

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



HIV/AIDS Bureau
Division of Policy and Data

***Emerging Strategies to Improve Health Outcomes for People Aging with HIV:
Evaluation Provider***

Funding Opportunity Number: HRSA-22-029

Funding Opportunity Type: New

Assistance Listings (AL/CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

Application Due Date: January 25, 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, 2022

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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**.

The Emerging Strategies to Improve Health Outcomes for People Aging with HIV 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](#) (HAB IS) 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 evidence¹ 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-22-029 Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Evaluation Provider**, solicits a recipient who will develop and carry out a multi-site evaluation that includes a customized site-specific evaluation for each of the 10 demonstration sites (HRSA-22-028) that will identify, refine, and implement 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 existing resources and infrastructure of organizations funded through the RWHAP. In addition to the site-specific components, the evaluation will

include cross-site components that are consistent across all of the demonstration sites. The evaluation provider's activities and products will align with the [HAB implementation science framework](#). Throughout this initiative, the evaluation provider will work closely with the demonstration sites (HRSA-22-028) and capacity-building provider (HRSA-22-027). The capacity-building provider will lead and implement the dissemination plan, which will include the evaluation findings produced by the evaluation provider.

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: Evaluation Provider
Funding Opportunity Number:	HRSA-22-029
Due Date for Applications:	January 25, 2022
Anticipated Total Annual Available FY 2022 Funding:	\$750,000
Estimated Number and Type of Award(s):	One (1) cooperative agreement
Estimated Annual Award Amount:	Up to \$750,000 per year (Subject to the availability of appropriated funds)
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: Wednesday, November 17, 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: 161 311 8611

Passcode: 76925383

Weblink: Join ZoomGov Meeting

<https://hrsa-gov.zoomgov.com/j/1613118611?pwd=ZW1yeWk4NlZxRnBEVFFsV2FMUHJXdz09>

Meeting ID: 161 311 8611

Passcode: Yy5SBv5g

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-22-029) 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: Evaluation Provider**.

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](#) (HAB IS) 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 evidence¹ 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-22-029) is to support one evaluation provider to develop and carry out a multi-site evaluation that includes a customized site-specific evaluation for each of the 10 demonstration sites (HRSA-22-028) that will identify, refine, and implement 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 existing resources and infrastructure of organizations funded through the RWHAP. The evaluation provider will establish and implement an evaluation design that analyzes the uptake, implementation, cost, and associated client outcomes of the emerging strategies at the demonstration sites. In addition to the site-specific components, the evaluation will include cross-site components that are consistent across all of the demonstration sites. Throughout this initiative, the evaluation provider will work closely with the demonstration sites (HRSA-22-028) and the capacity-building provider (HRSA-22-027). The capacity-building provider will lead and implement the dissemination plan, which will include the evaluation findings produced by the evaluation provider.

The evaluation provider's activities and products will align with the [HAB implementation science framework, which](#) 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 evidence¹ or evaluation to document the 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 funding opportunity will support an organization that has the capacity, infrastructure, and experience to: 1) develop and carry out an evaluation focused on uptake, implementation, cost, and associated client outcomes of the emerging strategies at the demonstration sites; 2) communicate and coordinate with the capacity-building provider and demonstration sites to achieve the goals of the initiative; and 3) prepare evaluation findings and products for dissemination.

The capacity-building provider (HRSA-22-027) will:

1. Assist the demonstration sites in identifying, documenting, and refining 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 and address the needs; manage and provide peer-to-peer technical assistance, and provide 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 project 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 demonstration sites (HRSA-22-028) will:

1. Implement: Identify, implement, and refine emerging strategies to comprehensively screen and manage comorbidities, geriatric conditions, behavior health and psychosocial concerns of people 50 years and older with HIV within 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 strategy(ies) 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).

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 HAB IS when proposing activities and

products. The evaluation provider will engage with the demonstration sites (HRSA-22-028) and capacity-building provider (HRSA-22-027) in planning and implementing all activities and should budget accordingly. Please review the demonstration sites (HRSA-22-028) and capacity-building provider (HRSA-22-027) 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:

- 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](#).
- 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 HAB also recognizes the importance of addressing emerging issues, as well as supporting the needs of special populations. To help recipients in responding to these critical issues, HRSA HAB 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 a 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’ achieve 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 HRSA HAB implementation science framework (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 HAB developed these criteria in collaboration with the CDC and the NIH (see Fig 1 in Psihopoulos 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 HAB 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 project, 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 cooperative agreement. A cooperative agreement is a financial assistance mechanism where HRSA anticipates substantial involvement with the recipient during performance of the contemplated project.

HRSA program involvement will include:

- Providing the expertise of HRSA personnel and other relevant resources to the project.
- Facilitating relationships between the demonstration sites, capacity-building provider, evaluation provider, and other relevant stakeholders.
- Reviewing and providing feedback on the evaluation activities, documentation, procedures, measures, and tools established and implemented for accomplishing the goals of the cooperative agreement throughout the duration of the initiative.
- Reviewing, providing feedback and concurring with, on an ongoing basis, prior to external communication and dissemination: evaluation activities, procedures, measures, written materials to support and implement the initiative, tools and all information products developed for accomplishing the goals of the cooperative agreement.
- Facilitating, communicating, and disseminating status updates, lessons, results, best practices, evaluation data, and other information developed as part of this project to the broader network of RWHAP recipients and subrecipients, and the HIV care and treatment community.

The cooperative agreement recipient's responsibilities will include:

- Developing and carrying out a tailored demonstration-site and a multi-site evaluation.
- Developing a publication and dissemination plan in collaboration with the capacity-building provider.
- Developing an assessment of learning session activities hosted by the capacity-building provider.

- Interpreting the evaluation findings of the overall effectiveness of the intervention strategies in terms of uptake, integration, implementation, and cost, and associated client outcomes relevant to the initiative.
- Providing evaluation findings and insights to inform replication products developed by the capacity-building provider.
- Developing evaluation-related dissemination materials to describe this initiative and evaluation findings, such as manuscripts and professional conference presentations.
- Monitoring and informing the capacity-building provider of data quality and completeness of data submissions.
- Providing a data portal or other necessary data system and training demonstration sites' staff on the data portal and other necessary data systems before and throughout the implementation period.
- Anticipating and responding to the changes taking place in the health care environment as they impact or may impact the initiative and/or evaluation.
- Collecting and analyzing data relative to national health issues, unmet needs, marketplace conditions, special populations, and other key health indicators to guide current/future strategic planning, developmental efforts, and work plan activities.

2. Summary of Funding

HRSA estimates approximately \$750,000 to be available annually to fund one (1) recipient. 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 \$750,000 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 Emerging Strategies to Improve Health Outcomes for People Aging with HIV: Evaluation Provider in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government.

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 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.4NOTE: 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](https://www.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-22-029 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

Section 4 of HRSA’s [SF-424 Application Guide](#) provides 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-22-029, 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

- 1) 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.
- 2) 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).
- 3) If you are unable to attest to the statements in this certification, you must include an explanation shall be included in *Attachments 8-15: Other Relevant Documents*.

See Section 4.1 viii of HRSA's [SF-424 Application Guide](#) for additional information on all certifications.

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.

<u>Narrative Section</u>	<u>Review Criteria</u>
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response and (4) Impact
Work Plan	(2) Response
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (4) Impact
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 alignment with the sections and format below so that reviewers can understand the proposed project. Post award, HRSA will share the project narrative with the capacity-building provider for it to prepare the technical assistance activities.

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.

At least annually, the successful applicant should plan to collaborate with HRSA to update existing work plans and, as needed, integrate new priorities during the funding period. The recipient should plan for monitoring calls with HRSA every other week.

Below are the overall phases for the Emerging Strategies to Improve Health Outcomes for People Aging with HIV demonstration sites (HRSA-22-028), the capacity-building provider (HRSA-22-027), and the evaluation provider (HRSA-22-029). This notice outlines anticipated project 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 project activities.

Table 1. 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 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)	• 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 structure, activities, and timeline • Finalize technical assistance plan including process for tracking technical assistance provided and outcome • Develop a communication and dissemination plan	• 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 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 institution review board package
Year 1, Quarter 2	• Implement and refine emerging strategies • Participate in the evaluation activities (ongoing)	• Support demonstration sites to finalize and document emerging strategies	• Finalize data collection system and tools • Receive institutional review board determination or approval

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
	• 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	• 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	• 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 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)	• Provide, track, and report technical assistance to demonstration sites (ongoing)	• Collect baseline data • Support demonstration sites in collecting and reporting evaluation data

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
	• Submit baseline data collection		
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)
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

Phase	Demonstration Sites (HRSA-22-028)	Capacity-Building Provider (HRSA-22-027)	Evaluation Provider (HRSA-22-029)
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

Please review and incorporate information discussed in capacity-building provider (HRSA-22-027) and demonstration sites (HRSA-22-028) funding announcements in your response.

Use the following section headers for the narrative:

▪ **INTRODUCTION** -- Corresponds to [Section V's Review Criterion #1 Need](#)

Briefly describe the purpose of the project as set forth in the purpose section of the NOFO. Provide a clear and succinct description of your roles and activities as the evaluation provider. Describe your overall approach to conduct the initial, interim, and final assessments and evaluations of the intervention strategies and implementation strategies used by the demonstration sites. Describe your organization's current capacity and infrastructure to conduct both the multiple site-tailored evaluations simultaneously, as well as the multi-site evaluations with common variables across sites.

▪ **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 approach and activities.

Provide a summary of the literature that demonstrates a comprehensive understanding of the issues regarding the role of emerging strategies in screening and managing comorbidities, geriatric conditions, behavior health, and psychosocial needs of people 50 years and older with HIV.

Discuss the role of implementation science in advancing evaluation frameworks, and in particular, discuss the relationship between, and significance of, intervention strategies vis-à-vis implementation strategies. Describe the techniques used to evaluate health care interventions aimed at improving health outcomes in an effective manner. Include examples of your previous evaluation findings related to HIV care and treatment.

- **METHODOLOGY** -- Corresponds to Section V's Review Criteria [#2 Response](#) and [#4 Impact](#)

Provide detailed information regarding the proposed approaches that you will use to address the sections below.

Emerging strategies

- Describe the process you will use to identify, catalog, and assess each demonstration site's emerging strategies to screen and manage comorbidities, geriatric conditions, behavioral health, and psychosocial needs of people 50 years and older with HIV.
- Describe the processes that you will use to ensure that you can assess and evaluate the selected emerging strategies.

Needs assessment/baseline evaluation

Describe the approaches and methods you will use to develop the multi-site evaluation including site-specific and cross-site components for each demonstration site. The proposed evaluation plan must include, but is not limited to:

- A review of relevant literature on your proposed evaluation methodologies and identification of their theoretical basis
- Evaluation components
- Staffing and programmatic requirements
- Costs
- Existing resources, where available

Data collection

Describe your plan to develop, with input from the capacity-building provider, a data collection tool for use by demonstration sites to collect data at regular intervals in an electronic format.

Describe your approach for working directly with the demonstration sites for collection of outcome and process data including:

- Training demonstration sites' staff in use of data collection instruments and web-based data entry portal
- Regular monitoring of data collection and reporting efforts of demonstration sites
- Remedial action when necessary to ensure data collection is of the highest quality

Describe how you will collect evaluation data from the demonstration sites. Specifically, include the structure, process, and vehicle you plan to use. Describe how you will monitor data quality and data completeness of regular data submissions and how you will communicate results to the capacity-building provider.

Describe your experience establishing data use agreements with other organizations.

Describe the procedures for the electronic and physical protection of participant information and data. Identify any client-level data with the potential for disclosure of Protected Health Information (PHI). Describe your organization's Institutional Review Board (IRB) process for reviewing the multi-site evaluation protocol and data collection instruments.

Institutional Review Boards

Should the IRB of the evaluation provider or the demonstration sites determine that the multi-site evaluation is subject to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and human subjects research protections, discuss your plan for serving as a resource for the demonstration sites regarding their IRBs' review, approval and renewals of their client-level data collection instruments, informed consents, and any other relevant evaluation documentation.

Evaluation

Describe the evaluation plan you will use to assess the outcomes and impact of implemented emerging strategies by the demonstration sites at regular intervals, and at the conclusion of the period of performance related to the following aging-related matters:

- Receipt of health maintenance screenings;
- Receipt of appropriate referrals or care plans;
- Quality of life; patient satisfaction/patient experience;
- Partnerships with organizations focused on providing services to older adults;
- 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 consideration in resource allocation, service standards, and grant monitoring, among others.

Describe how you will evaluate complex and multi-faceted intervention strategies. Describe the variables that you will include to assess successful implementation and the above aging-related matters. Those may include:

- Intervention exposure variables
- Organizational structure variables
- Contextual variables and barriers/facilitators
- Aging-related matters variables based on medical record data
- Costing variables

You may propose the use of other measures, if applicable, from the CMS, United States Preventive Services Taskforce, National HIV/AIDS Strategy (NHAS), EHE, or HAB. Please provide a justification and explanation of the measures proposed, if applicable.

Describe a method to assess the likelihood of long-term sustainability/program integration of the intervention strategies.

Discuss the process evaluation plan, which will determine whether the goals of the evaluation plan are being met over the course of the initiative. Please include measures that will be part of the evaluation process. Describe how the process evaluation methodology will ensure effective completion of project activities as outlined in the work plan and how it will identify needed process improvements where applicable.

Describe techniques/methods to evaluate implementation fidelity when adapting the original intervention strategy for a specific population. Implementation fidelity increases the likelihood that the participants will experience similar outcomes to those found in the original intervention.

Describe a plan for the development of an evaluation data collection portal that demonstration sites will use to report evaluation data.

Describe a plan for developing a highly accessible evaluation tool that can be included within the final replication materials to allow for assessment of implementation and associated client outcomes by other RWHAP providers not funded through this initiative.

Describe a plan to provide evaluation-related technical assistance to up to 10 demonstration sites over the course of the cooperative agreement.

Mid-implementation adjustments assessment:

Discuss a plan for assessment of learning session activities.

Describe the approach you will use to assess any mid-implementation adjustments made to the emerging strategies as a result of the learning sessions. Describe how this assessment will support determining the effectiveness and impact on outcomes or processes this change has for a particular demonstration sites.

Describe a process to provide support to the capacity-building provider to ensure adaptations and improvements in implementation plans are measurable.

Dissemination:

The evaluation provider (HRSA-22-029) will establish and implement the evaluation design. The capacity-building provider will develop and disseminate information about the initiative evaluation and products that support and promote replication.

- Describe a plan to coordinate with and provide content and information to the capacity-building provider for dissemination within the timeframe of the project period of performance.
- Describe a plan for disseminating project information, activities, and preliminary findings throughout the project period at national conferences.
- Describe a plan to support the capacity-building provider and demonstration site staff in preparing presentations of project information, activities, and preliminary findings throughout the project period.

▪ *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. The work plan should include the project phases, timeframes, and key activities outlined in Table 1. The work plan should directly relate to the methods described in the Methodology section and for this NOFO. The work plan is to be used as a tool to actively manage the project including all aspects of the evaluation and coordinated activities with the capacity-building provider.

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, responsible staff, and measures to evaluate success (as relevant). 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. Write objectives and key action steps in time-framed and measurable terms, providing numbers for targeted outcomes where applicable, not just percentages. Key activities to address in the timeline include, but are not limited to, start-up activities, assessments, establishment and implementation of evaluation design, training activities, and documentation of the comprehensive emerging strategy(ies). Include the project 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 ensuing 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, approaches that you will use to resolve such challenges, and how you will document these as part of the evaluation process. Specifically,

- Describe the challenges that are likely to occur in the implementation of the evaluation design in varied program settings with different emerging strategy(ies) and propose potential strategies to overcome these challenges.
- Describe challenges to providing evaluation and data collection assistance to RWHAP recipients within a variety of settings and techniques that you may use to address these challenges.
- Describe any anticipated challenges to collaborating with the capacity-building provider and the techniques that you may use to address these challenges.

▪ **EVALUATION AND TECHNICAL SUPPORT CAPACITY** -- Corresponds to Section V's [Review Criteria #3 Evaluative Measures](#) and [#4 Impact](#)

Describe a plan for evaluating your organization's performance and a process for continuous quality improvement. This evaluation should monitor ongoing processes and the progress toward the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

Describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how your organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe the current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature.

Describe your organization's capacity to conduct a comprehensive multi-site evaluation of the proposed project. Describe your organization's capacity to disseminate evaluation-related information. Describe the knowledge and expertise of proposed staff, including any consultants and subcontractors, if applicable, in conducting health care evaluations among people with HIV. Provide evidence of their experience, skills, training, and knowledge in achieving scientific excellence and evaluation integrity. Discuss any examples of previous projects that reflect the

expertise of proposed staff, as well as proficiency in working collaboratively with demonstration projects.

Describe the plan to develop and maintain the initiative's data portal, and your documented procedures for the electronic and physical protection of participant information and data.

Describe your organization's plan to establish data use agreements with the demonstration sites and capacity-building provider.

Describe your organization's familiarity with the processes on how to submit data collection instruments, informed consents, and any other related materials to your proposed IRBs for review and approval on an annual basis.

Describe how the proposed key project personnel have the necessary knowledge, experience, training, and skills to provide evaluation-related and data collection technical assistance. Describe the experience of proposed key project staff (including any consultants and subcontractors) in collaborative writing and in making presentations at conferences. Describe any experience in partnering with other entities for close collaboration as will be required in this initiative with the capacity-building provider.

▪ **ORGANIZATIONAL INFORMATION -- [Corresponds to Section V's Review Criterion #5 Resources/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 conduct the project requirements and expectations. Include an organizational chart as Attachment 5. Describe your organization's program experience in research, evaluation, and dissemination of findings on issues related to comprehensive HIV medical care.

Describe specific organizational capabilities, resources, years of experience, and staffing that will contribute to successfully implementing the proposed activity related to:

- Developing and carrying out an evaluation focused on uptake, implementation, cost, and associated client outcomes of the emerging strategies at the demonstration sites; and cost of emerging strategies;
- Communicating and coordinating with the capacity-building provider and demonstration sites to achieve the goals of the initiative; and
- Preparing evaluation findings and products for dissemination.

Provide a staffing plan (Attachment 2) describing the roles and responsibilities for each person contributing to the project and job descriptions. Provide biographical sketches (Attachment 3) for all personnel included in the budget (Attachment 6) highlighting their experience relevant to this project. Include biographical sketches for all staff appearing the staffing plan. If you plan to use consultants or contractors to provide any of the proposed services, describe their roles and responsibilities on the project, experience relevant to the project, and amount of time contributing

to each project activity. Include signed letters of agreement, memoranda of understanding, and descriptions of proposed and/or existing contracts related to the proposed project in Attachment 4. See Section 4.1. of HRSA's SF-424 Application Guide for information on the content for the sketches.

Describe collaborative efforts with other pertinent agencies that enhance your ability to accomplish the proposed project. Discuss any examples of previous projects that reflect the experience of proposed staff in working collaboratively with RWHAP-funded organizations.

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. In addition, describe your experience with the fiscal management of grants and contracts. Include information on your organization's experience managing multiple federal grants.

Discuss your organization's experience with implementing a cooperative agreement. Discuss how your organization will follow the approved work plan, properly account for the federal funds, and document all costs to avoid audit findings. Provide a description of the strength of the organization's fiscal and management information systems, and the capacity to meet program requirements.

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 sub categorical 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. 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 agreement and proof of non-profit status. 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](https://sam.gov))
- 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 federal-wide. 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 located at [SAM.gov](https://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 *January 25, 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: Evaluation Provider 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 \$750,000 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](#).

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: Evaluation Provider 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](#)

Introduction (5 points)

- The strength and feasibility of the overall approach to conducting the initial, interim, and final assessments and evaluations of the emerging strategies.
- The clarity of the brief descriptions of the organization and the ability to conduct multiple tailored or customized and multi-site evaluations.

Needs Assessment (5 points)

- The extent to which the summary of the literature demonstrates a comprehensive understanding of issues regarding the role of emerging strategies in screening and managing comorbidities, geriatric conditions, behavior health, and psychosocial needs of people 50 years and older with HIV.
- The ability to effectively describe the role of an implementation science framework in the effective implementation and evaluation of innovative emerging strategies.
- The clarity of the discussion of techniques used to effectively evaluate health care interventions aimed at improving health outcomes in an effective manner.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's [Methodology](#), [Work Plan](#), and Resolution of Challenges

Methodology (20 points)

- The strength and feasibility of the plan for the implementation of the multi-site evaluation.
- The strength, clarity, and feasibility of the process to identify, catalog, and assess each demonstration site's emerging strategies.

- The strength, clarity, and feasibility of the approach to develop a data portal or other data system to collect data from the demonstration sites.
- The strength and clarity of the approach to provide technical assistance to demonstration sites regarding data collection.
- The feasibility of the plan to collect data for the multi-site evaluation.
- The strength and clarity of the planned structure, process, and vehicle for data collection.
- The strength, clarity, and feasibility of the plan for monitoring data quality and data completeness, and communicating results to the capacity-building provider.
- The extent to which the procedures for the electronic and physical protection of participant information and data are comprehensive and clear.
- The strength and clarity of the plan for serving as a resource for demonstration sites regarding IRB approval.

Work Plan (10 points)

- The strength and clarity of the work plan and its goals for the three-year period of performance.
- The extent to which the work plan relates to the Methodology section of the Narrative and addresses the program requirements of this announcement.
- The extent to which the work plan includes clearly written (1) objectives that are specific, time-framed, and measurable; (2) action steps and activities; and (3) anticipated dates of completion in table format.
- The extent to which the work plan demonstrates the ability to achieve the proposed goals for the 3-year period of performance.

Resolution of Challenges (5 points)

- The strength and clarity of the description of the challenges encountered in the designing and implementing the evaluation activities.
- The clarity and feasibility of the approaches to resolve such challenges and documentation of the challenges as part of the evaluation process.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's [Evaluation section of Methodology](#) and [Evaluation and Technical Support Capacity](#)

Methodology (15 points)

- The strength and effectiveness of the method proposed to support a needs assessment for each demonstration sites, led by the capacity-building provider, particularly in terms of evaluation-related needs such as organizational capacity for data collection.
- The strength and completeness of the plan for evaluating each demonstration site's emerging strategy.
- The strength and clarity of the multi-site evaluation plan's theoretical basis for its proposed evaluation methodology.

- The extent to which the proposed evaluation plan can assess the effectiveness and impact of implemented emerging strategies.
- The strength and clarity of the proposed multi-site evaluation plan, including outcomes measures and process evaluation.
- The strength and clarity of the methodology to be used as part of the process evaluation plan.
- The strength and feasibility of the proposed methods for assessing the likelihood of long-term sustainability/integration of emerging strategies.
- The strength and feasibility of the proposed methods for measuring associated costs of implementing the emerging strategies for those who may seek to replicate it.
- The strength and clarity of the rationale for any additional evaluation domains and measures, if applicable.
- The strength of the plan for developing an evaluation tool.
- The strength and clarity of the plan to assess learning session activities.
- The strength and clarity of the plan for the provision of evaluation-related technical assistance to the demonstration sites.

Evaluation and Technical Support Capacity (5 points)

- The strength and clarity of the comprehensive plan for the process evaluation that will contribute to continuous quality improvement.
- The strength and clarity of the comprehensive plan for the development and maintenance of the initiative's data portal and procedures for the electronic and physical protection of participant information and data.

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

- The strength and clarity of the approach to assessing improved implementation plans resulting from any mid-implementation adjustments to implementation strategies based on the learning sessions.
- The strength and clarity of the plan for the final dissemination of findings from the multi-site evaluation.
- The specificity and feasibility of the proposed plan to complete the evaluation within the last project year.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – [Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information](#)

Evaluation and Technical Assistance Capacity (8 points)

- The extent of experience, skills, training, and knowledge to conduct a comprehensive multi-site evaluation of the proposed project.
- The extent of experience, skills, training, and knowledge in evaluation and timely publication of manuscripts and other dissemination products to describe the evaluation findings.

- The extent of experience, skills, training, and knowledge of proposed staff (including any consultants and subcontractors, if applicable) in conducting health care evaluations among people with HIV.
- The extent of experience, skills, training, and knowledge of proposed key staff (including any consultants and subcontractors, if applicable) in achieving scientific excellence and evaluation integrity in conducting a multi-site evaluation of national scope.
- The extent of experience, skills, training, and knowledge of proposed key staff (including any consultants and subcontractors, if applicable) in providing evaluation-related technical assistance.

Organizational Information and Staffing Plan (7 points)

- The extent of experience, knowledge, and skill in conducting multi-site evaluations assessing the effectiveness of emerging strategies.
- The extent of experience in research, evaluation, and dissemination of findings on issues related to comprehensive HIV medical care.
- The extent of experience and ability to successfully disseminate findings of the findings and lessons learned from multi-site evaluations, specifically those with cross-site and site-specific components.
- The extent of experience with using management information systems to support a comprehensive multi-site evaluation in the collection, reporting, and secure storage of client-level data.
- The extent of experience, skills, knowledge, and ability to successfully provide evaluation-related technical assistance.
- The clarity of the one-page project organizational chart depicting the organizational structure of the project, not the entire organization.
- The extent to which the staffing plan is consistent with the project description and project activities.
- 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.
- The appropriateness of the job descriptions for key staff.
- The strength and appropriateness of the biographical sketches.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's [Budget](#) and [Budget Narrative](#)

- The clarity of the line item budgets for each year of the period of performance and their appropriateness to the work plan.
- The clarity of the budget narrative's support for each line item.
- If applicable, the clarity of the description of costs (and the basis for the costs) for proposed contractors and consultants.

2. Review and Selection Process

The objective review process provides an objective evaluation 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. 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. See Section 5.3 of HRSA's [SF-424 Application Guide](#) for more details.

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. Non-discrimination legal requirements for recipients of HRSA federal financial assistance are available at the following address:

<https://www.hrsa.gov/about/organization/bureaus/ocrdi#non-discrimination>. 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:

- 1) **Progress Report(s).** The recipient must submit a progress report to HRSA on an annual basis. Further information will be available in the NOA.
- 2) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in [FAPIS](#), 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 and Quality Branch
Division of Policy and Data
HIV/AIDS Bureau
Health Resources and Services Administration
Attn: Funding Program – HRSA-22-027
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: Wednesday, November 17, 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: 161 311 8611

Passcode: 76925383

Weblink: Join ZoomGov Meeting

<https://hrsa->

[gov.zoomgov.com/j/1613118611?pwd=ZW1yeWk4NiZxRnBEVFFsV2FMUHJXdz09](https://hrsa-gov.zoomgov.com/j/1613118611?pwd=ZW1yeWk4NiZxRnBEVFFsV2FMUHJXdz09)

Meeting ID: 161 311 8611

Passcode: Yy5SBv5g

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: 1

References

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- ² Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2019. <http://hab.hrsa.gov/data/data-reports>. Published December 2020. Accessed December 2, 2020.
- ³ Black/African American clients went from 79.4 percent viral suppression in 2015 to 85.2 percent in 2019, while 88.3 percent of white clients were virally suppressed in 2015 and 91.8 percent in 2019
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