FY2022 EHE CFAR/ARC Supplement Announcement

Purpose

The NIH invites eligible NIH CFARs and NIMH ARCs to submit administrative supplements in support of the Ending the HIV Epidemic in the United States initiative. Eligible CFARs and ARCs must collaborate with partners in the 57 priority areas: community, local, county and state health departments, CBOs, and clinics funded by the CDC, HRSA, SAMHSA, or IHS. These implementation research projects should be developed by a team of CFAR/ARC investigators, community partners, implementing collaborators, and people with lived experience to support the local ending the HIV epidemic plans.

Background

The role of the NIH, as a research platform in the EHE initiative, is to support **implementation 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 funded by the participating HHS agencies to support local EHE plans.

Several critical principles should guide these efforts:

- For this announcement, the EHE project team is defined as the CFAR/ARC investigator(s), community partner(s), implementing collaborator(s), and people with lived experience.
- 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 partnership, including representation of <u>people with lived experience</u>. This includes **communication** and **collaboration** with all partners in all phases of the project including planning/development, initiation, execution, and dissemination.
- Partnerships with community members depend on trust, shared values, goals, equitable decision-making, and a diversity of perspectives, knowledge, and lived experiences. Thus, in this funding announcement, meaningful community engagement is defined as shared partnership as described in the community engagement continuum between communities and academic partners and should be mutually beneficial (<u>Sanders, et al., 2021</u>).
- Teams should examine any local policies that have created unintended structural barriers to HIV treatment and prevention and seek ways to transform these processes.
- Applications must propose **creative**, **locally defined**, **and culturally relevant** concepts that align with the <u>local EHE plans</u>. 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.
- CFAR/ARC investigators are encouraged to connect with the <u>local or state EHE</u> <u>point of contact</u> to increase community participation in their projects.
- All projects should focus on either the 50 priority areas or the 7 states with a substantial rural HIV burden. CFARs and ARCs may work with priority areas outside of their institution's immediate location, particularly if relationships have already been established, and/or these relationships can be strengthened by collective work.

Additional Considerations:

- 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 implementation science partnerships in communities served by HBCUs.
- The updated <u>National HIV/AIDS Strategy</u> was released in December 2021, with several important modifications. Across the strategy, there is an enhanced focus on quality of life among people with HIV. As a result, in the indicator section, <u>quality of life for people with HIV</u> has been designated as the subject for a developmental indicator, meaning that data sources, measures, and targets will be identified, and progress monitored thereafter. While proposing projects in any of the topics listed, wherever feasible, applicant teams are strongly encouraged to integrate formative mixed method work to explore stakeholder perspectives and experiences in the quality of their lives, collect data on existing quality of life measures, pilot new quality of life assessments, ascertain any existing data sources, and explore future strategies to assess quality of life in varied community settings.

FY22 EHE Topics

Each Center is limited to submitting a total of **five applications** for topics 1-5.

1. Planning projects to support participatory data science research efforts toward Ending the HIV Epidemic in the United States

Advances in HIV prevention and treatment have resulted in lower HIV acquisition and improved life expectancy for people with HIV in the United States (U.S.). But, even in high resourced countries such as the U.S., HIV continues to disproportionately affect certain populations. Social and structural determinants of health (SSDoH) are key drivers of these health inequities. Innovative approaches are needed to understand the interplay of complex individual, community, social, and structural factors that influence HIV outcomes and disparities over time and allow for a deeper

understanding of the strategies that are more likely to improve HIV outcomes. Data science approaches (e.g., statistical, computational, and mathematical modeling) can help identify important predictors of HIV prevention and treatment at multiple levels, can identify individuals or groups who are most vulnerable and might benefit most from an intervention, and can use simulations to test the potential effectiveness of an intervention, set of interventions, or an integrated response to a cluster or outbreak within the social environmental context in which people live, work, and interact with others. Community members belonging to priority populations can also provide valuable insight into these questions. Therefore, engaging community members and other key stakeholders in the model development is a necessary, critical piece of this process that requires expertise in implementation science methods for improving the uptake of evidence-based strategies and ensuring they are rooted in the local context, address local priorities, and can have real-world impact.

A critical step to Ending the HIV Epidemic in the U.S. is to develop strategies to address HIV prevention and treatment efforts that are informed by the communities they serve. Each EHE project team should propose planning and research activities to develop and foster partnerships among data scientists, implementation scientists, and community partners. Training for people with lived experience who are involved in the project is highly encouraged, as needed. Teams should propose collaborative approaches that will enable the construction of a hypothetical model representing the dynamic and complex factors, including SSDoH, that influence the prevention and treatment of HIV for future collaborative research efforts using data science approaches to model potential strategies to improve the implementation of evidencebased HIV interventions, while clearly reflecting the priorities of the community. The EHE project team should evaluate and consider a wide array of available data sources (e.g., electronic health records, public health data, state, and local policies) that can be used in their future modeling efforts. Proposals must demonstrate how data and implementation scientists, implementing partners, community members, and other key stakeholders will be meaningfully engaged as partners in every project stage. The application should clearly describe the partnership, including the roles and responsibilities within the EHE project team.

The maximum funding allowed per application is \$200,000 Direct Costs for up to 1 year.

2. Equity-focused approaches to reduce HIV-related health disparities

Scientific advances in HIV prevention and treatment have substantially reduced the number of new HIV cases and allowed people to live long, healthy lives. However, optimal implementation of existing HIV prevention and treatment tools to reach racial and ethnic minority communities <u>disproportionately impacted by HIV</u> requires using an equity-focused approach through meaningful partnerships with the community, including people with lived experience. The EHE initiative emphasizes the importance

of community engagement in achieving the goal to end the HIV epidemic by 2030. Empowering communities through community engaged research is one way to address issues around health disparities in the HIV epidemic, including disparities in communities experiencing rapid transmission, and implement strategies that have a greater likelihood of uptake within communities for testing, treatment, and prevention of HIV.

Applications for this topic should address SSDoH, as well as barriers, including stigma and unconscious bias, to HIV care and prevention. EHE project teams must include community partners as Multiple Principal Investigators (MPIs) from an organization or coalition that represents an underserved or marginalized community impacted by health disparities. Teams should propose projects using equity approaches to reduce HIV-related health disparities that meet the needs of the community. Proposals must demonstrate how academic and community partners, including community members from the priority population(s) will be engaged as partners in every stage of the project. These proposals should be driven by the needs and priority of the community, and the shared goals of the project should be determined by consensus. The application should clearly describe the partnership, including the roles and responsibilities within the EHE project team. Proposals should describe how decisions are made, how the research focus was identified, and how it will build community power. Additionally, the proposed activities should clearly reflect the priorities of the community.

The maximum funding allowed per application is \$200,000 Direct Costs/year for up to 2 years.

3. Strategic alliances across jurisdictions to reach EHE goals through implementation research

The scale up of HIV prevention, diagnosis, care, treatment, and cluster and outbreak response strategies to meet the goals of the EHE initiative will require the coordination, dissemination, and implementation of innovative, community-driven solutions. There is an urgent need to leverage existing scientific advances to create generalizable implementation research knowledge. The NIH CFAR and NIMH ARC programs are well-positioned to develop this knowledge through existing and new alliances across multiple sites in 57 EHE priority jurisdictions and beyond. Additionally, alliances with existing networks such as the Positive Women's Network, the US People Living with HIV Caucus, or other networks are encouraged to support community-driven solutions. Each EHE project team should propose projects with community and/or implementing partners at two or more sites. One proposed site must represent a new or expanded partnership. Additionally, one site must be identified one of the <u>57 EHE priority jurisdictions</u>, the other(s) could expand to counties or states with <u>significant new HIV diagnoses</u> (>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).

The multi-site projects supported will seek to contribute both practical and conceptual advances. In practical terms, these studies should aim to develop strategies and identify barriers and facilitators that could be used to effectively deploy guidelines, practices, and policies across entire systems of care. In conceptual terms, these studies should also leverage the multi-site platform to test implementation science hypotheses or explore novel methodological approaches that can inform future implementation research and establish a base of generalizable solutions. Alliances should be regarded as opportunities for organizational learning and a way to combine complementary strengths.

Applications should clearly describe the alliance(s), including the roles and responsibilities within the EHE project team and the added value created. The proposal should detail the rationale for including each proposed site. The proposed activities should reflect the priorities of the community and reach one or more of the groups at a disproportionately high risk for HIV.

The maximum funding allowed per application is \$250,000 Direct Costs for up to 1 year.

4. Applying behavioral economic approaches to design implementation strategies for HIV testing, prevention, and care

Behavioral economics combines tenets from psychology and economics by considering cognitive factors that influence human decision-making and behavior. Behavioral economics maintains that people rely on mental heuristics and cognitive biases when making choices, such as present bias (discounting future outcomes in favor of ready benefits), inertia bias (thinking and acting in familiar ways), and loss aversion (preferences for avoiding losses over acquiring gains). Behavioral economic interventions seek to leverage these cognitive processes in a manner that can 'nudge' people to make healthy choices and adopt healthy behaviors. These interventions can be non-monetary and often include the strategic design of 'choice architecture' (e.g., providing an option for opt-out versus opt-in), key communications (e.g., citing social norms), and other behavioral strategies (e.g., inviting people to make a commitment or a plan). Such nudges may have small individual-level effects but are often inexpensive and can therefore be implemented widely; when implemented widely, they can have an important public health impact for minimal cost.

Although behavioral economics has been utilized in many areas of health research and promotion, the field has less commonly been applied to address the challenges of implementing strategies and tools for HIV testing, prevention, and treatment. In HIV research to date, there is a stronger tradition of conditional cash incentives or

contingency management approaches that center more on classical economic theory than behavioral economics. There is an opportunity to develop and test implementation strategies that use behavioral economic frameworks to advance HIV testing, prevention, and treatment.

All supplement applications submitted to this topic must specify how a behavioral economic framework or principles guide the research. Applicants proposing intervention development are required to describe how their intervention approach is not strictly monetary in nature. Due to the NIAID clinical trials policy, CFAR supplement applications are limited to studies on feasibility/acceptability (i.e., no clinical trials). However, NIMH ARC supplements may include feasibility/acceptability and/or preliminary impact on health behaviors. Each EHE project team should propose research activities to address local EHE plans. The application should clearly describe the partnership, including the roles and responsibilities within the EHE project team.

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

- Research to understand whether and how behavioral economic principles, heuristics, or cognitive biases influence HIV testing, prevention, or treatment decision-making or behavior to inform future interventions
- Research that uses behavioral economic principles to facilitate uptake of voluntary HIV testing
- Research that uses behavioral economic principles to facilitate PrEP screening or use
- Research that uses behavioral economic principles to develop innovations in prescription refill reminders, medication labeling, or other approaches that could facilitate adherence and persistence
- Research that combines any conditional incentives with behavioral economic principles that attend to the form, timing, and manner of incentive delivery
- Research on behavioral economic approaches at the healthcare provider or healthcare system level that could improve the delivery or quality of HIV testing, treatment, or prevention services
- Research to inform the cost-effectiveness of non-financial incentive-based behavioral economic interventions for HIV testing, prevention, and treatment

The maximum funding allowed per application is \$200,000 Direct Costs for up to 1 year.

5. Implementation Strategies to Facilitating a Status Neutral Approach to HIV Prevention and Treatment

A "status neutral" approach is a 'whole person' approach to health care and service delivery, one that meets people where they are at regardless of their HIV status. The framework is called "status neutral" because the same approach is used to engage and retain people in care, whether they need or are receiving HIV treatment or HIV prevention services.

Focusing on the needs of the person rather than their HIV status helps improve care. Features of the status-neutral approach include continual assessment of each person's needs and ongoing engagement in HIV prevention and care, including access to support services for anyone who could benefit from them, regardless of HIV status. This continuous, high-quality care provides people with the tools they need to stay healthy and help stop HIV—either by maintaining an undetectable viral load through effective daily treatment, or by taking PrEP daily as prescribed. By offering HIV services alongside other local health care and social support services used by the community, HIV prevention and treatment become part of the fabric of holistic care designed to meet the needs of each person. As a person's needs evolve, they can be seamlessly connected to new services. The outcome is not only improved HIV care, but better overall health and social stability for every individual.

A status neutral approach also addresses HIV-related stigma supported by the historical silos of HIV prevention and care. Mitigating stigma is essential to ensure that people with HIV are not defined by their status, and that people seeking HIV prevention services are empowered to access these tools without facing judgment or feeling that they are viewed as the result of a lab test. Parallel services and structures historically created for people with HIV or those who could benefit from prevention may hinder connection to care by maintaining stigmatizing structures in health care. In addition to integrating HIV and prevention services to better address social determinants of health regardless of HIV status, the status-neutral framework encourages the delivery of culturally affirming care by ensuring providers recognize and address their implicit bias on issues like race, ethnicity, sexual orientation, or gender identity, biases which prevent people from returning for care.

As should be clear from this background on the import of status-neutral approaches, implementation of these approaches requires change at multiple levels, including, for example, individual, familial, provider, and systems-level changes.

Implementation research can help to answer many questions related to how best to initiate, integrate, and sustain such approaches in clinics and a range of community settings. Applications are especially encouraged in jurisdictions that have already transitioned or are planning to transition their HIV service delivery to a status neutral model.

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

• Studies to identify barriers and/or facilitators to providing status-neutral HIV services at the policy/organizational or provider level to inform selection of implementation strategy, including incorporation of readiness assessments for

incorporating status-neutral models into current programs or portfolios.

- Studies to develop and test implementation strategies in a range of settings, to
 optimize uptake and fidelity to interventions designed to (a) increase rates of
 sexual health discussions (b) promote consideration of HIV-testing and/or PreP for
 a next step, and (c) offering of PrEP prescription (linkage to PrEP services if not
 one-stop services) or HIV care and treatment.
- Testing of implementation strategies to modify practices at publicly funded sexually transmitted diseases clinics into culturally competent, gender affirming sexual health clinics that offer more comprehensive status-neutral HIV services, including immediate antiretroviral therapy for those that test positive for HIV and pre-exposure prophylaxis for those testing negative for HIV, with navigation to clinical sites in the community for ongoing care or prevention services.
- Studies to implement and strengthen post-exposure prophylaxis (PEP) as a part of status-neutral approaches to HIV prevention.
- Development and testing of implementation strategies to connect home selftesting for HIV to prevention services (e.g., PrEP) or HIV care and treatment services.
- Development and testing of community-based implementation approaches for HIV status neutral care, including use of mobile approaches to implementation.
- Studies to implement approaches to initiate immediate, field-based antiretroviral therapy (as treatment or prevention) including those that are initiated through partner services.
- Tailored interventions for status-neutral approaches using technology-based platforms, such as mobile phone apps, interactive games, or socially and culturally relevant videos
- Evaluate the impact of status-neutral approaches on other important client, provider, system, and community-level variables, especially personal experience of stigma (internalized and enacted), provider attitudes towards and use of destigmatizing dialogue, and stigma measured at the community level.
- Studies to utilize and evaluate implementation strategies for status-neutral approaches in the context of integrated care for mental health services, substance use disorder services, TB, and/or Hepatitis.
- Studies to test implementation strategies that employ attention and intervention for social determinants of health in status-neutral approaches.

The maximum funding allowed per application is \$200,000 Direct Costs for up to 1 year.

6. New EHE CFAR/ARC Implementation Science Consultation Hubs

In FY20, five implementation science (IS) hubs were funded to support EHE projects funded to the CFARs and ARCs. With the expansion of EHE projects, this topic invites CFARs and ARCs that do not have an existing implementation science hub to submit a maximum of one application per Center. CFARs and ARCs that have strong IS expertise to serve as an IS hub to provide consultation and technical assistance to EHE project

teams and to coordinate and collaborate with the Implementation Science Coordination, Consultation, and Collaboration Initiative (ISC³I). Applicants should communicate with the ISC³I team (<u>isc3i@northwestern.edu</u>) while developing their applications to ensure coordination of efforts and include a letter of support.

CFAR and ARC investigators are encouraged to collaborate on IS hub applications based on implementation science 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 IS hub, including IS hub team members, their roles and responsibilities and how the IS hub will interact with ISC³I. The IS hub 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.

Scope of Work for the Implementation Science Consultation Hub must include, but are not limited to, 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 ISC³I.
 - Collect data on measures and outcomes from awarded projects based on established criteria from ISC³I from all EHE projects receiving consultation and technical assistance from the IS hub.
 - Provide data to ISC³I on information requested by NIH/HHS for the EHE projects with which the IS hub has established a consultation agreement. Identify IS hub representative(s) for the Executive Committee.

The maximum funding allowed per application is \$250,000 Direct Costs for up to 1 year. Each Center is only allowed to be involved in one implementation science hub. Therefore, CFARs and ARCs currently affiliated with an existing implementation science hub are ineligible to apply to this topic. However, existing hubs without FY2022 funding approved in FY2021 should also submit an application. 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 Instructions

Requests submitted in response to this opportunity must follow instructions outlined in <u>PA-20-272</u>. Administrative supplement <u>requests must be</u> submitted through Grants.gov using electronic submission processes (NOT-OD-20-128). Follow all instructions in the <u>SF424 (R&R) Application Guide</u> to ensure all appropriate required and optional forms are completed, with the following additional guidance:

1) SF424 R&R Cover Form:

a. Select "Revision" in the "Type of Application" field.

2) R&R Other Project Information Form:

- a. If applicable to the supplement activities, attach PDF documents in the "Other Attachments" field indicating that the proposed research experience was approved by human subjects Institutional Review Board (IRB) at the grantee institution. Name the document "IRB Documentation.pdf". Adherence to the NIH policy for including women and minorities in clinical studies must also be ensured, if additional human subjects' involvement is planned for the supplement. All appropriate IRB approvals must be in place prior to Notice of Award. NOTE: Studies involving <u>clinical trials</u> are not allowed for CFARs.
- b. Project summary and narrative is that of the administrative supplement, not the parent grant.
- c. Any CFAR clinical studies deemed above minimal risk or involving vulnerable populations requires CFAR clinical approval.
- d. NO facilities and other resources page (unless there are new resources that will be used for this request).
- 3) **Project/Performance Site Location(s) form**: Include the primary site where the proposed supplement activities will be performed. If a portion of the proposed supplement activities will be performed at any other site(s), identify the locations in the fields provided.
- 4) Sr/Key Person Profile (Expanded) form: List the PD/PI as the first person (regardless of their role on the supplement activities), include the Supplement PI and Senior/Key Personnel who are being added through this supplement for whom additional funds are being requested through this supplement; include a biographical sketch for each.
 - a. **Biographical Sketch** for all new Senior/Key Personnel. Please note the personal statement should be related to the CFAR/ARC supplement project.
 - b. NO other support. Complete and current "other support" information will be requested as part of Just-in-Time information collection.

5) Budget forms (e.g., R&R Budget, PHS 398 Training Budget):

- a. Budget for the supplement with a justification that details the items requested, including Facilities and Administrative costs and a justification for all personnel and their role(s) in this project. Note the budget should be appropriate for the work proposed in the supplement request. If funding for travel to a scientific meeting is included, it must be for the purpose of presenting data from this supplement award.
- b. A statement regarding the expenditure of currently available unobligated grant funds of the parent grant will be required. Both CFARs and ARCs must include a description of the plans to spend remaining funds to demonstrate the need for additional funds.
- 6) Research Plan form (e.g., PHS 398 Research Plan form, PHS 398 Research Training Program Plan).
 - 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-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:
 - Background and rationale for the proposed application
 - Clearly stated study/research question(s) and description of the underlying barriers or gaps in research to be addressed
 - Description of the activities proposed, and the roles and responsibilities of key staff, including EHE team as defined above
 - Description of the expected outcome of the proposed 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 the local EHE plan
 - Plans to monitor and evaluate the ability of the activities to achieve the outcome
 - Indication of how the proposed activities outlined in the supplement requests are expected to lead to development of the stated goals
 - An implementation research logic model and communication plan (see below for more info)

Provide an **implementation research 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.

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

Link to resources for the Implementation Research Logic Model

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 implementation science 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.

d. Letter(s) of Support

Submit letters of support from all implementing and collaborating partners which describes their roles and responsibilities on the project and how this project supports the local EHE plan.

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.

e. NO appendices

PHS Human Subjects and Clinical Trials Information form

If new recruitment or use of an additional existing dataset or resource is proposed in the supplement application, the Study Record should be revised and new Inclusion Enrollment Reports created, as well as other required sections, as appropriate for supplemental activities. NOTE: Studies involving <u>clinical trials</u> are not allowed for CFARs.

Eligibility

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

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 supplementrequest.

- Degree that the application iterates a process to fully collaborate with the community and implementing partner, such that any future project reflects locally defined HIV prevention and treatment needs. Applications should reflect the partnership with stakeholders such as people affected by HIV from priority populations, health departments, community-based organizations, health centers, etc.
- 2. Evidence of meaningful engagement of communities affected by HIV in the planning and implementation of the project (e.g., in the project description, letters of support, budget). This includes involvement of people with lived experience.
- 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.
- 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.
- 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, in consideration of the project described.
- 10. Feasibility to complete the project within the project period.