

# **Notice of Special Interest (NOSI): Administrative Supplements to NIH Centers for AIDS Research (CFAR) and NIMH AIDS Research Centers (ARC) for Ending the HIV Epidemic (EHE)**

Notice Number:  
NOT-AI-23-016

## **Key Dates**

Release Date:

December 28, 2022

First Available Due Date:

April 01, 2023

Expiration Date:

April 02, 2023

## **Related Announcements**

[PA-20-272](#) - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

[PAR-20-106](#) - Centers for AIDS Research (P30 Clinical Trial Not Allowed)

[PAR-20-107](#) - Developmental Centers for AIDS Research (P30 Clinical Trial Not Allowed)

[PAR-17-237](#) - Centers for AIDS Research (P30 Clinical Trial Not Allowed)

[PAR-17-238](#) - Developmental Centers for AIDS Research (P30 Clinical Trial Not Allowed)

[PAR-20-307](#) - Developmental AIDS Research Centers on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)

[PAR-20-308](#) - NIMH AIDS Research Center on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)

[PAR-18-832](#) - NIMH AIDS Research Center on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)

[PAR-18-833](#) - Developmental AIDS Research Centers on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)

[PAR-15-196](#) - Developmental AIDS Research Centers on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)

[PAR-15-197](#) - NIMH AIDS Research Center on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)

## **Issued by**

National Institute of Allergy and Infectious Diseases ([NIAID](#))

National Institute of Mental Health ([NIMH](#))

# Purpose

The overall objective of this Notice of Special Interest (NOSI) is to highlight interest in administrative supplement applications from eligible investigators to support (1) projects that conduct implementation research around evidence-based HIV interventions, care, and treatments tailored to communities disproportionately impacted by HIV; (2) Coordination, Consultation, and Data Management Center (CCDMC); and (3) Regional Consultation Hubs (RCHs). Collaborative and synergistic partnerships are critical in developing and defining approaches and models to scale up comprehensive, integrated interventions to expand testing, prevention, and treatment that optimize adherence, retention, and health outcomes, particularly in communities at highest risk for HIV infection.

## Background and Goals

Despite scientific advances in HIV prevention, treatment, and care, 34,800 cases of HIV in the United States (U.S.) were diagnosed in 2019, and disparities have been persistent, particularly for racial and ethnic minorities and gay, bisexual, and other men who have sex with men. The tools to end the HIV epidemic are available, but better implementation strategies are needed to reach the right people at the right time and place. The overall objective of the [Ending the HIV Epidemic in the United States \(EHE\)](#) initiative is 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.

In 2019, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary of Health launched EHE to leverage critical scientific advances in HIV prevention, diagnosis, treatment, and care through the successful programs, resources, and infrastructure of the Center for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and Indian Health Service (IHS). The EHE initiative focuses on the four pillars – Diagnose, Treat, Prevent, and Respond - that are the key strategies to the EHE initiative that together can end the HIV epidemic in the U.S.

The role of the NIH, as a research platform in the EHE initiative, is to support implementation research to inform HHS and partners on evidence-based practices and effectiveness. NIH-supported implementation research is critical to demonstrate the most effective strategies to adopt and integrate evidence-based HIV services, interventions, and policies to support the most affected populations. The success of this EHE initiative depends on collaborative and synergistic partnerships to develop and define approaches and models to scale up comprehensive, integrated interventions to expand testing, prevention, and treatment that optimize adherence, retention, and health outcomes, particularly in communities at highest risk for HIV infection. Projects funded under this initiative will create generalizable and actionable implementation knowledge and enhance the implementation science (IS) knowledge base needed for the EHE initiative.

## Scope of Interest

The administrative supplements under this NOSI will support EHE initiative through:

1. Projects: Eligible Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs) must collaborate with implementing partners located in the [57 priority jurisdictions](#). Implementing partners can include community, local, county and state health departments, community-based organizations, and clinics receiving funds from the CDC, HRSA, SAMHSA, or IHS. These implementation research projects should be developed by a team of CFAR/ARC investigators, community partners, implementing partners, and people with lived experience to support the [local ending the HIV epidemic plans](#).
2. Support of a Coordination, Consultation, and Data Management Center (CCDMC).
3. Support Regional Consultation Hubs (RCHs).

The CCDMC and RCHs will coordinate, collaborate, collect, and assemble data on progress from EHE projects funded under this NOSI. Thus, the recipients of EHE administrative supplements funded through this NOSI will be required to collaborate with and provide information requested by the NIH through the CCDMC and assigned RCHs on a regular basis. Information related to progress will be collected through data requests administered by the RCHs and harmonized by the EHE CCDMC for the NIH. Project recipients will further be expected to utilize the RCHs for IS consultation and technical assistance for their projects. Each project funded under this NOSI will be assigned to an RCH through a systematic process at the beginning of the project year.

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 (mutual benefit)** for all members of the EHE project team, including representation of people with lived experience. This includes communication and collaboration with all partners in all phases of the project including planning/development, initiation, execution, and dissemination. The EHE project team is defined as the CFAR/ARC investigator(s), community partner(s), implementing collaborator(s), and people with lived experience.
- Communities and/or people with lived experience must be meaningfully engaged through shared partnership. Partnerships with community members depend on trust, shared values, goals, equitable decision-making, and a diversity of perspectives, knowledge, and lived experiences.
- EHE project teams are encouraged to examine any local policies that have created unintended structural barriers to HIV treatment and prevention and work with their community partners to identify potential opportunities to either work around those barriers, find and harness facilitators to address the barriers that are unchangeable, and have ongoing dialogues about opportunities to affect those structural barriers directly.
- Applications must propose **creative, locally defined, and culturally relevant** concepts that align with the local EHE plans. Proposed project aims are especially encouraged that

innovate and build research-implementer strategies that differ substantially from conventional means of service delivery, particularly where more conventional standard practices and approaches are not effectively addressing the diversity of needs in their communities.

- Applications 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.
- CFAR/ARC investigators are encouraged to connect with the local or state EHE point of contact to increase community participation, buy-in, and ongoing sharing of research development and findings for their projects.
- All projects should focus on either the 50 priority jurisdictions or the 7 states with a substantial rural HIV burden. CFARs and ARCs may work in 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. Projects can include a county or state with significant new HIV diagnoses (>20 per 100,000 for counties or >10 per 100,000 for states) or one or more networks experiencing rapid transmission (i.e., clusters or outbreaks), as long as one EHE priority jurisdiction is also included.
- CFAR/ARC investigators are encouraged to collaborate with researchers from Historically Black Colleges and Universities (HBCUs) and Minority Serving Institutions (MSIs) in planning projects and in the formation of future IS partnerships in communities served by HBCUs.
- All supplemental research community collaborative projects are also strongly encouraged to assess, monitor and improve overall Quality of Life as an essential component of any intervention designed to improve HIV prevention and treatment outcome.

**EHE Scientific Priorities for FY23 are described below.**

**Each Center is allowed to submit a maximum of three applications total (i.e., any combination of three out of the four priorities) for project priorities 1. a through d.** Information on maximum funding and number of years allowed is located within the Budget and Funding Information section below. **Clinical trials are not allowed in CFAR applications according to NIAID clinical trials policy. However, clinical trials are allowed in NIMH ARC applications.**

**1. *Projects***

**a. *Syndemic Approaches to HIV Prevention, Treatment or Care***

*Objective: Using syndemic theory and approaches to (a) increase focus on intersecting diseases and social conditions that exacerbate health inequities, and (b) enhance the evidence base for effective successful approaches to assess, monitor, and intervene with respect to these intersections for optimal outcomes in HIV prevention or treatment.*

Syndemic theory emphasizes that adverse interactions between diseases and social conditions contribute to an excess burden of disease in a population. HIV and its common comorbid conditions such as viral hepatitis, sexually transmitted infections (STIs), and substance use and mental health disorders can be seen as an outcome of social inequities and disproportionately impact racial, ethnic, sexual, and gender minoritized populations. These same intersecting social determinants and co-morbid diseases can also affect optimal HIV prevention access, including PrEP, mental health, and substance use services that include syringe services and drug treatment.

Addressing a syndemic problem requires either interventions to account for these factors to successfully overcome and connect to HIV prevention and treatment (and other health care services), and/or interventions and strategies to alter the structures, systems and settings where care is delivered. Integrated services are one example of a change in service delivery to address multiple conditions. This type of change may be necessary but not sufficient to optimize care outcomes, unless individual and social conditions are also addressed.

Implementation strategies using systems approaches can help to shift perspectives and service delivery from siloed to integrated health care. System interventions such as changes to services reimbursement and novel delivery approaches have demonstrated reductions in health disparities, but many disparities remain. Consequently, there is a need for approaches grounded in syndemic theory that use an intersectional lens, in order to incorporate sufficient attention to multiple intersecting issues.

Other social determinants are known to impede optimal HIV prevention and treatment outcomes, such as economic inequality, unstable housing, and inadequate access to health services. Fear of reporting a positive HIV status may be experienced in many settings where disclosure may lead to stigmatizing attitudes and behaviors. Felt experience of enacted stigma in HIV prevention, HIV treatment, and other medical clinics and public health facilities continues to be a pervasive problem. Service delivery settings that are not welcoming to stigmatized populations can be exacerbated by stigmatizing attitudes, beliefs, and behaviors held by health care and community providers. Additionally, undocumented immigrants may experience worsening health inequities in syndemics with HIV and its comorbid conditions resulting from barriers to care in [EHE Phase I jurisdictions](#) where there is a significant increase in immigration.

Proposed projects should address individual, social and cultural factors, social and structural determinants of health and co-morbid diseases. Applicant teams are also encouraged to integrate approaches to explore stakeholder perspectives and experiences on the quality of life in the proposed projects. The proposed projects should be co-designed by a team of CFAR/ARC investigators, community partners, implementing partners, people with lived experience, and other key stakeholders to develop, implement, and evaluate implementation strategies. The application must clearly define the stage of the research project (e.g., planning, intervention and/or

implementation strategy). In addition, applicants should articulate how the proposed project fits into a longer timeline of research direction that will ultimately lead to intervention development and delivery, implementation strategies, and public health impact beyond their local community.

Applicants should include a conceptual or logic models and identify key variables to be collected that relate to syndemic production and reduction of disparities.

Applicants should also address co-morbid and/or intersecting individual and social determinants of health in their collaborative planning for intervention development, formative work, pilot intervention and implementation strategy.

Research topics may include, but are not limited to:

- Research that uses an integrated disease care model approach that incorporates strategies and interventions to reduce stigma and/or address social determinants of health that impact HIV outcomes.
- Research that uses integrated testing models for infectious diseases within care and other settings, including integrated self-testing options.
- Research that incorporates provider training approaches that support the knowledge and skills necessary to provide integrated care for syndemic conditions.
- Studies to assess the feasibility and acceptability of integrated service models that augment existing health or social service settings to address hardly reached populations.
- Early-stage research that supports reinvention of existing HIV/comorbid services with community input.
- Development and implementation of focal strategies to optimize timely and effective HIV prevention and timely HIV linkage, retention and viral suppression that account for syndemic factors. Projects could strengthen community members' utilization of HIV prevention, treatment and other important services by using innovative interventions, and implementation strategies.
- Development and implementation of strategies designed to enhance engagement in HIV prevention and HIV treatment by providing 'whole person care' and directly addressing barriers and facilitators to care engagement, by providing services for housing, food insecurity, employment, mental health, substance use, occupational, familial, faith-based, and other community social services that can contribute to optimal outcomes.
- Research that uses data, data integration and/or partnership approaches that provide evidence for the effectiveness or efficiencies created by integrated service delivery models.

1.

b. ***Leveraging Pharmacies to Advance HIV Testing, Prevention, and Care***

*Objective: This topic will support research projects designed to further capacitate, field, and scale the routine delivery of HIV testing, prevention, and care services through pharmacists and pharmacy settings in the U.S.*

Pharmacies have been valuable resources for delivery of vaccines for influenza and COVID-19 in the U.S. Pharmacies are viewed as neutral, non-stigmatizing locations to access healthcare, and they offer convenient access through extended store hours and co-location in neighborhoods and communities affected by HIV. Therefore, the updated [National HIV/AIDS Strategy](#) for 2022-2025 states that “Pharmacists” knowledge and accessibility in nearly every urban and rural community can be leveraged as part of a comprehensive HIV prevention and care strategy to expand access to care and improve population health.”

The existing research literature on HIV service delivery through pharmacies is limited but demonstrates the promise of pharmacy-delivered HIV testing, prevention, and care. Pharmacy programs can support HIV prevention by facilitating access to HIV testing alongside other health screenings. New models to provide pharmacy-based PrEP initiation or PrEP care have been pioneered. Adherence support is also a longstanding specialty of pharmacists and pharmacies, and there are opportunities to use pharmacy monitoring of antiretroviral prescription refills as a timely indicator of HIV care engagement – as well as a catalyst for intervention when needed.

Building models for successful pharmacy-based delivery and support of HIV testing, prevention, and care will require further implementation research and multisectoral collaboration. Central challenges include: creating effective strategies to engage populations placed at risk for HIV or living with HIV within pharmacy settings; developing pharmacist trainings and skill improvement programs to support HIV testing, service delivery, and client interactions; ensuring care linkage and collaboration by forming Collaborative Practice Agreements (CPAs) with local physicians where permitted; conducting pharmacy workflow implementation studies with attention to physical space needs for program administration; and consideration of reimbursement strategies and financing models.

This EHE supplement topic therefore calls for two-year implementation research projects co-designed by a team of CFAR/ARC investigators, community partners, implementing partners, people with lived experience, and other key stakeholders to further capacitate, field, and scale the routine delivery of HIV testing, prevention, and care services through pharmacists, pharmacy technicians and pharmacy settings in the United States. Research topics may include but are not limited to:

- Research that develops pharmacy-based health screenings for multiple chronic illnesses including HIV to advance uptake of HIV testing in communities heavily affected by HIV.
- Studies that develop models and training to advance pharmacy-based PrEP starts or delivery.

- Research that evaluates the potential to support the delivery of long-acting HIV regimens through pharmacies.
- Studies that develop approaches that use lapsed ART pharmacy refills as a timely catalyst for antiretroviral adherence and HIV care re-engagement interventions.
- Research that incorporates training pharmacists, pharmacy technicians, and pharmacy students to support HIV prevention and care, with emphasis on HBCUs and other minority-serving institutions.

1.

c. *Strategies to Improve Linkage to HIV Care and Services Post-Incarceration*

*Objective: Improving linkage and connection to mental health, substance use, social services, housing, job services, HIV care, and any other community resources **post-incarceration**. The goals are to optimize timely linkage to HIV care, retention, and viral suppression among people living with HIV (PLWH) re-entering their communities.*

It is estimated that about 15% (180,000) of the 1.2M people living with HIV (PLWH) in the U.S. have contact with some form of incarceration annually (e.g., pre-trial holding, city jails, and state or federal prisons). These are important opportunities for both HIV testing and HIV care after incarceration for innovative multi-level interventions to enhance timely linkage to HIV care, retention, and viral suppression.

EHE supplements on this topic will support-pilot, feasibility, and implementation research to understand and develop interventions to address the many interactional individual, social, structural, and community factors that are important for re-connection to community, health and other services; all of which can contribute to effective and timely linkage to HIV treatment and care services post-incarceration.

In addition, intersecting stigmas can adversely affect linkage to community, health, and mental health services among PLWH after incarceration. On its own, being identified as a formerly incarcerated person is already a known barrier to return to community among persons returning from correctional care. Taken together, re-entering their community as PLWH with any other additional intersecting stigmas (e.g., mental illness, substance use, sexual and gender minority status, being homeless) can further disrupt timely return to all health care services. Therefore, projects which also address intersectional sexual and gender minority facilitators and barriers to return to community post-incarceration are encouraged.

Research topics may include, but are not limited to:

- Research to develop and deliver focal strategies designed and implemented to optimize timely HIV linkage, retention, and viral suppression, using



innovative strategies to account for and overcome barriers building on the strengths of PLWH returning to their communities.

- Studies designed to better understand, partner, and intervene with strategies that focus on structural, policy and cultural factors.
- Studies that develop and implement interventions designed to assist PLWH returning to their communities with optimal preparation for plans upon return to home and community; for example, how can housing, mental health, substance use, occupational, familial, faith-based, and other community social services contribute to their timely HIV linkage, retention, and viral suppression?
- Research to assess the benefits of telehealth, mobile and other technological approaches to improve timely HIV linkage, retention, and viral suppression.
- Research to develop, pilot, and implement site(s) use of long-acting antiretroviral medications for PLWH returning to their communities.
- Studies that develop and implement interventions to address the barriers and facilitators to timely linkage to HIV care, retention, and viral suppression that relate to intersecting HIV and other stigmas (e.g., being identified as a person who was formerly incarcerated).
- Research to develop and implement strategies that are responsive to priority areas where there is a significant immigration, particularly for stigmatized communities such as racial-ethnic and religious minorities.

Proposed studies should clearly specify next steps for intervention research, in addition to clearly identifying and partnering with the end-users of the knowledge that would be generated (e.g., prevention scientists, public health officials, health departments, justice systems, policy makers, community organizations, etc.). Applicants should thoroughly explain how that knowledge might be used to inform decisions and implement change. The involvement of the end-users is to ensure that the proposed data and methods will be useful. The partnerships with key end-users can be existing, or new relationships initiated based on success of previous stakeholder engagement and preparation to implement proposed work in a new setting.

1.

d. ***Cluster Detection and Response Strategies***

*Objective:* *Using cluster detection and response strategies to address identified service gaps, reduce HIV-related health disparities, and contain outbreaks.*

Cluster detection and response (CDR) offers a strategic framework to guide tailored implementation of proven HIV prevention strategies where transmission is occurring most rapidly. Clusters of rapid HIV transmission can be detected in several ways including provider reporting, partner services, or analysis of case or molecular data from HIV surveillance. The presence of a rapid transmission cluster is an indication that prevention and care services are not reaching people who need them and indicates an opportunity to identify limitations or gaps in services and curate focused

and tailored interventions where general population interventions have failed. CDR involves adapting HIV resources and services to those who use them, rather than expecting people to adapt to access resources and services in a system that has failed them.

Engagement with both health departments and communities are an integral part of CDR planning and response efforts, including efforts to strengthen HIV prevention and treatment activities. Applications for this topic should propose CDR activities that foster partnerships among health departments, community partners (including but not limited to care, testing, and social services providers), and implementation scientists, and should clearly describe the partnerships, including the roles and responsibilities of individuals and partners across the entire project team. Activities should be proposed in locations where rapid transmission clusters meeting [CDC national priority criteria](#) have been recently identified. Applicants are encouraged to consider conducting CDR implementation research across a full range of cluster types, including smaller or larger clusters, clusters primarily among racial and ethnic minority groups, clusters associated with sexual transmission, and clusters among people who inject drugs. The proposed scope of work should include investigating cluster networks; using IS methods including formative/rapid ethnographic assessment to identify and address gaps in critical programs and services, including testing, PrEP, linkage to and retention in care; addressing identified social determinants of health, and advancing health equity.

Applications submitted under this topic may include but are not limited to:

- Research to identify and customize interventions to rapidly address specific identified gaps during cluster/outbreak response (e.g., accessible and culturally competent HIV testing, PrEP, syringe services, rapid linkage to care, treatment initiation, and retention in care) and assess related outcomes.
- Studies could include peer-driven recruitment strategies, expansion of low threshold services, health center quality initiatives, syndemic approaches, and improved or expanded partner services methods.
- Research to assess the direct impact of comprehensive cluster and outbreak responses on interrupting or preventing HIV transmission among cluster members and networks, on specific HIV prevention and care outcomes (e.g., PrEP use, viral suppression), and on outcomes for vulnerable populations. Assess programmatic gaps identified during responses and changes to programs, policies, or procedures (including data needs) resulting from cluster response.
- Studies to develop new or improved approaches to evaluate outcomes during and after cluster response, including developing specific indicators or metrics for real-time monitoring during a response and evaluation after a response, cost/cost-effectiveness and impact on HIV programs, and qualitative assessments among cluster members and networks and/or providers to assess the impact and value of CDR activities.

- Studies to identify effective models for engaging the public, key stakeholders, and specific communities in HIV outbreak preparedness, planning, and response, including approaches that identify and address HIV stigma, structural barriers, and social determinants of health, and improved models for collaboration with healthcare systems and providers and nonpublic health stakeholders.
- Studies that ask important questions about what may be important types of implementation approaches to apply - in order for sites, health departments, and communities to optimally carry out the CDR activities. In doing so, applicants are also encouraged to examine not just strategies and outcomes in a particular community or site, but also look across different types of settings in order to begin to ask questions about variable implementation outcomes, based upon the type of strategy applied.

## **2. Coordination, Consultation and Data Management Center**

*All centers may submit one application for the CCDMC. Only one CCDMC application will be funded.*

Supplemental funding will be awarded to support one Coordination, Consultation and Data Management Center (CCDMC). This Center will be expected to function as a supportive resource to EHE projects and Regional Consultative Hubs (RCHs) and provide regular updates on progress and outcomes to NIAID/NIMH Program Officers. The expected functions are described below, as well as expectations.

The CCDMC's resources are intended to provide the following:

### *Organization and management*

- Data management plans for EHE project site and Research Consultation Hub (RCH) data submissions. This will include collection of requested data at regular intervals.
- The CCDMC will also house potential common metric library/resource available for all EHE project-funded sites to utilize as needed or for proposed cross-site analyses and publications.
- Support plans and studies across RCHs and project sites in harmonization, with subsequent data being used by collaborating sites.
- Establish a policy for the use of shared project data for application consideration which will be vetted through a Steering Committee of CCDMC representatives across sites funded with EHE support to the RCHs and NIH program officials.
- Foster collaboration and regular interaction of research teams through scheduling and organizing conference calls, workshops, or webinars.
- Foster cross-RCH communication and planning for dissemination of research findings to communities, policymakers, and other relevant parties.
- Collaborate and assist the RCH that will host annual CFAR/ARC EHE meeting. Funding for an in person annual EHE national meeting for research and

community should be included in the CCDMC's request but funds will be provided to the host RCH. The applicant should allocate funding to support a 200-300 person 2-day meeting.

#### *Scientific Leadership*

- Provide scientific leadership and technical assistance in IS methods and protocol development across sites, in partnership with the RCH teams.
- Collaborate with RCH teams to develop plans for EHE-wide scientific advancement, including but not limited to:
  - Planning meetings in conjunction with HIV and Implementation Research conferences.
  - Develop a plan for EHE-related virtual webinars conducted by all members of EHE project teams.
  - Convene subgroups of expert personnel across sites to plan a variety of methods for dissemination and sharing of research findings and effective implementation strategies to optimally deliver effective intervention tools to U.S. Phase 1 priority jurisdictions, additional jurisdictions being reached by NIH funded projects in other jurisdictions, and in any innovative delivery settings. This should include, for example, in sociology, health communications, community organizing and engagement, all current media tested as EHE delivery methods, less conventional public health messaging and interventions, preventive health behavior change, and other relevant expertise to be determined.

#### *Training and capacity building*

- Support development of training and capacity-building programs for early-stage investigators, as well as secondary and post-secondary students, local implementers, community leaders, people living with HIV, and policymakers, as appropriate.
- Develop a cross-regional mentoring network and facilitate connection of early-stage investigators to relevant mentorship teams.
- Compile and disseminate relevant educational opportunities and resources related to IS for early-stage investigators.
- Provide mentorship opportunities for early-stage investigators in best practices for community-engaged research.

### **3. Regional Consultation Hubs (RCHs)**

*All centers may also submit one application for a regional consultation hub (RCH). However, each Center is only allowed to be involved in one RCH. A Center cannot be funded for both a CCDMC and an RCH. However, a Center can apply for both a*

*CCDMC and RCH, but the Center that is selected as the CCDMC will be ineligible to receive funding for an RCH, if both applications are meritorious.*

This supplement topic will support CFARs and ARCs that have strong IS expertise to serve as an RCH to provide consultation and technical assistance to EHE project teams and to coordinate and collaborate with the CCDMC. CFAR and ARC investigators are encouraged to collaborate on RCH applications based on IS expertise and are allowed to include IS experts from outside of the Centers and other institutions that are not part of a CFAR/ARC. IS experts are limited to participate as an IS team member on one IS hub application.

Applicants must describe the IS expertise, technical assistance, coaching, training, and consultative services that will be available through the RCH, including RCH team members, their roles and responsibilities and how the IS hub will interact with the CCDMC and CFAR/ARC Administrative Core. The RCH is expected to cover the scope of work described below, and should describe any regional, local, or unique expertise and services that could be provided.

The RCH must provide, at the minimum, the following activities and processes:

1. Define technical assistance available to projects on IS designs, frameworks, strategies, measures, and outcomes and on partnership formation (e.g., partnerships with health departments, CBOs, health systems).
2. Create opportunities to translate local knowledge within each project into generalizable knowledge.
3. Provide details on coaching/training sessions available to project teams seeking IS consultations and technical assistance.
4. Describe how a consultation agreement which includes a communication and data collection plan with project teams seeking consultations and technical assistance will be established and what it will entail.
5. Describe plans to facilitate coordination with the CCDMC.
6. Collect data on measures and outcomes from awarded projects based on established criteria from CCDMC from all EHE projects receiving consultation and technical assistance from the RCH.
7. Provide data to CCDMC on information requested by NIH for the EHE projects with which the RCH has established a consultation agreement. Identify RCH representative(s) for the Executive Committee.

## Eligibility

Currently funded Centers (not in a no cost extension/bridge year) that are awarded from the Funding Opportunities Announcements (FOAs) listed below are eligible to submit applications for this announcement. There is no restriction on NIH Investigator Status (e.g., Early Stage Investigator, New Investigator, etc.).

- Active P30 grants awarded under:

- [PAR-20-106](#) - Centers for AIDS Research (P30 Clinical Trial Not Allowed)
- [PAR-20-107](#) - Developmental Centers for AIDS Research (P30 Clinical Trial Not Allowed)
- [PAR-17-237](#) - Centers for AIDS Research (P30 Clinical Trial Not Allowed)
- [PAR-17-238](#) - Developmental Centers for AIDS Research (P30 Clinical Trial Not Allowed)
- Active P30 grants awarded under:
  - [PAR-20-307](#) - Developmental AIDS Research Centers on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)
  - [PAR-20-308](#) - NIMH AIDS Research Center on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)
  - [PAR-18-832](#) - NIMH AIDS Research Center on Mental Health and HIV/AIDS (P30 Clinical Trial Optional)
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**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 and Submission Information**

Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent.

- [PA-20-272](#)- Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

All instructions in the [SF424 \(R&R\) Application Guide](#) and [PA-20-272](#) must be followed, with the following additions:

- Application Due Date(s) –**April 1, 2023**, by 5:00 PM local time of applicant organization.
- For funding consideration, applicants must include “**NOT-AI-23-016**” (without quotation marks) in the Agency Routing Identifier field (box 4B) of the SF424 R&R form. Applications without this information in box 4B will not be considered for this initiative.
- Applicants are strongly encouraged to notify both the Scientific/Research Contact(s) listed below and the Program Official in eRA Commons for the parent grant that a request has been submitted in response to this NOSI to facilitate efficient processing of the request.

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. **Project summary** and **narrative** is that of the administrative supplement, not the parent grant.
2. List the CFAR or ARC PD/PI as the Project Director/Principal Investigator. The **Supplement PI** and Senior/Key Personnel who are being added through this supplement for whom additional funds are being requested are entered in the section “Senior/Key Person”; include a biographical sketch for each. Please note the personal statement should be related to the CFAR/ARC supplement project.
  - a. Implementing/Community partners listed as significant contributors are not required to have an eRA Commons account and/or NIH Biosketch. Implementing/Community partners without these elements should be designated as Co-Investigators. This designation will allow for the electronic submission process. If the roles and responsibilities of the implementing/community partner are equivalent to an MPI, this should be described in detail in the application. The NIH biosketch can be uploaded as an “Other Attachment”.
3. **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 application.

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.

4. 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.
5. Any CFAR **clinical studies** deemed above minimal risk, involving vulnerable populations, or populations with special considerations requires CFAR clinical approval. All appropriate IRB approvals must be in place prior to Notice of Award. NOTE: Studies involving [clinical trials](#) are not allowed for CFARs.
6. **Research Plan information and page limits**
  - 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, to the local EHE plan, and how the project addresses the NIH HIV/AIDS Research Priorities ([NOT-OD-20-018](#)). **One page limit.**
  - 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. **One page limit.**
  - c. The **research strategy** is limited to **six pages** and should include:
    - i. Background and rationale for the proposed application

- ii. Clearly stated study/research question(s) and description of the underlying barriers or gaps in research to be addressed
- iii. Description of the activities proposed, and the roles and responsibilities of key staff, including EHE team as defined above
- iv. Description of the expected outcome of the proposed activities
- v. Expected follow-up plan upon completion of the supplement
- vi. A description of how the supplement and follow-up plan are expected to add value by addressing the local EHE plan
- vii. Plans to monitor and evaluate the ability of the activities to achieve the outcome
- d. Indication of how the proposed activities outlined in the supplement requests are expected to lead to development of the stated goals
- e. An **implementation research logic model** and **communication plan** (see Additional Requirements below)

## 7. 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.

Letters of support that are the same for all partners may fail to establish a level of credibility, may not show a true commitment to the project, or may fail to demonstrate authentic collaboration.

## 8. No Appendices allowed

## 9. Additional Requirements within the 6-page Research Strategy (applies only to the projects – EHE Priority 1a-1d)

- Applicants must include a copy of the project **implementation research logic model**. 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.

[Link to resources for the Implementation Research Logic Model](#)

Describe the **IS framework or model** utilized to support the logic model and to guide the study design and evaluation methods.

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 IS theories, models, and/or frameworks appropriate for implementation research to inform study hypotheses, measures, implementation outcomes, and health outcomes if able to be measured.

Another tool that applicants should reference is the **Implementation Outcomes Crosswalk**, which aims to offer standard measurements of key constructs in the context of HIV services and programs.

Coordination data collection among the projects funded at the CFARs and ARCs is critical for local knowledge to become generalizable implementation knowledge. There is a balance to strike in capturing uniform data across varied contexts and in respecting researcher autonomy to develop metrics that are specific to a given study. HIV IS experts have ascribed relevance ratings to each measure in the Crosswalk across several stages of implementation research.

Applicants are expected to measure, at a minimum, those that are “Required” for the appropriate study stage or otherwise justify why a measure is not applicable for your study. You may also choose additional outcomes apart from those listed in the Crosswalk that are relevant to your research question.

[Link to resources for the Implementation Outcomes Crosswalk](#)

- 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. Please refer to language under the reporting section regarding requirements.

## **Budget and Funding Information**

Funding for supplements will be supported by the NIH. The maximum funding allowed per application is:

1. Projects: *The maximum funding allowed per application is up to \$150,000 per year (direct costs) for up to 2 years*
2. CCDCMC: *The maximum funding allowed is up to \$1,000,000 per year (direct costs) for up to 2 years, which includes funding for the annual national EHE meeting for research and community.*
3. RCH: *The maximum funding allowed per application is up to \$350,000 per year (direct costs) for up to 2 years.*

Note: The proposed project period of the supplement cannot extend beyond the project period of the parent award.

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.

### **Administrative Review Considerations**

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.

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. This criterion applies only to the projects.
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). This includes involvement of people with lived experience. This criterion applies only to the projects.
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 priority communities. This criterion applies only to the projects.
5. 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.
6. 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.
7. Innovation is particularly encouraged for approaches that circumvent barriers to conventional prevention and treatment access. This criterion applies only to the projects.
8. 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).
9. Appropriateness of the budget and the time requested, in consideration of the project described.
10. 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.

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[Weekly TOC for this Announcement](#)  
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