Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

Office of AIDS Research (OAR (https://www.oar.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

Funding Opportunity Title

Advancing HIV service delivery through pharmacies and pharmacists (R21 Clinical Trial Optional)

Activity Code

R21 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Research Grant

Announcement Type

New

Related Notices

- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).

Funding Opportunity Number (FON)

RFA-MH-25-186

Companion Funding Opportunity

RFA-MH-25-185 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-25-185.html), R01 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R01&&Search.x=0&&Search.y=0&&Search_Type=Activity) Research Project

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.242, 93.847, 93.865, 93.855, 93.273, 93.310, 93.307

Funding Opportunity Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to solicit research designed to capacitate, transform, and scale the delivery of HIV testing, prevention, and care services through pharmacists and pharmacies in US and/or global settings. This includes the advancement of training curricula to enable pharmacy students, pharmacists, pharmacies, and pharmacy systems to deliver the spectrum of needed HIV services with ease, equity, and effectiveness.

This NOFO uses the R21 grant mechanism, while RFA-MH-25-185 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-25-185.html)uses the R01 mechanism. Projects that lack preliminary data or that propose to pilot a novel intervention may be most appropriate for the R21 mechanism. Applications with preliminary data and those proposing large-scale clinical trials or longitudinal analyses should consider using the R01 mechanism.

Key Dates

Posted Date

April 29, 2024

Open Date (Earliest Submission Date)

July 13, 2024

Letter of Intent Due Date(s)

July 13, 2024.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
Not Applicable	Not Applicable	August 13, 2024	November 2024	January 2025	April 2025

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

Expiration Date

August 14, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)).

Conformance to all requirements (both in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=RFA-MH-25-186) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

The US National HIV/AIDS Strategy (NHAS (https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025)) for 2022-2025 highlights the important role that pharmacists and pharmacies can play in HIV prevention and care. The NHAS affirms 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." This NOFO calls for research that will help reach this goal in the US, as well as in global settings.

Pharmacies and pharmacists offer many advantages for HIV service delivery. Pharmacists provide trusted sources of information, consultation, and care in the settings and communities in which they serve. Community pharmacies offer convenient evening and weekend hours within local neighborhoods, providing strong community reach. Many chain and independent pharmacies have expanded onsite clinical services in recent years, creating new capacities for service delivery and care. A growing number of US states have passed legislation that allow licensed pharmacists to prescribe or initiate HIV preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) for those who would benefit.

Pharmacists and pharmacies have made significant contributions to HIV prevention and care. Clinical pharmacists strengthen comprehensive care teams in many HIV clinics by providing essential services like medication management and adherence support. Pharmacy-based delivery of comprehensive health screenings can improve HIV testing uptake in populations that may not otherwise access these services. Innovative models for HIV (PrEP) delivery through pharmacies or pharmacists have been pioneered in both US and global settings. Specialty pharmacies offer comprehensive services and support for people with HIV and can facilitate access to new long-acting injectable antiretroviral therapy (ART) regimens.

Efforts to adapt, adopt, and scale these accomplishments face many challenges. Key challenges in pharmacy-based HIV service delivery include creating appropriate strategies to engage populations disproportionally affected by HIV; developing and using pharmacist training and skill improvement programs to support effective and equitable client interactions; addressing the burdens of an overworked pharmacy workforce; ensuring care linkage and clinical collaboration by forming Collaborative Practice Agreements with local physicians where indicated; and considering available options for reimbursement strategies and financing models.

We need research to address these challenges, scale promising pilot programs, and create innovative models of HIV service delivery through pharmacies and pharmacists, including novel pharmacy settings and modalities such as mobile services and telehealth. The increasing role of pharmacies in public health and health care delivery means that models for successful pharmacy-and pharmacist-based delivery of HIV testing, prevention, and care services are timely and have promise for large scale implementation.

Research Objectives

The purpose of this Notice of Funding Opportunity (NOFO) is to solicit research designed to capacitate, transform, and scale the delivery of HIV testing, prevention, and care services through pharmacists and pharmacies in US and/or global settings. This includes the advancement of training curricula to enable pharmacy students, pharmacists, pharmacies, and pharmacy systems to deliver the spectrum of needed HIV services with ease, equity, and effectiveness.

Key Considerations for this NOFO

- Applicants must propose a research team that includes one or more pharmacists.
- Applicants should additionally:
    - Partner with chain, independent, or specialty pharmacies on their work, or pharmacies in diverse settings such as hospitals, correctional health, or tribal health settings.
    - Provide letters of support from research partners that demonstrate commitment to provide pharmacists' protected time for any expanded practice activities and for participation in the research activities (e.g., meetings, research documentation).
    - Discuss potential reimbursement models for any pharmacist- or pharmacy-based services that they will advance.
    - Describe plans for developing collaborative practice agreements that cover the scope of care described in the grant application.
    - Describe an approach that meaningfully incorporates input from relevant community members with a diversity of perspectives, knowledge, and lived experiences. Community members may include people with HIV, people placed at risk for HIV, and representatives of pharmacy groups, public health agencies, healthcare organizations, social service agencies, faith-based communities, or other stakeholders.
    - Employ and document implementation science frameworks, approaches, and research designs or methodologies in the proposed research.
    - Identify policy, regulation, or other potential challenges and barriers that may exist to implementing and/or scaling study results. Projects proposing innovative implementation strategies designed to address these barriers, or that take advantage of new or pending regulatory or policy changes, are welcome.
    - Consider examining the resource needs and/or cost effectiveness of the care model being tested.
    - Budget funds for travel to one meeting of awardees at NIH in Bethesda, MD. PDs/PIs are expected to attend the meeting and may also budget for other key personnel to attend.

Specific Areas of Research Interest

Research applications that respond to this NOFO can include, but are not limited to, the following topics. Further Institute-specific research priorities follow below.

- Research to advance pharmacy-based health screenings for HIV alongside screenings for multiple chronic illnesses and common comorbid conditions.
- Studies designed to create and scale models of pharmacy-based HIV PrEP delivery and adherence support.
- Research to improve access and use of HIV post-exposure prophylaxis (PEP) through pharmacies.
- Studies to expand the delivery and use of long-acting injectable PrEP and/or ART regimens though pharmacists and pharmacies.
- Studies that test pharmacy-based monitoring and support for antiretroviral treatment adherence.
- Research to advance prescription refill synchronization for HIV and other chronic conditions to improve medication adherence and health outcomes.
- Research to advance integrated services for HIV and other common comorbid conditions or chronic illnesses through pharmacies and pharmacists.
- Research that uses pharmacists and pharmacies as a vector for engaging youth, pregnant persons, or minoritized populations in HIV testing, prevention, or care.
- Research to advance programs that train pharmacists, pharmacy students, and pharmacy technicians and allied health professionals (e.g., nurse practitioners, mental health providers) to support HIV prevention and care and address barriers such as stigma, bias, discrimination, or practice information gaps related to HIV and its comorbidities, as well as programs for continuing education and maintenance of knowledge and expertise in HIV prevention and care.
- Research in implementation strategies for pharmacist and pharmacy-delivered HIV services, including strategic collaborations with health ministries, health departments, medical centers, schools of pharmacy, Historically Black Colleges and Universities, Minority Serving Institutions, community-based and non-governmental organizations, or other partners.
- Studies to understand and address social and structural constraints and business needs of pharmacists' and pharmacy systems regarding HIV service delivery.
- Studies that model the impact and cost-effectiveness of pharmacy-delivered HIV services.

Non-responsive Research

Applications proposing the following will be considered non-responsive and will not be reviewed:

- Applications that propose a research team without one or more pharmacists.
- Applications that include investigational drug or device trials which must be registered with the FDA.

Pre-application Webinar

NIMH will lead a web-based pre-application webinar for applicants to RFA-MH-25-185 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-25-185.html) and RFA-MH-25-186 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-25-186.html). Information on how to attend the optional webinar will be published through a Guide Notice.

This NOFO uses the R21 grant mechanism, while RFA-MH-25-185 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-25-185.html) uses the R01 mechanism. Projects that lack preliminary data or that propose to pilot a novel intervention may be most appropriate for the R21 mechanism. Applications with preliminary data and those proposing large-scale clinical trials or longitudinal analyses should consider using the R01 mechanism.

In recognition of the many considerations and requirements above, applicants are strongly encouraged to read the Institute-specific research priorities follow below and consult with the Scientific/Research Contact(s) listed in Section VII: Agency Contacts when developing plans for an application.

National Institute of Mental Health (NIMH)

NIMH is interested in global and US-based projects that align with the Research Objectives of this RFA. In addition to the Specific Areas of Research Interest above, related areas of interest to NIMH include, but are not limited to:

- Research to improve delivery and use of long-acting HIV treatment or prevention regimens at primary care clinics through integration of pharmacists and pharmacy technicians into clinic procedures and workflows.
- Studies to advance pharmacy-based “data-to-care” programs that monitor and address ART prescription refill timeliness as a method of ensuring continued HIV treatment engagement.
- Implementation science that scales evidence-based HIV service delivery programs piloted at one or more pharmacies across a broader pharmacy chain, metropolitan area, state, region, or nation.
- Research on pharmacy-based HIV service delivery that partners with insurance providers, departments of public health, or other groups who will cover the cost of pharmacist- and pharmacy-delivered services.

The NIMH has published updated policies and guidance for investigators regarding human research protection and clinical research data and safety monitoring (NOT-MH-19-027 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html)). The application's PHS Human Subjects and Clinical Trials Information, including the Data and Safety Monitoring Plan, should reflect the policies and guidance in this notice. Plans for the protection of research participants and data and safety monitoring will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations.

National Institute of Allergy and Infectious Diseases (NIAID)

For the purposes of this RFA, NIAID is interested in research on the implementation of evidence-based HIV interventions, including integrated health services, tailored to communities disproportionately impacted by HIV *in the United States*. Applicants to NIAID should identify partnerships with relevant policy and/or program leaders with a stated commitment to evaluate and incorporate changes which are proven to be both successful and cost-effective. Along with the Specific Areas of Research Interest above, *additional* areas of interest to NIAID include, but are not limited to:

- Research on forming and/or sustaining collaborative efforts between public health departments and pharmacies to achieve public health goals for HIV testing, prevention and treatment.
- Studies that test integrated approaches to deliver screening, prevention, treatment and care services for HIV and common co-infections, including interventions to address sexually transmitted (e.g. doxyPEP) and opportunistic infections.
- Research on pharmacy-based testing, prevention, and treatment strategies directed towards communities experiencing HIV clusters and outbreaks.
- Studies designed to assess or prepare for the implementation of FDA-approved ‘next generation’ HIV interventions, such as long-acting injectable ART.
- Research that leverages information and communication technologies in the pharmacy, including digital technology, telehealth, electronic health records, and data exchange, to facilitate response to HIV outbreaks, or engagement and retention in HIV prevention, treatment, or care services.
- Studies on pharmacy-centered service delivery models tailored to adolescents.

NIAID will not support clinical trials using experimental drugs or diagnostic tools, or using existing drugs or diagnostics for new purposes in response to this NOFO. However, clinical trial methodology to assess the impact of new strategies for disseminating and/or implementing accepted/validated interventions for diagnosis, prevention or treatment will be allowed.

National Institute of Drug Abuse (NIDA)

Additional and specific areas of interest to NIDA include, but are not limited to:

- Integration of harm reduction with pharmacy services, which may include provision of harm reduction in pharmacy settings (e.g., syringe sales, opioid overdose reversal medication [e.g., naloxone] distribution, safe syringe disposal) or referral services for HIV prevention and care from harm reduction providers.
- Development and testing of pharmacy training programs that enable pharmacists to be better integrated to the care team to address HIV and HIV-associated comorbidities among people with substance use disorder (SUD) e.g., dispensing medications for SUD, harm reduction interventions, PrEP, and/or viral hepatitis vaccination and treatment.
- Assessment of training needs and/or impact of existing training programs for pharmacy staff that specifically address HIV- and substance use-related stigma and discrimination, pharmacy staff’s knowledge and ability to provide quality HIV prevention and care services to people with SUD.
- Development of mobile pharmacy services that incorporate novel strategies to engage people with SUD and HIV or at risk for HIV into prevention and treatment for HIV and substance use and to link them to recovery support services.
- Development and testing of novel models of pharmacy-based delivery of prevention and treatment services for HIV, SUD, and/or viral hepatitis that can be generalized to broader pharmacy practice settings.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

NIAAA supports research on the prevention and treatment of alcohol use problems among people living with HIV. This includes the development, testing, and implementation of effective interventions within a wide range of settings by health professionals including pharmacists to address problems with alcohol use. Accurately communicating about risks and dispelling misinformation to individuals living with HIV by pharmacists can motivate behavior change and prevent new infections and improve medication adherence. However, this remains a significant challenge when addressing both alcohol use and HIV in clinical practice and other intervention settings in the community.

- Develop and test interventions to demonstrate feasibility, acceptability, and efficacy in promoting comprehensive health screening related to alcohol use and readiness to change behavioral risk among people living with HIV (PLWH).
- Characterize alcohol and polypharmacy risk for adverse health outcomes and examine determinants of readiness to change among PLWH.
- Increase patient readiness to report willingness to change unhealthy alcohol and polypharmacy use after combined with direct alcohol measurement (e.g., Phosphatidylethanol or PEth levels and other alcohol monitoring technology) and other risk assessments (e.g., risks of falls and fractures, genetic risk).
- Assess additional environmental factors and social determinants that increase risk for adverse outcomes and contribute to risk through social/behavioral and/or epigenetic phenomena.
- Assess scalability and feasibility of implementing interventions to a wider range of pharmacy settings and locations, and to assess the overall impact of expanded programs.
- Develop messages for specific populations such as people aging with HIV, including a focus on subpopulations at greatest risk for poor prevention or treatment outcomes and incorporate.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

NIDDK seeks projects that will improve or expand pharmacy-based service delivery in terms of prevention, treatment, and diagnosis of comorbidities with the mission of NIDDK (https://www.niddk.nih.gov/about-niddk/research-areas (https://www.niddk.nih.gov/about-niddk/research-areas)). NIDDK supports clinical and implementation research to reduce disease and increase equitable access to care. In addition to those stated above, areas of interest to the NIDDK include, but are not limited to projects that:

- Develop, scale, and/or integrate pharmacy-based programs to screen for, treat, and/or prevent NIDDK-related comorbidities.
- Assess the scalability and sustainability of proven effective implementation strategies to address NIDDK-related comorbidities in the pharmacy setting.
- Identify, assess, and/or address barriers to pharmacy service delivery affecting the treatment or prevention of NIDDK comorbidities in pharmacy deserts.
- Develop and implement interventions aimed at reducing the impact of NIDDK-related health disparities and risk factors in pharmacy settings.

Investigators planning to apply are strongly encouraged to consult with the NIDDK Scientific Contact listed in Section VII of this NOFO.

***Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)**

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is interested in supporting research on topics relevant to NICHD's populations of interest, including children; adolescents; pregnant and/or lactating individuals; and persons with intellectual, developmental, and/or physical disabilities across the lifespan. NICHD is particularly interested in research that relates to the Institute's high-priority research areas: see https://www.nichd.nih.gov/grants-contracts/research-areas/priorities (https://www.nichd.nih.gov/grants-contracts/research-areas/priorities) for current research priorities, and https://www.nichd.nih.gov/about/org/strategicplan (https://www.nichd.nih.gov/about/org/strategicplan) regarding research themes for the Institute. In this NOFO, topics on HIV prevention and care that are of interest to the NICHD include, but are not limited to:

- Research on utilization of pharmacies and pharmacists to promote gynecologic, andrologic and reproductive health for those affected by HIV.
- Research on the utilization of pharmacies and pharmacists on HIV prevention and HIV management to maintain healthy pregnancies.
- Research on the utilization of pharmacies and pharmacists to improve child and adolescent health and the transition to adulthood for youth affected by HIV.
- Research on the utilization of pharmacies and pharmacists to advance safe and effective therapeutics for pregnant and lactating women, children, and people with disabilities.

National Institute on Minority Health and Health Disparities (NIMHD)

NIMHD is interested in supporting research on topics relevant to the Institute's priority research areas (https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-scientific-goals-research-strategies-priority-areas.html). Topics on HIV prevention and care that are of interest to the NIMHD may include, but are not limited to:

- Have a primary focus on race and ethnic minority populations disproportionately affected by HIV, such as African American or Black and Latino or Hispanic Men who have Sex with Men (MSM) and persons of low socioeconomic status (SES). These populations account for about 75% of people living with HIV as well as new HIV infections.
- The effects of experiencing multiple intersectional identities, with emphasis on the intersectionality of race and ethnicity and/or low SES with rural populations or sexual and gender minority (SGM) groups, and people with disabilities. These NIH/NIMHD-designated populations that experience health disparities (https://www.nimhd.nih.gov/about/overview/), are of interest through an intersectional perspective such as underserved rural communities and people living with disabilities.
- Understanding the pathways by which social and structural determinants intersect to widen the disparity that prevents equitable access to pharmacists and pharmacies.
- Development of tailored, multilevel interventions focused on the National HIV/AIDS Strategy (NHAS) priority populations (Black, Latino, American Indian/Alaska Native, MSM, Black women, Youth aged 13-24, People who inject drugs) and the pharmacy providers, healthcare system, interpersonal, community and societal factors.
- Studies focused on developing and testing strategies to address health disparities among those living with HIV.
- Multi-level approaches as identified in the NIMHD Research Framework (https://www.nimhd.nih.gov/about/overview/research-framework.html) and addresses the relevant social determinants using measures available in the Social Determinants of Health Collection of the PhenX Toolkit (https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.phenxtoolkit.org%2F&data=05%7C02%7Cstirrattm%40mail.nih.gov%7C4170b607e36f47393cb608dc0d7e26e0%7C14b77578977342d58507251ca2 as appropriate.
- Leveraging implementation science methods that prioritize health equity targets to ensure that effective interventions and quality improvement programs will improve minority health and reducing health disparities in areas of HIV testing, treatment (e.g., ART access and adherence) and prevention (e.g., PrEP awareness and uptake).

NIH Office of AIDS Research (OAR)

NIH OAR, as part of the Office of the Director (OD), NIH, is interested in research to advance the delivery of HIV testing, prevention, and care services through pharmacists and pharmacies in US and global settings. Because the NIH OAR does not award grants, applications must be relevant to the objectives of at least one of the participating NIH Institutes and Centers (IC) listed in this announcement. Please contact the relevant IC program contacts listed for questions related to funding.
See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources (https://researchmethodsresources.nih.gov/) website for information about developing statistical methods and study designs.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

NIMH along with the participating ICs intend to commit a total of 11,250,000 in FY 2025 to fund 8-12 awards in response to this NOFO and/or the companion NOFO (RFA-MH-25-185).

Award Budget

The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 2 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information

- System for Award Management (SAM) – (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.

- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html) NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement NIH Grants Policy Statement Section 1.2 Definition of Terms. (//grants.nih.gov/grants/guide/url_redirect.php?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Email: nimhpeerreview@mail.nih.gov (mailto:nimhpeerreview@mail.nih.gov)

Page Limitations

All page limitations described in the How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (https://grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Applicants should include all institutions where research will occur as performance sites, including relevant U.S. and foreign institutions.

SF424(R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

R&R or Modular Budget

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Applicants should budget funds for travel to one meeting of awardees in Bethesda, MD. PDs/PIs are expected to attend the meeting and may also budget for other key personnel to attend.

R&R Subaward Budget

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

PHS 398 Cover Page Supplement

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

PHS 398 Research Plan

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

Research Strategy: The following are comprised within the Research Strategy.

- Describe how the proposed project will partner with chain, independent, or specialty pharmacies, or pharmacies in diverse settings such as hospitals, correctional health, or tribal health settings.
- Discuss potential reimbursement models for any pharmacist- or pharmacy-based services that they will advance.
- Describe plans for developing collaborative practice agreements that cover the scope of care described in the grant application.
- Describe an approach that meaningfully incorporates input from relevant community members with a diversity of perspectives, knowledge, and lived experiences. Community members may include people with HIV, people placed at risk for HIV, and representatives of pharmacy groups, public health agencies, healthcare organizations, social service agencies, faith-based communities, or other stakeholders.
- Document any use of implementation science frameworks, approaches, and research designs or methodologies in the proposed research.
- Discuss policy, regulation, or other potential challenges and barriers that may exist to implementing and/or scaling study results, and strategies designed to address these barriers.

Letters of Support:

- All collaborating institutions and key personnel should provide letters of support for the proposed research program.
- Letters of support from research partners should evidence a commitment to provide pharmacists' protected time for any expanded practice activities and for participation in the research activities (e.g., meetings, research documentation).

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Other Plan(s): Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

To advance the goal of advancing research through widespread data sharing among researchers, investigators funded by NIMH under this NOFO are expected to share those data via the National Institute of Mental Health Data Archive (https://nda.nih.gov/) (NDA; see NOT-MH-23-100 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-100.html)). Established by the NIH, NDA is a secure informatics platform for scientific collaboration and data-sharing that enables the effective communication of detailed research data, tools, and supporting documentation. NDA links data across research projects through its Global Unique Identifier (GUID) and Data Dictionary technology. Investigators funded under this NOFO are expected to use these technologies to submit data to NDA.

To accomplish this objective, it will be important to formulate a) an enrollment strategy that will obtain the information necessary to generate a GUID for each participant, and b) a budget strategy that will cover the costs of data submission. The NDA (https://nda.nih.gov/) website provides two tools to help investigators develop appropriate strategies: 1) t (https://nda.nih.gov/contribute_cost_estimation.html)he NDA Data Submission Cost Model (https://nda.nih.gov/contribute/contribute-data.html#cost)which offers a customizable Excel worksheet that includes tasks and hours for the Program Director/Principal Investigator and Data Manager to budget for data sharing; and 2) plain language text to be considered in your informed consent available from the NDA's Data Contribution page (https://nda.nih.gov/contribute/contribute-data.html). Investigators are expected to certify the quality of all data generated by grants funded under this NOFO prior to submission to NDA and review their data for accuracy after submission. Submission of descriptive/raw data is expected semi-annually (every January 15 and July 15); submission of all other data is expected at the time of publication, or prior to the end of the grant, whichever occurs first (see NDA Sharing Regimen (https://nda.nih.gov/contribute/sharing-regimen.html) for more information); Investigators are expected to share results, positive and negative, specific to the cohorts and outcome measures studied.For more guidance on submitting data to NDA, refer to the NDA Data Management and Sharing Plan on the NDA website (https://nda.nih.gov/). NDA staff will work with investigators to help them submit data types not yet defined in the NDA Data Dictionary (https://nda.nih.gov/data_dictionary.html).

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.
Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Foreign Organizations

Foreign (non-U.S.) organizations must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11137), and procedures for foreign organizations described throughout the How to Apply Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423).

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

Use of Common Data Elements in NIH-funded Research

Many NIH ICs encourage the use of common data elements (CDEs) in basic, clinical, and applied research, patient registries, and other human subject research to facilitate broader and more effective use of data and advance research across studies. CDEs are data elements that have been identified and defined for use in multiple data sets across different studies. Use of CDEs can facilitate data sharing and standardization to improve data quality and enable data integration from multiple studies and sources, including electronic health records. NIH ICs have identified CDEs for many clinical domains (e.g., neurological disease), types of studies (e.g., genome-wide association studies (GWAS)), types of outcomes (e.g., patient-reported outcomes), and patient registries (e.g., the Global Rare Diseases Patient Registry and Data Repository). NIH has established a "Common Data Element (CDE) Resource Portal" (http://cde.nih.gov/ (http://cde.nih.gov/)) to assist investigators in identifying NIH-supported CDEs when developing protocols, case report forms, and other instruments for data collection. The Portal provides guidance about and access to NIH-supported CDE initiatives and other tools and resources for the appropriate use of CDEs and data standards in NIH-funded research. Investigators are encouraged to consult the Portal and describe in their applications any use they will make of NIH-supported CDEs in their projects.

NIMH expects investigators for this funding announcement to collect Common Data Elements (CDEs) for HIV-related human subjects research funded by NIMH. Unless NIMH stipulates otherwise during the negotiation of the terms and conditions of a grant award, this Notice applies to all grant applications involving human research participants. The necessary funds for collecting and submitting these CDE data from all research participants to the NIMH Data Archive (NDA) (https://nda.nih.gov/) should be included in the requested budget. A cost estimator (https://nda.nih.gov/ndarpublicweb/Documents/NDA_Data_Submission_Costs.xlsx (https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fnda.nih.gov%2Fndarpublicweb%2FDocuments%2FNDA_Data_Submission_Costs.xlsx&wdOrigin=BROWSELINK)) is available to facilitate the calculation of these costs. NIMH may seek further information regarding CDEs prior to award. Details for HIV-funded NIMH research can be found at NOT-MH-23-105 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-105.html)and the NIMH webpage on Data Management and Sharing for Applicants and Awardees (https://www.nimh.nih.gov/funding/managing-your-grant/nimh-data-management-and-sharing-for-applicants-and-awardees).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//grants.nih.gov/grants/guide/url_redirect.php?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-

time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.
Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299)

Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular NOFO, note the following:

> The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased

approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?
Specific to this NOFO:

- How adequate is the discussion of potential reimbursement models for any pharmacist- or pharmacy-based services that the project will advance?
- How appropriate are the plans for developing collaborative practice agreements that cover the scope of care described in the grant application?
- To what extent does the approach meaningfully incorporate input from relevant community members with a diversity of perspectives, knowledge, and lived experiences?
- For studies that involve implementation science, t o what degree does the project describe any use of implementation science frameworks, approaches, and research designs or methodologies in the proposed research?
- How well does the project discuss policy, regulation, or other potential challenges and barriers that may exist to implementing and/or scaling study results, and strategies designed to address these barriers?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Specific to this NOFO:

- How adequate is the plan to partner with chain, independent, or specialty pharmacies, or pharmacies in diverse settings such as hospitals, correctional health, or tribal health settings?
- To what degree have collaborating institutions provided letters of support for the proposed research program, and to what extent to these letters evidence a commitment to provide pharmacists' protected time for any expanded practice activities and for participation in the research activities?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.php?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.php?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals Section. (//grants.nih.gov/grants/guide/url_redirect.php?id=11150)

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not applicable

Renewals

Not applicable

Revisions

Not applicable.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) of initial peer review will not be accepted for applications submitted in response to this NOFO.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Relevance of proposed project to priorities of co-funding components.
- Geographic balance of programs.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement Section 2.4.4 Disposition of Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82416).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

The NIMH has published policies and guidance for investigators regarding human research protection, data and safety monitoring, Independent Safety Monitors and Data and Safety Monitoring Boards, reportable events, and participant recruitment monitoring (NOT-MH-19-027 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html)). The application's PHS Human Subjects and Clinical Trials Information should reflect the manner in which these policies will be implemented for each study record. These plans will be reviewed by the NIMH for consistency with NIMH and NIH policies and federal regulations. The NIMH will expect clinical trials to be conducted in accordance with these policies including, but not limited to: timely registration to ClinicalTrials.gov, submission of review determinations from the clinical trial's data and safety monitoring entity (at least annually), timely submission of reportable events as prescribed, and establishment of recruitment milestones and progress reporting.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (https://register.clinicaltrials.gov/)). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm (//grants.nih.gov/grants/policy/hs/data_safety.htm) and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159), including of note, but not limited to:

- Federalwide Standard Terms and Conditions for Research Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (//grants.nih.gov/grants/guide/url_redirect.php?id=82417)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).

HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to System for Award Management (SAM.gov) requirements. SAM.gov requires Federal agencies to review and consider information about an applicant in the designated integrity and performance system (currently SAM.gov) prior to making an award. An applicant can review and comment on any information in the responsibility/qualification records available in SAM.gov. NIH will consider any comments by the applicant, in addition to the information available in the responsibility/qualification records in SAM.gov, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82419).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82420). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over the threshold. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (Responsibility/Qualification in SAM.gov, formerly FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Michael J. Stirratt, PhD
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Franklin W. Yates, MD
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Telephone: 240-890-3679
Email: franklin.yates@nih.gov (mailto:franklin.yates@nih.gov)

Peer Review Contact(s)

Center for Scientific Review (CSR)
Email: NOFOReviewContact@csr.nih.gov (mailto:NOFOReviewContact@csr.nih.gov)

Financial/Grants Management Contact(s)

Rita Sisco
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Ms. Felecia Bush, Senior Budget Advisor
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Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?05-03-24)
NIH Funding Opportunities and Notices (/grants/guide/index.html)
