

Notice of Special Interest (NOSI): Ending the HIV Epidemic (EHE)

Notice Number:

NOT-AI-23-070

Key Dates

Release Date:

September 29, 2023

First Available Due Date:

January 07, 2024

Expiration Date:

January 10, 2024

Related Announcements

May 12, 2023 - HIV Prevention and Alcohol (R34 Clinical Trials Optional). See NOFO [PAS-23-172](#)

May 12, 2023 - HIV Prevention and Alcohol (R01 Clinical Trials Optional). See NOFO [PAS-23-173](#)

January 11, 2023 - Formative and Pilot Intervention Research to Optimize HIV Prevention and Care Continuum Outcomes (R34 Clinical Trial Optional). See NOFO [PAR-23-060](#)

January 11, 2023 - Innovations to Optimize HIV Prevention and Care Continuum Outcomes (R21 Clinical Trial Optional). See NOFO [PAR-23-061](#)

January 11, 2023 - Innovations to Optimize HIV Prevention and Care Continuum Outcomes (R01 Clinical Trial Optional). See NOFO [PAR-23-062](#)

January 08, 2021 - Priority HIV/AIDS Research within the Mission of the NIDDK (R01 Clinical Trial Optional). See NOFO [PAS-21-031](#)

May 10, 2020 - Dissemination and Implementation Research in Health (R01 Clinical Trial Optional). See NOFO [PAR-22-105](#)

May 10, 2020 - Dissemination and Implementation Research in Health (R21 Clinical Trial Optional). See NOFO [PAR-22-109](#)

May 07, 2020 - NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed) See NOFO [PA-20-195](#)

May 07, 2020 - NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required). See NOFO [PA-20-194](#)

May 05, 2020 - NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed). See NOFO [PA-20-185](#)

May 05, 2020 - Research Project Grant (Parent R01 Clinical Trial Required). See NOFO [PA-20-183](#)

Issued by

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

Office of AIDS Research ([OAR](#))

National Heart, Lung, and Blood Institute ([NHLBI](#))

National Institute on Aging ([NIA](#))

National Institute on Alcohol Abuse and Alcoholism ([NIAAA](#))

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National Institute on Drug Abuse ([NIDA](#))

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

National Institute of Nursing Research ([NINR](#))

National Institute on Minority Health and Health Disparities ([NIMHD](#))

Purpose

The objective of this Notice of Special Interest (NOSI) is to solicit applications proposing research that is grounded in implementation science and can address the goals of the *Ending the HIV Epidemic in the U.S. (EHE)* initiative. The overall objective of EHE is to address the ongoing public health crisis with goals of first reducing the number of incident infections in the U.S. by 75% by 2025, and at least 90% by 2030, compared to the baseline infection rate in 2017. Projects will leverage research-community collaborations and scientific advances in HIV prevention, diagnosis, treatment, and outbreak response to advance the EHE goals, using innovations to tailor strategies for the multi-level barriers and strengths in communities disproportionately impacted by HIV.

Background

The EHE initiative, coordinated by the HHS Office of the Assistant Secretary of Health, focuses on four key strategies – Diagnose, Treat, Prevent, and Respond - that represent key strategies to end the HIV epidemic in the U.S. For this federal response, NIH is collaborating with the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to support implementation research to address the four key strategies of the EHE initiative. Success of the EHE initiative depends on trusted partnerships among local and state health departments, communities, service providers, and research institutions.

Although efficacious HIV prevention and treatment tools, including new long-acting formulations, are available, the effectiveness of these regimens is only optimized if individuals are engaged in prevention, care and treatment, so they achieve HIV viral suppression or protection from HIV. For example, more than half of people with HIV in the U.S. do not receive regular HIV medical care. People with HIV also frequently face comorbidities and coinfections that impact treatment and prevention efforts. Creative healthcare delivery strategies implemented by multidisciplinary and/or multisectoral teams are needed to improve the reach of testing, treatment, and prevention interventions, particularly in communities disproportionately impacted by HIV.

Moreover, social and structural determinants of health, including poverty, stigma, and discrimination, combined with factors such as mental health and substance use disorders (i.e., alcohol, drug, and polysubstance), underlie and contribute to inequities in HIV prevention, linkage to care, and optimal uptake of antiretroviral therapy (ART). The EHE initiative addresses these inequities by prioritizing efforts in [U.S. localities](#) where more than 50% of new HIV diagnoses occur, as well as seven states with a substantial rural HIV burden. Limitations inherent in some healthcare systems hinder the ability to serve communities highly affected by HIV and other structural and social challenges.

Innovative healthcare delivery strategies are needed that overcome social and structural barriers to better reach and retain those most vulnerable. Implementation research is a key approach to identifying and understanding such strategies, and to assessing their effectiveness in specific populations and geographic contexts.

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 factors that are impeding, implementing and sustaining intervention delivery.

Implementation strategies are “the actions taken to enhance adoption, implementation, and sustainability of evidence-based interventions.”

Research Objectives

This NOSI invites research applications to advance the goals of EHE through the conduct of implementation research in communities disproportionately impacted by HIV in the EHE geographic priority areas. 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 mechanisms of action, moderators and mediators, sustainability, and costs of implementation strategies will greatly aid decision-making on which strategies work for which interventions, in which settings, and for what populations.

Applications should include innovative approaches and study designs to enhance engagement efforts across diverse community settings interacting with people at risk for or living with HIV, including public health agencies, healthcare organizations, health departments, behavioral health settings providing mental health and treatment for substance use disorders, the justice system, faith-based communities, social service agencies, and implementing partners. It is expected that community-based and outreach approaches will be incorporated to remove or alleviate barriers to conventional prevention and treatment access. 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.

Applications led by or with investigator collaborations from Historically Black Colleges and Universities (HBCUs) and Minority Serving Institutions (MSIs) are encouraged in planning projects and in the formation of future implementation science partnerships in communities served by HBCUs and MSIs.

Research projects are solicited in the following priority topic domains:

Expanding and/or improving engagement and re-engagement in HIV prevention, testing, treatment, and care services. Studies focused on people experiencing unstable housing or homelessness, including those within communities affected by clusters and outbreaks, are especially encouraged.

- Deploy innovative community-based prevention strategies directed toward populations at an increased likelihood of HIV largely unreached by current programs, including people living in rural or medically underserved areas, or people and communities experiencing clusters and outbreaks. Strategies may include peer community outreach, navigation for transitional housing programs, tele-prevention, mobile health (mHealth) for prevention, HIV self-testing, community-delivered pre-exposure prophylaxis (PrEP), and programs to reduce stigma and bias (related to HIV, sexual orientation, patterns of alcohol use, drug user status, mental health, and/or race/ethnicity).
- Implement strategies appropriate for persons across the lifespan, including youth and aging or older adults, and racial and ethnic minorities to identify and retain individuals at-risk for disengagement from HIV prevention and care.
- Implementation strategies to integrate long-acting PrEP and ART into HIV services, particularly for populations who could benefit most from these new advances.
- Leverage information and communication technologies, including telehealth, digital technology, electronic health records, and data exchange, to identify those out of care and to facilitate engagement and retention in HIV treatment and care.

Scale-up of strategies to deliver integrated HIV prevention, treatment, and care services to address comorbidities and coinfections, health conditions associated with HIV risk, and/or underlying social determinants of health that adversely affect HIV prevention and treatment outcomes.

- Examine multi-component strategies for scaling up HIV testing and prevention services in a cost-effective manner in conjunction with mental health/substance use treatment programs, family planning service centers, other health screening/health promotion programs, and community- and faith-based programs capable of providing PrEP and other HIV treatment and/or prevention services.
- Identify and implement sustainable models for integrating routine mental health screening, assessment and treatment, including the evaluation of mental health symptom remission and treatment response, into HIV care.
- Examine multisectoral interventions and/or integrated disease care models to sustainably address structural and other social barriers to care and retention (e.g., mental health, substance use, medication adherence, and management of chronic health conditions, housing instability, food insecurity, racism, poverty, transportation, stigma, etc.), including in communities experiencing clusters and outbreaks.
- Identify and address, through integrated disease care models, barriers to HIV prevention or treatment outcomes posed by chronic health comorbidities, including comorbidities associated with HIV and aging, and coinfections, including STI detection and treatment. This could include novel programs in conjunction with community-based services (e.g., community pharmacies, community health clinics).
- Implement strategies to improve HIV testing, care and prevention services for and engagement among people in sexual and needle sharing networks affected by rapid HIV transmission (i.e., clusters and outbreaks).

Additional application requirements

- Interventions must be grounded in a foundational implementation science or health systems research framework. **Applicants must include an [implementation logic model](#) in the **Research Strategy** section** that outlines the determinants, strategies, mechanisms of action, and implementation outcomes being studied.
- Research must involve one or more collaborations with local implementing partners supported by the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the United States Department of Housing and Urban Development (HUD), and/or other implementing agencies. 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.
- Research Strategy should include attention to issues of resources expended, program costs, cost-effectiveness, or other economic outcomes related to dissemination and/or implementation.

- **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.
- Research must focus on one of the geographically defined [priority areas](#); the 48 counties, Washington, DC, and Puerto Rico, where the majority of the new HIV diagnoses are reported, as well as in 7 states with a disproportionate occurrence of new HIV diagnoses in rural areas.

Expectations around communication and reporting

Awardees funded through this NOSI will have additional expectations around communication and reporting in support of the broader HHS EHE initiative.

- Awardees are expected to work with the NIH-funded Coordination, Consultation and Data Management Center, currently funded through [Northwestern University](#), to report project plans, progress, and outcomes on a quarterly basis. Awardees should utilize the [Implementation Outcomes Crosswalk](#) tool developed by the coordinating center to harmonize data collection.
- Awardees are additionally encouraged to leverage implementation science resources available through the NIH-funded [Regional Implementation Science Hubs](#), which include training, consultation, and technical assistance.
- Awardees will be expected to participate in an annual meeting which will include other NIH-funded researchers working on implementation science to support ending the HIV epidemic, as well as federal staff and community partners.

The research areas below will NOT be supported through this NOSI:

- Research focused only on surveillance to identify people with HIV who are sub-optimally engaged in existing HIV treatment programs.
- Interventions that are not substantially different from conventional service delivery that failed to engage patients with extensive adherence challenges.
- Drug or device safety trials with registrational requirements.
- Studies that do not include a multidisciplinary team approach, including a community partner. Community partners may be community-based organizations, public health agencies, healthcare organizations, health departments, behavioral health settings providing mental health and treatment for substance use disorders, the justice system, faith-based communities, social service agencies, and other relevant stakeholders.
- Projects to develop *de novo* health interventions with a primary aim of testing efficacy.
- Research focused on identifying social determinants as risk factors, without implementing interventions.

Application and Submission Information

This notice applies to due dates on or after **January 7, 2024**, and subsequent receipt dates through **January 9, 2024**.

NIH ICs have other published NOFOs relevant to EHE that are not included in this NOSI. These NOFOs might be specific to each IC mission area.

Applicants are advised to consider the missions of the participating ICs and are encouraged to contact the appropriate Scientific/Research Contact(s) listed at the bottom of this NOSI prior to application submission.

Applicants must select the IC and associated NOFO to use for submission of an application in response to the NOSI. The selection must align with the IC requirements listed in order to be considered responsive to that NOFO. Non-responsive applications will be withdrawn from consideration for this initiative.

Submit applications for this initiative using one of the following NOFO or any reissues of these announcements through the expiration date of this notice.

In addition, applicants using NIH Parent announcements (listed below) will be assigned to those ICs on this NOSI that have indicated those NOFOs are acceptable and based on usual application-IC assignment practices.

NOTE: NHLBI will only accept **mechanistic** clinical trials in response to [PA-20-183](#), in accordance with [NOT-HL-19-690](#). Applicants wishing to propose non-mechanistic clinical trials may consider applying to one of the NHLBI clinical trial mechanisms described at <https://www.nhlbi.nih.gov/grants-and-training/clinical-trial-development-continuum>. Non-mechanistic clinical trials submitted in response to this NOSI via [PA-20-183](#) will be withdrawn.

Activity Code	NOFO	Title	First Available Due Date	Participating IC(s)

R01	PA-20-185	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	January 7, 2024	NIAID, NHLBI, NIA, NIAAA, NICHD, NIDDK, NIDA, NIMH, NIMHD, NINR
R01	PA-20-183	Research Project Grant (Parent R01 Clinical Trial Required)	January 7, 2024	NIAID, NHLBI, NIA, NIAAA, NICHD, NIDDK, NIDA, NIMH, NIMHD, NINR
R21	PA-20-195	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)	January 7, 2024	NIAID, NIA, NIAAA, NICHD, NIDA, NINR
R21	PA-20-194	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)	January 7, 2024	NIAID, NIA, NIAAA, NICHD, NIDA, NIMH, NINR
R01	PAR-22-105	Dissemination and Implementation Research in Health (R01 Clinical Trial Optional)	January 7, 2024	NIAID, NHLBI, NIA, NIAAA, NICHD, NIDDK, NIDA, NIMH, NIMHD, NINR
R21	PAR-22-109	Dissemination and Implementation Research in Health (R21 Clinical Trial Optional)	January 7, 2024	NIAID, NIA, NIAAA, NICHD, NIDA, NIMH, NINR
R34	PAR-23-060	Formative and Pilot Intervention Research to Optimize HIV Prevention and Care Continuum Outcomes (R34 Clinical Trial Optional)	January 9, 2024	NIMH
R21	PAR-23-061	Innovations to Optimize HIV Prevention and Care Continuum Outcomes (R21 Clinical Trial Optional)	January 9, 2024	NIMH
R01	PAR-23-062	Innovations to Optimize HIV Prevention and Care Continuum Outcomes (R01 Clinical Trial Optional)	January 9, 2024	NIMH
R01	PAS-21-031	Priority HIV/AIDS Research within the Mission of the NIDDK (R01 Clinical Trial Optional)	January 7, 2024	NIDDK
R34	PAS-23-172	HIV Prevention and Alcohol (R34 Clinical Trials Optional)	January 7, 2024	NIAAA
R01	PAS-23-173	HIV Prevention and Alcohol (R01 Clinical Trials Optional)	January 7, 2024	NIAAA

All instructions in the [SF424 \(R&R\) Application Guide](#) and the funding opportunity announcement used for submission must be followed, with the following additions:

- For funding consideration, applicants **must** include “**NOT-AI-23-070**” (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.

Applications nonresponsive to terms of this NOSI will not be considered for the NOSI initiative.

Inquiries

Please direct all inquiries to the contacts in Section VII of the listed notice of funding opportunity with the following additions/substitutions:

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[Weekly TOC for this Announcement](#)
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