing/PrEP integrated with other services for women (e.g., sexual and reproductive health, post-partum care, primary health care) and how to integrate culturally sensitive risk assessments into the context of PrEP screening
- Studies focusing on how best to integrate innovative technology-based strategies to routinize HIV testing and PrEP screening services within clinical settings (e.g. integrate lab panels; use of EMR prompts for providers)
- Studies of the integration of innovative methods to encourage, promote, normalize, and routinize HIV testing among cisgender women with subsequent linkage to care for those who test positive or subsequent linkage to appropriate prevention education efforts and services, including PrEP care, for those who test negative
- Implementation research on rapid PrEP initiation programs among cis-gender women, by targeting providers, clinics, or systems to improve implementation of these programs; or strategies to improve the subsequent PrEP care continuum

(Note: For studies focused on communication strategies and messaging tailored for cisgender women and PrEP, see topic 3 below).

Each Center can submit one application for this topic. The maximum funding allowed per application is **\$150,000 Direct Costs for up to 1 year**.

### **3. Evaluating and Developing Data-Driven Messages and Communication Strategies for EHE**

As an important component of the EHE initiative, there will be increased communication and messaging activities intended to expand awareness of HIV testing, prevention, retention in care, and stigma-reduction. Although broader messaging campaigns may succeed at reaching the general population, there should also be culturally competent and tailored messaging to communities disproportionately affected by HIV. A one-size-fits all messaging approach may not always be effective when focusing on specific jurisdictions and communities. Additionally, it is important to address messaging geared towards providers who may not recognize that they should offer routine HIV testing and prevention services to their patients. Innovative strategies for providers are needed to strengthen their ability to effectively communicate with their patients about the importance of HIV testing and prevention.

An important aspect of messaging is how the information is disseminated and ensuring that the intended message reaches the intended audience. Information can be communicated through various platforms including traditional mass media, social media platforms, through provider communication, among peers and social networks, via community leaders, social influencers and other innovative efforts. It is important to know whether these strategies are effective in reaching the intended audience, understood by the audience, and leading to adoption of intended behaviors among consumers and providers.

This supplement opportunity encourages research to help understand the implementation of various communication strategies and delivery platforms to reach impacted populations and providers in the United States -- to increase utilization of HIV testing, prevention, retention in care, and promote stigma-reduction. In addition to collaborating with local implementing partners, applicants are also encouraged to expand their team science approach, where appropriate, to work with Schools of Communication(s), Journalism, Business (e.g., marketing, public relations), media companies with a health-related mission, and community-based organizations.

Responsive studies may address, but are not limited to:

- Studies to assess implementation of current communication strategies and messaging in priority populations to assess barriers and facilitators, reach in communities, and effectiveness – and if needed, to inform the modification of these strategies.
- Studies to evaluate the implementation of social marketing campaigns to increase awareness of HIV testing, prevention (especially PrEP), retention in care, and stigma-reduction.
- Studies to evaluate the effects of culturally competent messaging that is designed to reach those disproportionately affected by HIV, particularly for those who may not have previously considered HIV testing or PrEP.
- Studies to determine the effects of regionally focused messaging on HIV testing, prevention, and treatment outcomes.

- Studies employing implementation research methods to enhance uptake of effective communication strategies in varied contexts, such as health care providers, among peers and social networks, via community leaders, and other innovative efforts.
- Studies to evaluate messaging to providers (i.e., ID doctors, ER/urgent care providers, primary care, OB/GYNs, and etc.) regarding the importance of offering routine testing and prevention services.
- Studies to develop appropriate communication strategies for providers when approaching their patients about HIV testing, sexual health, and general HIV prevention as part of their routine visit.
- Experimental or quasi-experimental studies evaluating message content to address known barriers or challenges in HIV prevention messaging such as:
  - perceived stigma and targeting- What are optimal targeting strategies for priority populations that do not result in more perceived stigma? This can apply to messages (e.g. optimal framing of health disparities to not stigmatize most affected groups), messengers, as well as imagery used in messages developing tailored messages for both people with HIV and people without HIV. (E.g. U=U messaging effectiveness, stigma, and motivation toward preventive behaviors and adherence

Each Center can submit one application for this topic. The maximum funding allowed per application is **\$150,000 Direct Costs for up to 1 year.**

### **Application Instructions (ONLY APPLICABLE IF YOU'RE SELECTED FOR FULL PROPOSAL)**

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
- Research topic for this supplement request
- Name of primary implementing partner, affiliated organization, and supporting federal agency
- Project jurisdiction
- Study population, if defined
- 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 research topic 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. For research topic 1, 2019 planning 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.

## 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.

## 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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