U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

HIV/AIDS Bureau
Division of Policy and Data

Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Demonstration Sites

Funding Opportunity Number: HRSA-22-028
Funding Opportunity Type: New
Assistance Listings (AL/CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

Letter of Intent Requested by: December 1, 2021

Application Due Date: February 8, 2022

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
HRSA will not approve deadline extensions for lack of registration.
Registration in all systems
may take up to 1 month to complete.

Issuance Date: October 26, 2021
Modified on January 10, 2022 to extend the application due date to February 8, 2022

Modified on October 28, 2021.
The letter of intent due date was changed to December 1, 2021 on the cover and on page 26; the application due date was corrected on page 24.

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See Section VII for a complete list of agency contacts

Authority: 42 USC § 300ff-101 (§ 2691 of the Public Health Service Act)

508 Compliance Disclaimer

Note: Persons using assistive technology may not be able to fully access information in this file. For assistance, please email or call one of the HRSA staff in Section VII. Agency Contacts.

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2022 Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS) Program initiative, **Emerging Strategies to Improve Health Outcomes for People Aging with HIV**.

This initiative will fund three components: **one capacity-building provider (HRSA-22-027, 10 demonstration sites (HRSA-22-028), and one evaluation provider (HRSA-22-029).** All three components of the initiative will work together using the HRSA HIV/AIDS Bureau (HAB) implementation science framework to conduct the following activities simultaneously:

- Implement emerging strategies that comprehensively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV;
- Assess the uptake and integration of emerging strategies;
- Understand implementation processes, including assessing specific implementation strategies;
- Understand and document broader contextual factors affecting implementation;
- Evaluate the impact of the emerging strategies; and
- Document and disseminate the emerging strategies.

HRSA defines emerging strategies as innovative strategies that address disparities and improve health outcomes for people with HIV. Real world validity and effectiveness have been demonstrated, but emerging strategies do not yet have sufficient published research evidence[1] or evaluation to document their effectiveness. The initiative will strengthen the evidence base for clinical and psychosocial services that improve the lives and health outcomes of people with HIV who are aging.

This NOFO, HRSA-22-028 Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Demonstration Sites, will fund up to **10 demonstration sites** to identify, implement, refine, and evaluate emerging strategies to comprehensively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV with the existing resources and infrastructure of organizations funded through the RWHAP. This funding opportunity will support organizations that have the capacity and infrastructure to successfully execute the project and that have some experience implementing emerging strategies to comprehensively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with

HIV. Working in partnership with the evaluation provider and capacity-building provider, the demonstration sites will participate in evaluating their strategies and developing replication tools for use by other RWHAP recipients and subrecipients.

The demonstration sites must provide comprehensive screening and management of comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV or have an agreement with an organization that can provide these services (referred to as partner organization in the NOFO).

This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. You should note that this program may be cancelled before award.

Funding Opportunity Title:	Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Demonstration Sites
Funding Opportunity Number:	HRSA-22-028
Due Date for Applications:	February 8, 2022
Anticipated Total Annual Available FY 2022 Funding:	$3,000,000
Estimated Number and Type of Award(s):	Up to 10 grants
Estimated Annual Award Amount:	Up to $300,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	August 1, 2022 through July 31, 2025 (3 years)
Eligible Applicants:	Eligible applicants include entities eligible for funding under RWHAP Parts A - D of Title XXVI of the Public Health Service (PHS) Act, including public and nonprofit private entities; state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; community health centers receiving support under Section 330 of the PHS Act; faith-based and community-based organizations; and Indian Tribes or Tribal organizations with or without federal recognition. See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide,* available online at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Tuesday, November 16, 2021
Time: 2:00 – 3:30 p.m. ET
Call-In Number:
Dial by your location
+1 (669) 254-5252 US (San Jose)
+1 (646) 828-7666 US (New York)
+1 (669) 216-1590 US (San Jose)
+1 (551) 285-1373 US
(833) 568-8864 US Toll-free

Meeting ID: 160 096 8222
Passcode: 39942016

Weblink: Join ZoomGov Meeting
https://hrsa-gov.zoomgov.com/j/1600968222?pwd=TTU5bHJCYitOU29yTUtMcnRJWmVwUT09

Meeting ID: 160 096 8222
Passcode: 8hhkdjHK

Playback: The webinar will be recorded and should be available within 10 business days on the TargetHIV website. Answers to questions posed before and during the webinar will also be posted there.

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I. Program Funding Opportunity Description

1. Purpose

This notice (HRSA-22-028) announces the opportunity to apply for FY22 Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program (RWHAP) Part F:Special Projects of National Significance (SPNS) funding for the **Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Demonstration Sites project**.

This initiative will fund three components: a capacity-building provider (HRSA-22-027), demonstration sites (HRSA-22-028), and an evaluation provider (HRSA-22-029). All three components of the initiative will work together using the HRSA HIV/AIDS Bureau (HAB) implementation science framework to conduct the following activities simultaneously:

- Implement emerging strategies that comprehensively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV;
- Assess the uptake and integration of emerging strategies;
- Understand implementation processes including assessing specific implementation strategies;
- Understand and document broader contextual factors affecting implementation;
- Evaluate the impact of the emerging strategies; and
- Document and disseminate the emerging strategies.

HRSA defines emerging strategies as innovative strategies that address disparities and improve health outcomes for people with HIV. Real world validity and effectiveness have been demonstrated, but emerging strategies do not yet have sufficient published research evidence[1] or evaluation to document their effectiveness. The initiative will strengthen the evidence base for clinical and psychosocial services that improve the lives and health outcomes of people with HIV who are aging.

The purpose of this funding opportunity (HRSA-22-028) is to support up to 10 demonstration sites to identify, demonstrate, refine, and assess emerging strategies to comprehensively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV within the context of the RWHAP. HRSA defines emerging strategies as innovative strategies that address emerging priorities for improving care and treatment of people with HIV. Real world validity and effectiveness have been demonstrated, but emerging strategies do not yet have sufficient published research evidence or evaluation to document their effectiveness.

This funding opportunity will support organizations that have the capacity, infrastructure, and some experience implementing emerging strategies to comprehensively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV. Each demonstration site will implement at least one emerging strategy.

The demonstration sites must provide comprehensive screening and management of comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV or have an agreement with an organization that can provide these services (referred to as partner organization in the NOFO).

Successful demonstration sites and their partner organizations need a range of resources, skills, and decision-making authority. The demonstration sites and partner organizations need the capacity (e.g., personnel), infrastructure (e.g., information system with data extract methods, protocols, and workflows), and a substantial population (at least 30percent of clients served by the organization) of clients 50 years and older with HIV. Successful demonstration site and partner organization staff need authority to make changes or refinements quickly to their emerging strategy and make decisions that require the deployment of resources rapidly (such as extraction of data from an electronic health record) to successfully implement the project and to partner with the capacity-building provider and evaluation provider. Each demonstration site will involve clients 50 years and older with HIV in the implementation, refinement, evaluation, and dissemination of the emerging strategy(s).

The three main objectives of the demonstration sites are to:

1. Implement: Identify, implement, and refine emerging strategies to comprehensively screen and manage comorbidities, geriatric conditions, and psychosocial concerns of people 50 years and older with HIV with the existing resources and infrastructure of organizations funded through the RWHAP;
2. Evaluate: Collaborate in the design of the evaluation and participate in the evaluation of the emerging strategies with the evaluation provider (HRSA-22-029). Demonstration sites will participate in the evaluation of their own emerging strategy(ies) and in a multi-site evaluation; and
3. Partner: Work closely with the other demonstration sites, the capacity-building provider (HRSA 22-027), and the evaluation provider (HRSA-22-029) for this initiative to refine, evaluate, and disseminate the emerging strategy(ies).

The objectives of the capacity-building provider (HRSA-22-027) are to:

1. Assist the demonstration sites in identifying, refining, and documenting the emerging strategies through the use of clinical workflows, roles and responsibilities of personnel, process maps, and swim lane flowcharts;
2. Assess individual organizations' technical needs; manage and provide peer-to-peer technical assistance, coaching, and capacity development to implement, refine, and document their emerging strategies;
3. Develop and implement the Institute for Healthcare Improvement (IHI) Learning Collaborative Model for Achieving Breakthrough Improvement with learning sessions, action periods, and performance measurement to refine the emerging strategies;
4. Create forums to facilitate and foster exchange of information between organizations to improve processes and outcomes;
5. Develop and communicate information to RWHAP recipients, subrecipients, and stakeholders throughout the duration of the project such as initiative status, lessons learned, and tools developed and used; and

6. Develop and disseminate information about the initiative evaluation and products that support and promote replication.

The evaluation provider (HRSA-22-029) will establish an evaluation and implement an evaluation design that analyzes the uptake, implementation, cost, and associated client outcomes of the emerging strategies at the demonstration sites.

Awardees under HRSA-22-027, HRSA-22-028, and HRSA-22-029 will work together to achieve the overall goals of this initiative. The demonstration sites, capacity-building provider, and evaluation provider will use the HRSA HAB implementation science (HAB IS) approach when proposing activities and products. The demonstration sites will participate in all activities of the capacity-building provider and evaluations provider, and should budget accordingly. Please review the capacity-building provider and evaluation provider NOFOs for more information about these activities.

2. Background

The SPNS Program is authorized by 42 USC § 300ff-101 (§ 2691 of the Public Health Service Act). The SPNS Program supports the development of innovative models of HIV care to quickly respond to the emerging needs of clients served by the Ryan White HIV/AIDS Program. The SPNS Program evaluates the effectiveness of these models' design, implementation, utilization, cost, and health-related outcomes while promoting the communication, dissemination and replication of successful models.

The Ryan White HIV/AIDS Program (RWHAP) provides a comprehensive system of HIV primary medical care, essential support services, and medications for low-income people with HIV. The program funds grants to states, cities, counties, and local community-based organizations to provide care and treatment services to people with HIV to improve health outcomes and reduce HIV transmission among hard-to-reach populations.

The RWHAP has five statutorily defined Parts (Parts A, B, C, D and F) that provide funding for core medical services, support services, and medications; technical assistance; clinical training; and the development of innovative models of care to meet the needs of different communities and populations affected by HIV.

An important framework in the RWHAP is the HIV care continuum, which depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication to achieve viral suppression. Supporting people with HIV to reach viral suppression not only increases their own quality of life and lifespan, it also prevents sexual transmission to an HIV-negative partner.

The HIV care continuum framework allows recipients and planning groups to measure progress and to direct HIV resources most effectively. RWHAP recipients are encouraged to assess the outcomes of their programs and should work with their community and public health partners to improve outcomes across the HIV care continuum. HRSA encourages recipients to use the performance measures developed for the RWHAP at their local level to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

Strategic Frameworks and National Objectives

National objectives and strategic frameworks like the Healthy People 2030, the HIV National Strategic Plan: A Roadmap to End the HIV Epidemic (2021–2025); the Sexually Transmitted Infections National Strategic Plan for the United States (2021–2025); and the Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025) are crucial to addressing key public health challenges facing low-income people with HIV. These strategies detail the principles, priorities, and actions to guide the national public health response and provides a blueprint for collective action across the federal government and other sectors. The RWHAP supports the implementation of these strategies and recipients should align their organization's efforts, within the parameters of the RWHAP statute and program guidance, with these strategies to extent possible.

Expanding the Effort: Ending the HIV Epidemic in the United States

According to recent data from the 2019 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2015 to 2019, HIV viral suppression among RWHAP patients who have had one or more medical visits during the calendar year and at least one viral load with a result of <200 copies/mL reported, has increased from 83.4 percent to 88.1 percent. Additionally, racial/ethnic, age-based, and regional disparities reflected in viral suppression rates have significantly decreased.[2] For example, the disparities in viral suppression rates between Black/African Americans and White clients have decreased since 2010.[3] These improved outcomes mean more people with HIV in the United States will live near normal lifespans and have a reduced risk of transmitting HIV to others.[4]

In February 2019, the Ending the HIV Epidemic in the United States (EHE) initiative was launched to further expand federal efforts to reduce HIV infections. This 10-year initiative seeks to achieve the important goal of reducing new HIV infections in the United States to fewer than 3,000 per year by 2030. The initiative promotes and implements four strategies to substantially reduce HIV transmissions – Diagnose, Treat, Prevent, and Respond. The initiative is a collaborative effort among key Department of Health and Human Services (HHS) agencies, primarily HRSA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

For the RWHAP, the EHE initiative expands the program's ability to meet the needs of clients specifically focusing on linking people with HIV who are either newly diagnosed, diagnosed but currently not in care, or are diagnosed in care but not yet virally suppressed to the essential HIV care and treatment and support services needed to help them achieve viral suppression.

Using Data Effectively: Integrated Data Sharing and Use

HRSA and CDC's Division of HIV/AIDS Prevention support integrated data sharing, analysis, and utilization for the purposes of program planning, conducting needs assessments, determining unmet need estimates, reporting, quality improvement,

enhancing the HIV care continuum, and public health action. HRSA strongly encourages RWHAP recipients to:

1. Follow the principles and standards in the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action.
2. Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated data sharing, analysis, and utilization of HIV data by state and territorial health departments can help further progress toward reaching the HIV National Strategic Plan goals and improve outcomes on the HIV care continuum.

HRSA strongly encourages complete CD4, viral load (VL) and HIV nucleotide sequence reporting to the state and territorial health departments' HIV surveillance systems to benefit fully from integrated data sharing, analysis, and utilization. State health departments may use CD4, VL, and HIV nucleotide sequence data to identify cases, stage of HIV disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into and retention in HIV care, measure viral suppression, monitor prevalence of antiretroviral drug resistance, detect transmission clusters and understand transmission patterns, and assess unmet health care needs. Analyses at the national level to monitor progress toward ending the HIV epidemic in the United States can only occur if all HIV-related CD4, VL, and HIV nucleotide sequence test results are reported by all jurisdictions. CDC requires the reporting to the National HIV Surveillance System (NHSS) all HIV-related CD4 results (counts and percentages), all VL results (undetectable and specific values), and HIV nucleotide sequences.

Program Resources and Innovative Models

HRSA has a number of projects and resources that may assist RWHAP recipients with program implementation. These include a variety of HRSA HAB cooperative agreements, contracts, and grants focused on specific technical assistance (TA), evaluation, and intervention activities. A list of these resources is available on **TargetHIV**. Recipients should be familiar with these resources and are encouraged to use them as needed to support their program implementation.

In addition, many RWHAP Special Projects of National Significance (SPNS) projects have demonstrated promising new approaches for linking and retaining priority populations into care. As resources permit, RWHAP recipients are encouraged to review and integrate these tools within their HIV system of care in accordance with the allowable service categories defined in Policy Clarification (PCN) 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds. Examples of these resources include:

- **E2i: Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV**
  E2i uses an implementation science approach to evaluate and understand existing and new intervention strategies that can be used in RWHAP provider settings. Once

interventions or strategies are demonstrated and evaluated using implementation science, manuals, guides, interactive online tools, publications, and instructional materials are developed and disseminated for replication and integration into RWHAP provider settings.

- **Integrating HIV Innovative Practices (IHIP)**
  Resources on the IHIP website include easy-to-use training manuals, curricula, case studies, pocket guides, monographs, and handbooks, as well as informational handouts and infographics about SPNS generally. IHIP also hosts TA training webinars designed to provide a more interactive experience with experts, and a TA help desk exists for you to submit additional questions and share your own lessons learned.

- **Replication Resources from the SPNS Systems Linkages and Access to Care**
  There are intervention manuals for patient navigation, care coordination, state bridge counselors, data to care, and other interventions developed for use at the state and regional levels to address specific HIV care continuum outcomes among hard-to-reach people with HIV.

- **Dissemination of Evidence Informed Interventions**
  The Dissemination of Evidence-Informed Interventions initiative ran from 2015-2020 and disseminated four adapted linkage and retention interventions from prior SPNS and the Minority HIV/AIDS Funds (MHAF) from the HHS Secretary's Office initiatives to improve health outcomes along the HIV care continuum. The initiative produced four evidence-informed care and treatment interventions (CATIs) that are replicable, cost-effective, capable of producing optimal HIV care continuum outcomes, and easily adaptable to the changing healthcare environment. Manuals are currently available at the link provided and will be updated on an ongoing basis.

HRSA also recognizes the importance of addressing emerging issues, as well as supporting the needs of diverse populations. To help recipients in responding to these critical issues, HRSA funds projects to provide technical assistance and resources for recipients. Examples of projects include:

- **Building Futures: Supporting Youth Living with HIV**
- **The Center for Engaging Black MSM Across the Care Continuum (CEBACC)**
- **Using Community Health Workers to Improve Linkage and Retention in Care**

HIV and Aging

According to the CDC, there are 1.1 million people with diagnosed HIV in the United States and six (6) dependent areas at the end of 2019. The RWHAP provides services to half of the people with diagnosed HIV. Half of the people receiving services through the RWHAP are 50 years and older. People with HIV have a life expectancy near that of the general population due to the availability and use of HIV antiretroviral therapy and high rates of viral suppression among people 50 years and older.[5-7] Even with their HIV

disease well managed, people aged 50 and older with HIV are at increased risk for and experience a vast host of comorbidities (e.g. cardiovascular disease, diabetes, osteoporosis), geriatric conditions (frailty, falls, neurocognitive impairment), and psychosocial needs (e.g. isolation, loneliness, lack of caregivers, and behavioral health).[8-10] People aging with HIV experience the same health concerns as the general aging population except that they experience the health concerns earlier[11] in life, more severely, and at a greater disproportion for comorbidities.[12] Turrini, et al. found older people with HIV have a higher overall hazard of mortality as well as higher odds of having depression, chronic kidney disease, COPD, osteoporosis, colorectal cancer, lung cancer, hypertension, ischemic heart disease, diabetes, chronic hepatitis, and end-stage liver disease compared to those without HIV, even after adjusting for demographic characteristics.[13] As summarized in a September 2020 Medscape article,[14] "they are also at higher risk for depression, frailty, polypharmacy, and other age-related conditions. Women may be especially vulnerable."

HIV medical care has evolved to focus not only on helping clients reach and sustain viral suppression, but to screen for and manage comorbidities, geriatric conditions, behavioral health and psychosocial needs.[15] The HIV Medicine Association of the Infectious Diseases Society of America published an update to its primary care guidelines for people with HIV[16] in November 2020, which includes recommendations for people 50 years and older. The body of evidence for models and strategies to effectively screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV is growing. The emerging strategies include multidisciplinary care teams, focusing on the "M's" of geriatric care (mind, mobility, medications, multi-complexity, matters most, and modifiable), utilizing a comprehensive geriatric assessment, imbedding a geriatrician in the HIV clinic, and incorporating geriatric consultants.[17-22]

HHS implements many programs for people aging throughout the U.S. The Centers for Medicare & Medicaid Services (CMS) has a number of programs, including the Medicare program and Programs of All-Inclusive Care for the Elderly (also known as PACE), focusing on older people in the U.S. The Administration for Community Living implements the Older Americans Act, which supports the Area Agencies on Aging and the National Family Caregiver Support Program, among many others. HRSA funds the Geriatric Workforce Enhancement Program and Geriatric Academic Career Award Program. Even though the RWHAP funds over 30 core and support services, there are services that the RWHAP cannot provide or are not available in every service area in the U.S. It is essential that RWHAP recipients and subrecipients engage with all available aging resources for their clients in order to maximize clients' health outcomes, quality of life, and client experience and not duplicate services.

HRSA HAB Implementation Science Approach

This initiative will use the HAB IS to identify and demonstrate emerging strategies that could be effective for improving outcomes among people 50 years and older with HIV served by the RWHAP, thereby reducing disparities and moving toward ending the HIV epidemic in the U.S. HAB IS was developed to support the translation of insights from the implementation science literature to real-world settings.

HAB IS includes effectiveness criteria for three (3) categories of intervention strategies for the RWHAP: evidence-based interventions, evidence-informed interventions, and

emerging strategies. HRSA developed these criteria in collaboration with the CDC and the NIH (see Fig 1 in Psihopaidas et al. (2020) for detailed descriptions). This initiative will focus on evidence-informed interventions and emerging strategies (hereafter referred to collectively as "intervention strategies"). By focusing on these two categories, HRSA seeks to identify highly innovative intervention strategies that are most responsive to the current HIV epidemic.

HAB IS involves two core components. The first component is rapid implementation, which, for this initiative, includes (1) identifying existing emerging strategies with demonstrated effectiveness at improving outcomes for people 50 years and older with HIV, (2) pilot testing those emerging strategies for success specifically within the RWHAP, and (3) creating accessible dissemination products to promote the replication and scale-up of the intervention strategy. The second component is an implementation science evaluation plan.

II. Award Information

1. Type of Application and Award

Type of applications sought: **New**

HRSA will provide funding in the form of a grant.

2. Summary of Funding

HRSA estimates approximately $3,000,000 to be available annually to fund 10 recipients. The actual amount available will not be determined until enactment of the final FY 2022 federal appropriation. You may apply for a ceiling amount of up to $300,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. The period of performance is August 1, 2022 through July 31, 2025 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for the RWHAP Special Projects of National Significance Program in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government.

HRSA may reduce recipient funding levels beyond the first year if recipients are unable to fully succeed in achieving the goals listed in application.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include entities eligible for funding under RWHAP Parts A - D of Title XXVI of the Public Health Service (PHS) Act, including public and nonprofit private entities; state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; and community health centers receiving support under Section 330 of the PHS Act. Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

HRSA will may not consider an application for funding if it contains any of the non-responsive criterion criteria below:

- Exceeds the ceiling amount
- Fails to satisfy the deadline requirements referenced in Section IV.4

NOTE: Multiple applications from an organization are not allowable.

HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply electronically. HRSA encourages you to apply through Grants.gov using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

The NOFO is also known as “Instructions” on Grants.gov. You must select “Subscribe” and provide your email address for HRSA-22-028 in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements
Section 4 of HRSA's *SF-424 Application Guide* provides general instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, etc. You must submit the information outlined in the HRSA SF-424 Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the HRSA SF-424 *Application Guide* for the Application Completeness Checklist.

Application Page Limitation
The total size of all uploaded files included in the page limitation may not exceed the equivalent of **60 pages** when printed by HRSA. The page limitation includes the project and budget narratives, attachments, and letters of commitment and support required in the HRSA SF-424 *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Please note: If you use an OMB-approved form that is not included in the workspace application package for **HRSA-22-028**, it may count against the page limitation. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limitation. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limitation.**

Applications must be complete, within the specified page limitation, and validated by Grants.gov under the correct funding opportunity number prior to the deadline.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).
- If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment* 8-15: *Other Relevant Documents*.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on all certifications.

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 319(e) of the PHS Act provides the Secretary of HHS with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness (ASPR) website via http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

Program Requirements and Expectations

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

i. Project Abstract

See Section 4.1.ix of HRSA's *SF-424 Application Guide*.

Use the Standard OMB-approved Project Abstract Summary Form 2.0 that is included in the workspace application package. Do not upload the abstract as an attachment or it will count toward the page limitation. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's *SF-424 Application Guide.*

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	**Review Criteria**
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities

Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested

ii. Project Narrative

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and organized in alignment with the sections and format below so that reviewers can understand the proposed project.

To assist in preparing your work plan and budget, please see the anticipated overall timeframe and phases for this initiative. Plan to participate in National Ryan White Conferences that occur during the initiative by preparing and presenting on the initiative. If possible, learning sessions and annual initiative meetings will be held at HRSA headquarters in Rockville, Maryland. At least two members from each demonstration site, capacity-building provider, and evaluation provider will attend the learning sessions and annual initiative meetings.

Below are the overall phases for Emerging Strategies to Improve Health Outcomes for People with HIV demonstration sites (HRSA-22-028), capacity-building provider (HRSA-22-027), and evaluation provider (HRSA-22-029). This notice outlines anticipated phases that successful applicants should aim to address across the lifespan of this initiative. This notice also clarifies below the interrelationship between the HRSA-22-027, HRSA-22-28, and HRSA-22-029 as well as with HRSA, on specific initiative activities.

Table 1. Initiative phases and timeline.

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
Year 1, Quarter 1	• Participate in a meeting with HRSA, capacity-building provider, and evaluation provider to develop joint work plan, timeline, and internal communication strategy • Finalize and document emerging strategies to be implemented at demonstration site • Prepare institutional review board	• Convene a meeting with HRSA, demonstration sites, and evaluation provider to develop joint work plan, timeline, and internal communication strategy • Support demonstration sites in finalizing and documenting emerging strategies • Finalize learning collaborative	• Participate in a meeting with HRSA, capacity-building provider, and demonstration sites to develop joint work plan, timeline, and internal communication strategy • Support demonstration sites in finalizing and documenting emerging strategies • Finalize evaluation design including

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
	submission (if applicable) in coordination with evaluation provider • Prepare business associate agreement (if needed) with evaluation provider • Participate in learning collaborative and corresponding activities (ongoing)	structure, activities, and timeline • Finalize technical assistance plan including process for tracking technical assistance provided and outcome • Develop a communication and dissemination plan	approach, typology, evaluation questions, and goals • Develop data collection systems and tools • Assist in the development of the communication and dissemination plan • Assist demonstration sites with preparation of business associate agreement and institutional review board package
Year 1, Quarter 2	• Implement and refine emerging strategies • Participate in the evaluation activities (ongoing) • Receive institutional review board determination or approval (if needed) • Establish business associate agreement with evaluation provider (if needed) • Participate in an assessment of technical assistance needs • Finalize documentation of emerging strategies	• Support demonstration sites to finalize and document emerging strategies • Implement learning collaborative's first learning session • Assess demonstration sites' technical assistance needs • Develop site visit plan for demonstration sites in coordination with HRSA, demonstration sites and evaluation provider • Finalize and implement the communication and dissemination plan • Plan and participate in annual initiative meeting	• Finalize data collection system and tools • Receive institutional review board determination or approval • Establish business associate agreement with demonstration sites (if needed) • Support demonstration sites to finalize and document emerging strategies • Develop tailored and multi-site evaluation plans • Finalize typology of demonstration sites and emerging strategies • Evaluate the learning collaborative

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
			learning sessions (ongoing for each learning session) • Assist in the development of the communication and dissemination plan • Support demonstration sites in collecting and reporting evaluation data • Plan and participate in annual initiative meeting
Year 1, Quarter 3	• Implement and refine emerging strategies (ongoing) • Request and receive technical assistance from the capacity-building provider (ongoing) • Submit baseline data collection	• Provide, track, and report technical assistance to demonstration sites (ongoing)	• Collect baseline data • Support demonstration sites in collecting and reporting evaluation data
Year 1, Quarter 4 through Year 2	• Implement and refine emerging strategies (ongoing) • Assist in planning and participate in annual initiative meeting (ongoing) • Assist in the development and release of communication and dissemination materials (ongoing)	• Support demonstration sites in the implementation and refinement of the emerging strategies • Co-host with evaluation provider annual initiative meeting (ongoing) • Develop and release communication and dissemination materials (ongoing)	• Support demonstration sites in the implementation and refinement of the emerging strategies • Implement the evaluation plan • Co-host with capacity-building provider annual initiative meeting (ongoing) • Assist in the development and release of communication and dissemination materials (ongoing)

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
Year 3, Quarter 1	• Closeout the implementation of the emerging strategies • Document emerging strategies • Assist in development of dissemination materials	• Host final learning collaborative learning session • Assist demonstration sites in documenting emerging strategies • Lead the assessment of dissemination plans for each intervention strategy based on TA tracking, learning sessions, and preliminary evaluation findings • Develop tools for replication of strategies	• Support demonstration sites in the implementation and refinement of the emerging strategies • Implement the evaluation plan • Support demonstration sites to complete final data reporting • Develop evaluation-related dissemination materials
Year 3, Quarter 2	• Finalize documentation of the emerging strategies • Finalize dissemination materials	• Finalize communication and dissemination materials	• Present preliminary evaluation findings • Develop evaluation-related dissemination materials
Year 3, Quarter 3	• Disseminate materials	• Disseminate materials	• Finalize evaluation findings • Develop evaluation-related materials for dissemination • Develop evaluation tools for replication products
Year 3, Quarter 4	• Disseminate materials	• Disseminate materials	• Disseminate evaluation findings

Use the following section headers for the narrative:

- *INTRODUCTION -- Corresponds to Section V's Review Criterion #1 Need*

  Briefly describe the purpose of the initiative as set forth in the purpose section of the NOFO. Describe your organization's current capacity and infrastructure to screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV. Briefly describe the emerging strategy(ies) that your organization proposes to implement to screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV. Describe how your organization will use the funds for this project. Describe your organization's approach to collaborating with the capacity-building provider and evaluation provider to achieve the goals of the initiative.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 Need*

  Throughout the needs assessment section, use and cite the most recent and relevant organization, local, and national data and published research whenever possible to support the information you provide. This section will help reviewers understand your client population, organization, and service area/jurisdiction that you will serve with the proposed project.

  Provide a summary of the comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV.

  Describe the people 50 years and older with HIV served by your organization. Include demographic information, unmet needs for screening and managing of comorbidities, geriatric conditions, behavioral health, and psychosocial needs; and current gaps and barriers in your organization to screen and manage comorbidities, geriatric conditions, behavior health and psychosocial needs. Indicate if any disparities exist among the clients served in your organization for the management of comorbidities, geriatric conditions, behavioral health, and psychosocial needs.

  Describe your organization's current strategies to screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV. Include the successes, gaps, and barriers your organization encounters.

  Describe the availability and engagement of resources to serve people 50 years and older with HIV in your service area. Resources may include organizations, skilled personnel, technology, services, referral sources, and workflow, among other items. Include resources that exist in your organization, resources that exist in your service area, aging resources available that are specific to people with HIV, and aging resources available to the general population.

  Describe how this project builds upon the current service standards, policies and procedures, and furthers the objectives of your organization in maximizing impact.

- *METHODOLOGY -- Corresponds to Section V's Review Criteria #2: Response and #4 Impact*

  Emerging strategies to manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV

  Proposed emerging strategy(ies): Identify the proposed emerging strategy(ies) that your organization will implement and describe how the emerging strategy(ies) will result in the management of comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV. Describe the rationale for your proposed emerging strategy(ies) based on the information provided in the needs assessment section. Indicate the information to support the effectiveness of the emerging strategy(ies). Assess and describe how the implementation of the emerging strategy(ies) will affect the workload of the personnel involved in providing services to clients. Describe how the emerging strategy(ies) will address any disparities noted in the needs assessment section.

  Utilizing members of the staff: Describe the staff positions who will participate in implementing the emerging strategy(ies). Describe their roles and responsibilities. Identify which staff positions are currently filled and plans to fill vacant positions quickly. Identify the staff positions that are new for this project and plans to sustain the position after the end of the project period.

  Managing client needs based on difference and severity of need: Considering that clients' needs will change over time, describe how your organization will offer services based on increases in different types and severity of need after initial assessment and reassessment. Describe how your organization would manage clients with vastly different needs and different severity of needs.

  Care coordination: Describe how the organization and emerging strategy(ies) promote care coordination, especially given the diversity of potential comorbidities, geriatric conditions, behavioral health, psychosocial needs, personnel involved in the delivery of services, and clients.

  Utilizing internal and external resources: Describe the internal and external resources that your organization will utilize in the emerging strategy(ies). Indicate whether the organization will coordinate with the local Area Agency on Aging.

  Involvement of people 50 years and older with HIV: Describe how the organization will involve people 50 years and older with HIV in the implementation, refinement, evaluation, communication, and dissemination of the emerging strategy(ies).

  Refining emerging strategy(ies): Demonstration sites will routinely collect and submit performance measure data in order to monitor the emerging strategy(ies). The performance measures will focus on screening and managing client needs, quality of life, and patient experience, among others. Demonstration sites will need an agile approach for the continual refinement of the emerging strategy(ies), as the period of performance is three (3) years. Describe how your organization will use the performance measure data and other information to refine the emerging

strategy(ies), including the information used to assess the emerging strategy(ies), people involved in the refinement, and documentation of changes to the emerging strategy(ies).

Documentation of emerging strategy(ies): After receiving an award, recipients will create step-by-step guides of the workflows (via process maps, swim lane flowcharts, and written protocols) prior to implementation and at various times in the project (after refinement of the emerging strategy[ies]). HRSA and the capacity-building provider will provide feedback on the documents. Describe your plan for developing the step-by-step workflows, including staff involved in the development, and for responding to feedback. The step-by-step guides will be disseminated to the RWHAP and HIV care and treatment community.

Sustainability

HRSA expects recipients to sustain the effective elements of their strategy(ies) after the funding ends. Describe your organization's plan to sustain the emerging strategy(ies) after the period of federal funding ends, including the incorporation of your proposed emerging strategy(ies) into your service standard beyond the 3-year funded period of performance.

Collaborating with and supporting the capacity-building provider

Describe your organization's plan to participate in the activities implemented by the capacity-building provider. Demonstration sites will host one site visit each year for HRSA, the capacity-building provider, and the evaluation provider. Please read the capacity-building provider NOFO (HRSA-22-027) to understand the involvement of your organization in the technical assistance activities.

Collaborating with and supporting the evaluation provider

Demonstration sites will collect and report qualitative and quantitative data regarding the emerging strategy(ies), personnel, process, outcomes, and costs to the evaluation provider. Describe your organization's plan to participate in the activities implemented by the evaluation provider. Indicate if your organization needs to establish a business associate agreement or data use agreement with the evaluation provider. Indicate if your organization needs to submit an application to an institutional review board (IRB) for this initiative. Please read the evaluation provider NOFO (HRSA-22-029) to understand the involvement of your organization in the evaluation activities.

Communication and dissemination

The capacity-building provider and evaluation provider will share the initiative status, lessons, outputs, and results with RWHAP recipients, subrecipients, and stakeholders throughout the lifecycle of the initiative.. Describe your organization's plan to participate fully in the sharing, publication, and dissemination of information regarding the initiative, including initiative status, lessons, outputs, and results.

Collaborations

Describe the proposed collaborations needed to successfully implement the proposed emerging strategy(ies). For each partner, clearly describe their role and responsibilities and explain how their services and/or resources can augment and support the implementation activities you propose. Identify the tasks that each

partner proposes to perform. Include the partner(s) in your work plan. Include letters of agreement from each partner and/or collaborating entity as Attachment 4.

- *WORK PLAN -- Corresponds to Section V's Review Criterion #2: Response*

  A work plan is a concise, easy-to-read overview of your goals, strategies, objectives, activities, and timeline, and includes those responsible for making the program successful. The work plan is used post-award to manage and assess the implementation of the project.

  Describe the activities that you will implement during the entire period of performance. For each activity, include a description of the activity, targeted date for completion, staff responsible for completing the activity, and measures to evaluate success (as relevant). The work plan should include activities related to implementing, refining, and evaluating the emerging strategy(ies), and partnering with the capacity-building provider and evaluation provider. As appropriate, identify meaningful support and collaboration with key partners in planning, designing, and implementing all activities. Identify proposed staff members (in-kind and cooperative agreement-supported) responsible for each activity. The work plan should be presented in a table format and include (1) goals; (2) objectives that are specific, time-framed, and measurable; (3) action steps with corresponding due dates; (4) staff responsible for each action step, and; (5) anticipated dates of completion of goals. Key activities to address in the timeline include, but are not limited to, start-up activities, assessments, implementation of emerging strategy(ies), training activities, and documentation of the comprehensive emerging strategy(ies). Include the phases and activities as described in Table 1.

  Submit the work plan as **Attachment 1.** You must submit the detailed work plan for each 12-month period of the three-year period of performance of August 1, 2022 through July 31, 2025. The first 12-month budget period will address activities from August 1, 2022 to July 31, 2023, with subsequent work plans covering years two and three.

- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion #2: Response*

  Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria #3: Evaluative Measures and #5: Resources/Capabilities*

  Demonstration sites must work with the evaluation provider to participate in and submit data as part of a national multi-site evaluation. HRSA requires demonstration sites to collect and report relevant quantitative and qualitative data regarding the emerging strategy(ies), personnel, process, outcomes, and costs.

Describe your organization's capacity to participate in the national, multi-site evaluation including training, skills, and experience of staff to fulfill the required evaluation activities. Describe evaluation activities of similar scope to this project that your organization has successfully completed.

Describe your organization's plan to participate and cooperate in all aspects of a national, multi-site evaluation led by the evaluation provider including data sources and staff with designated responsibilities. The description should include the process for obtaining patient consent if needed, and the timely collection and submission of relevant qualitative and quantitative data related to the following performance measures:

- Receipt of health maintenance screenings;
- Receipt of appropriate referrals or care plans;
- Improvement in quality of life;
- Patient satisfaction/experience;
- Demonstrated partnerships with organizations focused on providing services to older adults;
- Demonstrated partnerships with Bureau of Aging or Area Agencies on Aging; aging stakeholders participating in planning processes;
- Aging as a component of strategic planning; and
- Aging considerations in resource allocation, service standards, and grant monitoring, among others.

HRSA expects the demonstration sites to stratify the performance measure data in order to assess for disparities. The stratifications should reflect important client characteristics such as race, ethnicity, gender, age, and sexual orientation, among others. Describe the stratifications your organization will use to assess your performance measure data for disparities.

Since demonstration sites will report relevant quantitative and qualitative outcome, process, and cost measures data to the evaluation provider, proposed staffing plans must include an evaluator to oversee the multi-site evaluation and a data coordinator to assist in data management, collection and reporting (Attachment 2). The data coordinator should have experience in data collection and reporting.

Describe your current ability to collect the above data. Describe your plan to collect and manage data for this project including using any electronic health record or data management software that allows for accurate and timely reporting of performance and implementation outcomes. Include information about how you will collect and share data with the evaluation provider, including participation in a cost analysis study that will collect labor, training, structural, and other relevant costs you may incur for the administration of the emerging strategy(ies).

Include a description of your plan to develop policies and procedures that ensure the privacy and confidentiality of clients participating in the proposed emerging strategy(ies). Describe your organization's experience and plan to establish data use agreements and business associate agreements with the capacity-building provider and evaluation provider. Include a description of procedures for the electronic and physical protection of study participant information and data, in accordance with HIPAA and Common Rule (45 CFR 46) regulations.

Funded organizations must acquire protections quickly (see Table 1 - Initiative phases and timeline) in order for the initiative to remain on schedule. Describe your organization's experience with and plan for obtaining IRB review, approval, and renewals for client-level data collection instruments, informed consents, and any other relevant evaluation documentation. Describe your plan to submit documentation and obtain IRB approval as per your organization's requirements, including the approval on all evaluation activities and data collection instruments for both your own evaluation (optional) and the multi-site evaluation (required).

Describe any potential obstacles for implementing the evaluation and your plan to address those obstacles.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion # 5 Resource and Capabilities*
  Succinctly describe your organization's current mission, structure, and scope of current activities, and how these elements all contribute to the organization's ability to implement the program requirements and meet program expectations. Include an organizational chart (Attachment 5).

  The demonstration sites must provide comprehensive screening and management of comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV or have an agreement with an organization that can provide these services (referred to as partner organization in the NOFO). Describe your organization's and partner organization's experience providing services to people 50 years and older with HIV. Describe your experience and your partner organization's experience in providing RWHAP outpatient ambulatory health services and support services, and your capacity to respond to the purpose of this initiative.

  Discuss how your organization will follow the approved work plan, properly account for the federal funds, and document all costs to avoid audit findings. Describe how you will routinely assess and improve the unique needs of priority populations of the communities served. Provide a description of the strength of the organization's fiscal and management information systems, and the capacity to meet program requirements. Describe your experience with the fiscal management of federal funds. Include information on your organization's experience managing multiple federal grants.

  Describe specific organizational capabilities that will contribute to successfully implementing the proposed activity. Describe the organizational skills, capabilities, and resources, including staff who will contribute to your organization's ability to carry out the proposed activity. Highlight key staff with relevant expertise and experience with similar work. This information should align with the staffing plan (Attachment 2), job descriptions (Attachment 2), and the biographical sketches of key personnel (Attachment 3).

iii. Budget

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's *SF-424 Application*

Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects your application for funding, you will have a well-organized plan and, by carefully following the approved plan, may avoid audit issues during the implementation phase.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the SPNS program requires the following:

As Attachment 6, submit a separate line item budget for years 1 through 3 as a spreadsheet using the Section B budget categories of the SF-424A and breaking down subcategorical costs.

As required by the Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 and Division A of the FY 2022 Extending Funding and Emergency Assistance Act (P.L. 117-43), "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. Budget Narrative

See Section 4.1.v. of HRSA's *SF-424 Application Guide*.

v. Attachments

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limitation.** Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limitation. **Clearly label each attachment**. You must upload attachments into the application. Any *hyperlinked* attachments will *not* be reviewed/opened by HRSA.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's *SF-424 Application Guide)*

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Identify staff by name (if already hired) who will fill each of the key personnel roles. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in *Attachment 2*, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are signed and dated.

Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of this project.

Attachment 6: Line Item Budget for Years 1 through 3

Using the Object Class Categories of the SF-424A, provide the object class category breakdown (i.e., line item budget) for each of the three budget years.

Attachment 7: Tables, Charts, etc.

To give further details about the proposal (e.g. Gantt or PERT charts, flow charts).

Attachments 8–15: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support, indirect cost rate agreements, proof of non-profit status and documentation of current RWHAP funding. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. In April 2022, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following

webpages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or you have an exception approved by the agency under 2 CFR § 25.110(d))**.** For your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator.

If you are chosen as a recipient, HRSA will not make an award until you have complied with all applicable SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award, and HRSA may use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

*Currently, the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (https://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://sam.gov/content/home | SAM.gov Knowledge Base)
- Grants.gov (https://www.grants.gov)

For further details, see Section 3.1 of HRSA's *SF-424 Application Guide*.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM.gov.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *February 8, 2022 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before**

the deadline to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Demonstration Sites is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to three (3) years, at no more than $300,000 per year (inclusive of direct **and** indirect costs). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) and Division A of the FY 2022 Extending Funding and Emergency Assistance Act (P.L. 117-43) apply to this program. See Section 4.1 of HRSA's SF-424 Application Guide for additional information. Note that these or other restrictions will apply in following fiscal years, as required by law.

You cannot use funds under this notice for the following purposes:

- Charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, HUD, etc.);
- Purchase or construction of new facilities or capital improvement to existing facilities;
- Purchase vehicles;
- International travel;
- Cash payments to intended RWHAP clients;
- Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (nPEP) medications or the related medical services. (Please note that RWHAP recipients and providers may provide prevention counseling and information to eligible clients' partners – see RWHAP and PrEP Program Letter, June 22, 2016);
- Syringe Services Programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy. See https://www.hiv.gov/sites/default/files/hhs-ssp-hrsa-guidance.pdf;

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all

other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

Be aware of the requirements for HRSA recipients and subrecipients at 2 CFR § 200.216 regarding prohibition on certain telecommunications and video surveillance services or equipment. For details, see the HRSA Grants Policy Bulletin Number: 2021-01E.

All program income generated as a result of awarded funds must be used for approved project-related activities. Any program income earned by the recipient must be used under the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

7. Other Submission Requirements

Letter of Intent to Apply
The letter should identify your organization and its intent to apply, and briefly describe the proposal. HRSA will ***not*** acknowledge receipt of letters of intent.

Send the letter via email by *December 1, 2021* to:

HRSA Digital Services Operation (DSO)
Please use the HRSA opportunity number as email subject (HRSA-22-028)
HRSADSO@hrsa.gov

Although HRSA encourages letters of intent to apply, they are not required. You are eligible to apply even if you do not submit a letter of intent.

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Six review criteria are used to review and rank The Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Demonstration Sites applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Needs Assessment

The extent to which the application demonstrates the problem and associated contributing factors to the problem.

Introduction (5 points)

- The strength and clarity of the description of the proposed project.
- The strength and clarity of the description of the applicant's current capacity and infrastructure to screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV.
- The strength and clarity of the brief description of the emerging strategy(ies) that the organization proposes to implement to screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV.

Needs Assessment (5 points)

- The extent to which the summary of the literature demonstrates a comprehensive understanding of the comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV.
- The extent to which the application describes the people 50 and older with HIV served by the organization including the client demographics and current strategies, unmet needs, gaps, and disparities related to screening and management of comorbidities, geriatric conditions, behavioral health, and psychosocial needs.
- The extent to which the applicant proposes to use the available resources in the service area that serve people 50 years and older.
- The strength and clarity of the description of how this initiative builds upon the current service standards, policies, and procedures, and furthers the objectives of the applicant in maximizing impact.

Criterion 2: RESPONSE (40 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

Methodology (20 points)

Emerging Strategy

- The strength, feasibility, and clarity of the emerging strategy(ies), including the rationale for proposing the emerging strategy(ies) based on information from the needs assessment section, effect on workload of personnel involved in providing services to clients, and description of how the emerging strategy(ies) will address disparities.

- The strength, feasibility, and clarity of the applicant's approach to offer different levels of services after initial assessment and reassessment and to manage clients with different needs and severity of need.
- The strength, feasibility, and clarity of the applicant's approach to coordinate care and utilize internal and external resources, including local Area Agencies on Aging.
- The strength, feasibility, and clarity of the applicant's approach to involve people 50 years and older in the implementation, refinement, evaluation, communication, and dissemination of the emerging strategy(ies).
- The strength, feasibility, and clarity of the applicant's approach to use performance measure data and other information to refine the emerging strategy(ies), including the information used to assess the emerging strategy(ies), people involved in the refinement, and documentation of changes to the emerging strategy(ies).

Collaborating with the Capacity-Building Provider and Evaluation Provider

- The strength and clarity of the applicant's plan to participate in the activities implemented by the capacity-building provider.
- The strength and clarity of the plan to participate in the activities implemented by the evaluation provider.

Collaborations

- The strength, feasibility, and clarity of the applicant's partners, including the roles and responsibilities and explanation of how the partner's services and/or resources can augment and support the implementation, tasks performed by the partner, and letter of agreement from each partner.

Work Plan (15 points)

- The strength, feasibility, and clarity of the work plan and its goals for the three-year period of performance (*Attachment 1*).
- The extent to which the work plan relates to the Methodology section of the narrative and addresses the program requirements in this announcement.
- The extent to which the work plan includes clearly written: (1) objectives that are specific, measurable, achievable, realistic and time-framed (SMART); (2) action steps and activities; (3) staff responsible for each action step; and (4) anticipated dates of completion.
- The extent to which the work plan demonstrates the ability to achieve the proposed goals during the three-year period of performance.
- The strength and clarity of the work plan to describe collaborating in capacity-building provider and evaluation provider activities during the three-year period of performance.
- The strength and clarity of the work plan to describe tasks and activities performed by partners during the three-year period of performance.

Resolution of Challenges (5 points)

- The strength, clarity, and feasibility of the plan to identify and mitigate challenges that you are likely to encounter in designing and implementing the activities described in the work plan.

Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity

The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

- The strength, feasibility, and clarity of the applicant's plan to participate and cooperate in all aspects of national, multi-site evaluation, including the staff who will provide data and data sources, including obtaining patient consent (if needed), timely collection and submission of performance measure data, and cost data.
- The strength, feasibility, and clarity of the applicant's plan to develop policies and procedures that ensure the privacy and confidentiality of clients participating in the proposed emerging strategy(ies).
- The strength, feasibility, and clarity of the applicant's plan to obtain IRB review, approval, and renewals for client-level data collection instruments, informed consents, and any other relevant evaluation documentation.
- The strength, feasibility, and clarify of the applicant's plan to establish data use agreements and business associate agreements with the capacity-building provider and evaluation provider.
- The strength, feasibility, and clarity of the applicant's plan to collect and manage data for this project.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Methodology

The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include: the effectiveness of plans for dissemination of initiative results, the impact results may have on the community or priority population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

Communication and Dissemination

- The strength and clarity of the applicant's commitment and plan to participate fully in the sharing, publication, and dissemination of information regarding the initiative including project status, lessons, outputs, and results.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

Evaluation and Technical Support Capacity (5 points)

- The extent to which the application demonstrates the capacity to participate in the national multi-site evaluation.

- The extent to which staff are qualified by training, skills, and experience to fulfill the evaluation activities.
- The extent to which the staffing plan and organizational chart (***Attachment 5***) are consistent with the project description and activities.

Organizational information (15 points)

- The extent to which the application describes how the applicant's mission, structure, and scope of activities contribute to its ability to fulfill the initiative requirements and expectations.
- The extent to which the application demonstrates knowledge and experience providing RWHAP outpatient ambulatory health services and support services, specifically HIV outpatient ambulatory health services and support services to people 50 years and older with HIV.
- The extent to which the application describes specific organizational capabilities that will contribute to successfully implementing the proposed activity, including the organizational skills, capabilities, resources, and staff that will contribute to carrying out the proposed activity.
- The strength, feasibility, and clarity of the applicant's experience and plan to implement the proposal in accordance with the approved work pan, accounting for federal funds, and documenting costs.
- The strength and appropriateness of the job descriptions for key staff based on the goals and objectives of this project (***Attachment 2***).
- The strength and appropriateness of the biographical sketches based on the goals and objectives of this project (***Attachment 3***).
- The extent to which the time allocated for staff is consistent with their anticipated workload toward the completion of the goals and objectives of the project.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Line Item Budget (Attachment 6) and Budget Narrative

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the complexity of the activities, and the anticipated results.

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- The strength and clarity of the budget narrative to support each line item budget.

2. Review and Selection Process

The objective review process provides an objective evaluation of applications to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting

applications for award. See Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

HRSA will consider past performance in managing contracts, grants, and/or cooperative agreements of similar size, scope, and complexity. Past performance includes timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous awards, and if applicable, the extent to which any previously awarded federal funds will be expended prior to future awards. HRSA will also consider the geographic distribution of the applicants, which will allow the diversity of demonstration sites based on geographic differences.

3. Assessment of Risk

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory, or other requirements (45 CFR § 75.205).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 CFR § 75.212).

VI. Award Administration Information

1. Award Notices

HRSA will release the Notice of Award (NOA)on or around the start date of August 1, 2022. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's *SF-424 Application Guide*.

If you are successful and receive a NOA, in accepting the award, you agree that the award and any activities thereunder are subject to:

- all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award,
- other federal regulations and HHS policies in effect at the time of the award or implemented during the period of award, and
- applicable statutory provisions.

Accessibility Provisions and Non-Discrimination Requirements
Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, *see* http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS-funded health and education programs must be administered in an environment free of sexual harassment. *See* https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience

protection and associated anti-discrimination laws, *see* https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Federal funding recipients must comply with applicable federal civil rights laws. HRSA supports its recipients in preventing discrimination, reducing barriers to care, and promoting health equity. For more information on recipient civil rights obligations, visit the HRSA Office of Civil Rights, Diversity, and Inclusion website.

Executive Order on Worker Organizing and Empowerment

Pursuant to the Executive Order on Worker Organizing and Empowerment, HRSA strongly encourages applicants to support worker organizing and collective bargaining and to promote equality of bargaining power between employers and employees. This may include the development of policies and practices that could be used to promote worker power. Applicants can describe their plans and specific activities to promote this activity in the application narrative.

Requirements of Subawards

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability for more details.

Data Rights

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

Human Subjects Protection

Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

- Refer to instructions provided in HRSA's *SF-424 R&R Application Guide*, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.
- Refer to HRSA's *SF-424 R&R Application Guide* to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application. If you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.
- In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following: (1) discuss plans to seek IRB approval or exemption; (2) develop all required documentation for submission of research protocol to IRB; (3) communicate with IRB regarding the research protocol; (4) communicate about IRB's decision and any IRB subsequent issues with HRSA.
- IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent any page limitation in the Methodology portion of the Project Narrative section.

3. Reporting

Award recipients must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

- **Progress Report**(s). The recipient must submit a progress report to HRSA on an annual basis. Further information will be available in the NOA.

- **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020.

VII. Agency Contacts

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Beverly Smith
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301)443-7065

Email: bsmith@hrsa.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Marlene Matosky
Chief, Clinical Quality Branch
Division of Policy and D
Attn: Funding Program – HRSA-22-028
HIV/AIDS Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 9N154
Rockville, MD 20857
Telephone: (301) 443-0798
Email: mmatosky@hrsa.gov

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International callers, dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). Always obtain a case number when calling for support. For assistance with submitting information in the EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Telephone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Tuesday, November 16, 2021
Time: 2:00 – 3:30 p.m. ET
Call-In Number:

Dial by your location
+1 (669) 254-5252 US (San Jose)
+1 (646) 828-7666 US (New York)
+1 (669) 216-1590 US (San Jose)
+1 (551) 285-1373 US
(833) 568-8864 US Toll-free

Meeting ID: 160 096 8222
Passcode: 39942016

Weblink: Join ZoomGov Meeting
https://hrsa-gov.zoomgov.com/j/1600968222?pwd=TTU5bHJCYitOU29yTUtMcnRJWmVwUT09

Meeting ID: 160 096 8222
Passcode: 8hhkdjHK

Playback: The webinar will be recorded and should be available within 10 business days on the TargetHIV website. Answers to questions posed before and during the webinar will also be posted there.

Tips for Writing a Strong Application

See Section 4.7 of HRSA's *SF-424 Application Guide*.

Appendix: References

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