

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

HIV/AIDS Bureau
Division of Policy and Data

***Using Innovative Intervention Strategies to Improve Health Outcomes among
People with HIV - Evaluation Center***

Funding Opportunity Number: HRSA-21-068
Funding Opportunity Type(s): Competing Continuation
Assistance Listings (CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: March 8, 2021

***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, including SAM.gov and Grants.gov,
may take up to 1 month to complete.***

Issuance Date: December 18, 2020

Demetrios Psihopaidas, Ph.D., MA
Senior Health Scientist, Evaluation, Analysis, and Dissemination Branch
Division of Policy and Data, HIV/AIDS Bureau
Telephone: (301) 443-1469
Fax: (301) 443-8143
Email: dpsihopaidas@hrsa.gov

Authority: 42 U.S.C. § 300ff-101 (§ 2691 of the Public Health Service Act)

EXECUTIVE SUMMARY

This notice announces the opportunity to apply for fiscal year 2021 (FY21) Health Resources and Services Administration (HRSA) Special Projects of National Significance (SPNS) Program funding for the initiative *Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Evaluation Center*. The purpose of this initiative is to use an implementation science framework to evaluate the pilot testing of innovative intervention strategies in four (4) focus areas at implementation sites subawarded through the companion cooperative agreement *Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Coordinating Center* (2iS CCTA; HRSA-21-076), and to disseminate the evaluation findings. HRSA will fund one organization through a cooperative agreement for up to four (4) years to serve as the Innovative Intervention Strategies Evaluation Center (2iS EC). The 2iS EC will develop and carry out a multi-site evaluation that includes a customized site-specific evaluation for each of the up to twenty (20) implementation sites subawarded through the 2iS CCTA. In addition to the site-specific components, the evaluation will include cross-site components that are consistent across all subawardee sites. Throughout this initiative, the 2iS EC will work closely with the 2iS CCTA, which will provide technical assistance to the subawardees. Ultimately, the 2iS EC's evaluation findings will determine dissemination plans for the replication tools developed by the 2iS CCTA. Please review the companion funding opportunity announcement for more information on the role of the 2iS CCTA (HRSA-21-076).

Funding Opportunity Title:	Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV - Evaluation Center
Funding Opportunity Number:	HRSA-21-068
Due Date for Applications:	March 8, 2021
Anticipated Total Annual Available FY 2021 Funding:	\$1,050,000
Estimated Number and Type of Award(s):	Up to 1 cooperative agreement
Estimated Award Amount:	Up to \$1,050,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	August 1, 2021, through July 31, 2025 (four (4) years)

Eligible Applicants:	<p>Eligible applicants include entities eligible for funding under the Ryan White HIV/AIDS Program Parts A, B, C, and D. These include but are not limited to: public and nonprofit private entities involved in addressing HIV related issues at the regional or national level; state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; community health centers receiving support under Section 330 of the Public Health Service Act; faith-based and community-based organizations; and Indian Tribes or Tribal organizations with or without federal recognition.</p> <p>See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.</p>
----------------------	--

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, January 13, 2021

Time: 2 p.m. – 3:30 p.m. ET

Call-In Number: 1-800-779-5244

Participant Code: 3606454

Weblink: <https://hrsa.connectsolutions.com/hrsa-21webinar/>

The webinar will be recorded and should be available within 10 business days at <https://targethiv.org/library/nofos>. Answers to questions posed during and after the webinar will also be posted there.

Table of Contents

I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION	1
1. PURPOSE	1
2. BACKGROUND	2
II. AWARD INFORMATION	9
1. TYPE OF APPLICATION AND AWARD	9
2. SUMMARY OF FUNDING	13
III. ELIGIBILITY INFORMATION	14
1. ELIGIBLE APPLICANTS	14
2. COST SHARING/MATCHING	14
3. OTHER	14
IV. APPLICATION AND SUBMISSION INFORMATION	14
1. ADDRESS TO REQUEST APPLICATION PACKAGE	14
2. CONTENT AND FORM OF APPLICATION SUBMISSION	15
i. <i>Project Abstract</i>	16
ii. <i>Project Narrative</i>	16
iii. <i>Budget</i>	23
iv. <i>Budget Narrative</i>	23
v. <i>Attachments</i>	24
3. DUN AND BRADSTREET DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER TRANSITION TO THE UNIQUE ENTITY IDENTIFIER (UEI) AND SYSTEM FOR AWARD MANAGEMENT (SAM)	25
4. SUBMISSION DATES AND TIMES	26
5. INTERGOVERNMENTAL REVIEW	27
6. FUNDING RESTRICTIONS	27
V. APPLICATION REVIEW INFORMATION.....	28
1. REVIEW CRITERIA	28
2. REVIEW AND SELECTION PROCESS	32
3. ASSESSMENT OF RISK	32
VI. AWARD ADMINISTRATION INFORMATION	33
1. AWARD NOTICES	33
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS	33
3. REPORTING	34
VII. AGENCY CONTACTS	34
VIII. OTHER INFORMATION.....	35

I. Program Funding Opportunity Description

1. Purpose

Initiative Overview

This notice announces the opportunity to apply for fiscal year 2021 (FY21) Health Resources and Services Administration (HRSA) Special Projects of National Significance (SPNS) Program funding for the initiative *Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Evaluation Center*. The purpose of this initiative is to use an implementation science framework¹ to evaluate the pilot testing of innovative intervention strategies in four (4) focus areas at implementation sites subawarded through the companion cooperative agreement *Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Coordinating Center* (2iS CCTA; HRSA-21-076), and to disseminate the evaluation findings. HRSA will provide funding in the form of a cooperative agreement to support one (1) organization for up to four (4) years to serve as the Innovative Intervention Strategies Evaluation Center (2iS EC). The 2iS EC will develop and carry out a multi-site evaluation that includes a customized site-specific evaluation for each of the up to twenty (20) Ryan White HIV/AIDS Program (RWHAP)-funded recipients/subrecipients (approximately five sites per focus area) to serve as implementation sites where one intervention strategy per site will be piloted. In addition to the site-specific components, the evaluation will include cross-site components (e.g., costing, organizational assessments) that are consistent across all subawardee sites. Throughout this initiative, the 2iS EC will work closely with the 2iS CCTA, which will provide technical assistance to the subawardees. Ultimately, the 2iS EC's evaluation findings will determine dissemination plans for the replication tools developed by the 2iS CCTA. Please review the companion funding opportunity announcement for more information on the role of the 2iS CCTA (HRSA-21-076). You may also review the previous initiative for which this is a competing continuation (HRSA-17-044; HRSA-17-049).

2iS Focus Areas

This recipient will evaluate the implementation and associated health outcomes of three (3) priority populations and one (1) area of opportunity to improve service delivery for people with HIV. Combined, these four (4) focus areas are:

- 1) Improving HIV health outcomes for people with substance use disorder
- 2) Improving HIV health outcomes for lesbian, gay, bisexual, transgender, or queer (LGBTQ+) youth
- 3) Improving HIV health outcomes for people who are or have been incarcerated
- 4) Improving HIV health outcomes by using telehealth services

¹ Psihopoulos D, Cohen SM, West T, et al. (2020) Implementation science and the Health Resources and Services Administration's Ryan White HIV/AIDS Program's work towards ending the HIV epidemic in the United States. *PLoS Med* 17(11):e1003128. <https://doi.org/10.1371/journal.pmed.1003128>.

The 2iS EC will evaluate the uptake and integration of the intervention strategies as well as the associated client outcomes of these intervention strategies at the subawarded sites. Please review the related 2iS CCTA (HRSA-21-076) announcement to understand the collaborative work between the 2iS CCTA and the 2iS EC.

2. Background

The Ryan White HIV/AIDS Program (RWHAP) funds direct health care and support services for over half a million people diagnosed with HIV in the United States. RWHAP funds are awarded to cities, states, and local community-based organizations to deliver efficient and effective HIV care, treatment, and support services for low-income people with HIV. Since the program's inception in 1990, RWHAP has developed a comprehensive system of safety net providers who deliver high quality, innovative HIV health care.

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

The HRSA HAB Implementation Science Approach

The goal of this initiative is to use the HRSA HAB implementation science framework (HAB IS)² to identify and pilot test proven intervention strategies that could be effective for improving outcomes among people 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 Centers for Disease Control and Prevention and the National Institutes of Health (see *Fig 1* in [Psihopaidas et al. \(2020\)](#) for detailed descriptions). This initiative will focus on evidence-informed interventions and emerging strategies (hereafter referred to collectively as “intervention strategies”). By focusing on these two categories, HRSA 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 includes (1) identifying existing intervention strategies with demonstrated effectiveness at improving outcomes for people with HIV, (2) pilot testing those for success specifically within the RWHAP, and (3) creating accessible dissemination products to promote the replication and scale-up of the intervention strategy. The 2iS CCTA will provide technical assistance (TA) to support implementation at the

² *ibid.*

subawarded sites. Details are outlined in the 2iS CCTA companion announcement (HRSA-21-076).

The second core component is *implementation science evaluation*. This type of evaluation is intended to provide standardized and systematic assessments of 1) the impact of the intervention strategy on client outcomes, 2) the penetration of the intervention strategy in a specific setting, 3) the utility of specific implementation strategies to achieve uptake and integration of the intervention strategy, and 4) the broader contextual factors that affect implementation. These components should inform the 2iS EC's development and delivery of the evaluation plan that covers the cross-site and customized site-specific components of the evaluation.

Through the multi-site evaluation, the 2iS EC will be able to determine which of the piloted intervention strategies can be successfully replicated by other RWHAP-funded providers to improve client outcomes. This multi-site evaluation plan will include both cross-cutting variables (e.g., costing data) and variables tailored specifically to the intervention strategy and the subawardee (e.g., intervention exposure data). The 2iS EC will also evaluate the impact of biannual learning sessions developed by the 2iS CCTA, in terms of their impact on uptake, integration, and associated client outcomes.

The 2iS EC will also closely collaborate with the 2iS CCTA throughout the entire period of performance to support TA activities and to ensure the TA activities do not negatively impact the ability to carry out the evaluation. The findings will be the key factor to inform dissemination plans for the replication tools created by the 2iS CCTA.

Health Disparities and Demonstrated Need in the RWHAP

Substance use disorder

Compared to other subpopulations of people with HIV, people who inject drugs (PWID) and/or people with substance use disorder (SUD) may face barriers to effective HIV treatment. Co-occurring HIV and SUD have long been stigmatized in the U.S. and are associated with lower health care access, income, educational attainment, and higher rates of unemployment or underemployment.³ Intervention strategies specifically addressing these needs are underutilized.^{4,5} Additionally, intervention strategies for SUD among people with HIV often specifically focus on injection drug use; however, alcohol, methamphetamine, and other drug use are also prevalent.⁶ For people with co-occurring HIV and SUD there is a need for intersecting innovative and holistic

³ Conrad C, Bradley HM, Broz D, et al.; Centers for Disease Control and Prevention (CDC). Community outbreak of HIV infection linked to injection drug use of oxycodone—Indiana, 2015. *MMWR Morb Mortal Wkly Rep* 2015; 64:443–4. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm>

⁴ Chander G, Himelhoch S, Moore RD. Substance abuse and psychiatric disorders in HIV-positive patients: epidemiology and impact on antiretroviral therapy. *Drugs* 2006; 66:769–89. <https://link.springer.com/article/10.2165/00003495-200666060-00004>

⁵ Durvasula R, Miller TR. Substance abuse treatment in persons with HIV/AIDS: challenges in managing triple diagnosis. *Behav Med* 2014; 40:43–52. <https://doi.org/10.1080/08964289.2013.866540>

⁶ Haldane V, Cervero-Liceras F, Chuah FL, et al. Integrating HIV and substance use services: a systematic review. *J Int AIDS Soc.* 2017;20(1):21585. <https://onlinelibrary.wiley.com/doi/full/10.7448/IAS.20.1.21585>.

intervention strategies in addition to understanding how to screen, refer, or treat substance use in a variety of service provision settings.⁷

LGBTQ+ youth

In the US, nearly one-quarter of new HIV diagnoses occur among youth and young adults aged 13-24 years. Lesbian, gay, bisexual, transgender, or queer (LGBTQ+) youth face additional barriers to care compared to youth overall. These barriers contribute to lower rates of viral suppression, lower rates of engagement in care, and lower rates of antiretroviral therapy (ART) adherence for LGBTQ+ youth, and many are unaware of their HIV status.⁸ The barriers that contribute to poorer HIV-related health outcomes among LGBTQ+ youth may include barriers navigating the health care system, transportation, a lack of youth-oriented care, and ineffective linkage to care.⁹

Incarceration

For all demographic groups, experiences of incarceration or other justice system involvement can significantly impact engagement in HIV care and treatment. While recent studies have shown improvements in HIV care continuum outcomes for those currently incarcerated, rates of engagement in care, receipt of ART, and virologic suppression have been shown to significantly decrease post-incarceration.¹⁰ Intervention strategies to improve linkage to and retention in HIV care and treatment following release from prisons and jails are necessary to improve viral suppression outcomes. Additionally, intervention strategies that expand and destigmatize HIV testing for those currently experiencing incarceration hold promise for improving outcomes, particularly among certain subpopulations including those who identify as transgender, women, and men who have sex with men.^{11,12,13}

⁷ Durvasula R, Miller TR. Substance abuse treatment in persons with HIV/AIDS: challenges in managing triple diagnosis. *Behav Med* 2014; 40:43–52. <https://doi.org/10.1080/08964289.2013.866540>

⁸ Kapogiannis BG, Koenig LJ, Xu J, et al. The HIV Continuum of Care for Adolescents and Young Adults Attending 13 Urban US HIV Care Centers of the NICHD-ATN-CDC-HRSA SMILE Collaborative. *J Acquir Immune Defic Syndr*. 2020;84(1):92-100. https://journals.lww.com/jaids/Fulltext/2020/05010/The_HIV_Continuum_of_Care_for_Adolescents_and_15.aspx.

⁹ Valencia, R, Wang, LY, Dunville, R, et al. Sexual Risk Behaviors in Adolescent Sexual Minority Males: A Systematic Review and Meta-Analysis. *J Primary Prevent* 39, 619–645 (2018). <https://doi.org.ezproxyhhs.nihlibrary.nih.gov/10.1007/s10935-018-0525-8>.

¹⁰ Iroh PA, Mayo H, Nijhawan AE. The HIV care cascade before, during, and after incarceration: a systematic review and data synthesis. *American journal of public health*. 2015 Jul;105(7):e5-16. <https://pubmed.ncbi.nlm.nih.gov/25973818>

¹¹ Harawa NT, Brewer R, Buckman V, Ramani S, Khanna A, Fujimoto K, Schneider JA. HIV, Sexually Transmitted Infection, and Substance Use Continuum of Care Interventions Among Criminal Justice–Involved Black Men Who Have Sex With Men: A Systematic Review. *American journal of public health*. 2018 Nov;108(S4):e1-9. <https://link.springer.com/article/10.1007/s11524-020-00428-8>

¹² Erickson M, Shannon K, Sernick A, et al. Women, incarceration and HIV: a systematic review of HIV treatment access, continuity of care and health outcomes across incarceration trajectories. *AIDS*. 2019 Jan 27;33(1):101-111. <https://www.ncbi.nlm.nih.gov/pubmed/30289811>

¹³ Fuge TG, Tsourtos G, Miller ER (2020) A systematic review and meta-analyses on initiation, adherence and outcomes of antiretroviral therapy in incarcerated people. *PLoS ONE* 15(5):e0233355. <https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0233355>

Telehealth

The COVID-19 public health emergency has demonstrated the need for innovative intervention strategies to engage people with HIV in care and treatment by adopting methods such as telehealth.¹⁴ Telehealth has demonstrated effectiveness in addressing barriers to HIV care and treatment such as HIV care provider shortages, transportation, and HIV-related stigma that may be experienced in clinical settings. However, people with HIV who are members of priority populations may face additional barriers to accessing telehealth services.¹⁵ For example, among racial/ethnic minorities, people with low income, people living in rural areas, and older people with HIV, barriers to telehealth services may include a lack of (1) access to digital devices and technology infrastructure (i.e., broadband internet), (2) health literacy, (3) privacy when engaging in telehealth visits. Addressing inequities among priority populations with HIV using telehealth will help to expand the benefits of telehealth and improve HIV outcomes along the HIV care continuum.¹⁶

To address disparities among people with HIV, the RWHAP needs innovative intervention strategies at all levels of HIV care. By increasing the scale at which effective intervention strategies are disseminated and replicated across the RWHAP, this initiative will bring us closer to ending the HIV epidemic.

The Strategic Framework

The RWHAP supports the implementation of the National HIV/AIDS Strategy for the United States: Updated 2020 (NHAS 2020). This strategy is a 5-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. The plan also provides a blueprint for collective action across the federal government and other sectors to help achieve the strategy's vision.

To ensure that RWHAP aligns with the National HIV/AIDS Strategy, to the extent possible, activities funded by the program focus on addressing the plan's four goals:

- 1) Reduce new HIV infections;
- 2) Increase access to care and improve health outcomes for people with HIV;
- 3) Reduce HIV-related health disparities and health inequities; and
- 4) Achieve a more coordinated national response.

To achieve these shared goals, recipients should align their organization's efforts, within the parameters of the RWHAP statute and program guidance, to ensure that people with HIV are linked to and retained in care, and have timely access to HIV treatment and the support services needed (e.g., mental health and substance use disorders services) to achieve HIV viral suppression. The RWHAP also provides technical

¹⁴ Young JD, Abdel-Massih R, Herchline T, et al. Infectious Diseases Society of America Position Statement on Telehealth and Telemedicine as Applied to the Practice of Infectious Diseases. *Clin Infect Dis*. 2019;68(9):1437–43. <https://pubmed.ncbi.nlm.nih.gov/30851042>

¹⁵ Dandachi D, Lee C, Morgan RO, et al. Integration of Telehealth Services in the Healthcare System: With Emphasis on the Experience of Patients Living with HIV. *J Investig Med*. 2019;67(5): 815–20. <https://pubmed.ncbi.nlm.nih.gov/30826803>

¹⁶ Mgbako, O, Miller EH, Santoro AF, et al. COVID-19, Telemedicine, and Patient Empowerment in HIV Care and Research. *AIDS Behavior* 24, 1990–1993 (2020). <https://doi.org/10.1007/s10461-020-02926-x>

assistance and training initiatives and promotes the effective use of data to enhance recipients' capacity to implement programs that support the strategy's objectives.

Expanding the Effort: Ending the HIV Epidemic: A Plan for America

In February 2019 the Administration launched the [Ending the HIV Epidemic: A Plan for America](#) (EHE) initiative to further expand federal efforts to reduce HIV infections. This 10-year initiative which began in FY 2020 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 first phase of the initiative is focused on 48 counties, Washington, D.C., San Juan, PR, and 7 states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the initiative, the U.S. Department of Health and Human Services (HHS) plans to reduce new HIV infections by 75 percent within five years. The initiative promotes and implements four Pillars to substantially reduce HIV transmissions – Diagnose, Treat, Prevent, and Respond. The initiative is a collaborative effort among key 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).

HIV Care Continuum

Diagnosing and linking people with HIV to primary care, and ensuring people with HIV achieve viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main stages that include: HIV diagnosis, linkage to care, retention in care, antiretroviral use, and viral suppression. The HIV care continuum provides a framework that depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication. It also demonstrates the proportion of individuals with HIV who are engaged at each stage. The HIV care continuum 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 along this continuum of care. Recipients 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.

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 decreased.¹⁷ These improved outcomes mean more people with HIV in the United States will live near normal lifespans and have a reduced risk of

¹⁷ 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.

transmitting HIV to others.¹⁸ Scientific advances have shown antiretroviral therapy (ART) preserves the health of people with HIV and prevents sexual HIV transmission. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner. Such findings underscore the importance of supporting effective interventions for linking people with HIV into care, retaining them in care, and helping them adhere to their ART.

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 NHAS 2020 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 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 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.

¹⁸ National Institute of Allergy and Infectious Diseases (NIAID). Preventing Sexual Transmission of HIV with Anti-HIV Drugs. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 Mar 29]. Available from: <https://clinicaltrials.gov/> NCT00074581 NLM Identifier: NCT00074581.

Program Resources and Innovative Models

Through the Minority HIV/AIDS Fund from the HHS Secretary's Office (MHAF) and HAB technical assistance (TA) cooperative agreements, HRSA has a number of projects that may be useful for RWHAP recipients to assist with program implementation. Some select examples are:

- **Building Futures: Supporting Youth Living with HIV** at <https://targethiv.org/library/hrsa-hab-building-futures-supporting-youth-living-hiv>
- **The Center for Engaging Black MSM Across the Care Continuum (CEBACC)** at <https://targethiv.org/cebacc>
- **E2i: Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV** at <https://targethiv.org/e2i>
- **Using Community Health Workers to Improve Linkage and Retention in Care** at <https://targethiv.org/chw>

Through HAB's SPNS Program, HRSA funds demonstration projects focused on the development of effective interventions to respond quickly to emerging needs of people with HIV that receive assistance under the RWHAP. Through these demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health related outcomes of innovative treatment models. Evaluating these models enables HRSA to identify successful interventions that can be replicated and disseminated nationally. SPNS findings have demonstrated promising new approaches for linking and retaining into care underserved and marginalized people with HIV. As resources permit RWHAP recipients are encouraged to review and integrate SPNS evidence-informed tools within their HIV system of care in accordance with the allowable service categories defined in [PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds](#). SPNS related tools may be found at the following locations:

- **Integrating HIV Innovative Practices (IHIP)** (<https://targethiv.org/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** (<https://targethiv.org/library/replication-resources-spns-systems-linkages-and-access-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**
(<https://targethiv.org/library/dissemination-evidence-informed-interventions>)

The Dissemination of Evidence-Informed Interventions initiative runs from 2015-2020 and disseminates 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 end goal of the initiative is to produce 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.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: Competing continuation

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 HAB personnel and other relevant resources to the project.
- Facilitating relationships between the 2iS CCTA, the 2iS EC, and other relevant stakeholders.
- Reviewing and concurring with, on an on-going basis, activities, procedures, measures, and tools to be established and implemented for accomplishing the goals of the cooperative agreement, including:
 - the process for identifying and assessing intervention strategies and implementation strategies using the HAB IS evidence rubrics,
 - the process for soliciting and selecting subawards to implementation sites to pilot test the interventions, and
 - determining dissemination plans for each of the piloted intervention strategies based on the evaluation findings.
- Reviewing and concurring with all information products prior to dissemination.
- Facilitating the dissemination of project findings, best practices, evaluation data, and other information developed as part of this project to the broader network of HIV providers.

The cooperative agreement recipient's responsibilities will include:

- Developing and carrying out a subawardee-tailored and multi-site evaluation.
- Developing a publication and dissemination plan in collaboration with the 2iS CCTA.
- Developing an assessment of learning session activities hosted by 2iS CCTA.

- Interpreting the evaluation findings of the overall effectiveness of the intervention strategies in terms of uptake, integration, and associated client outcomes along the HIV care continuum.
- Providing evaluation findings and insights to inform 2iS CCTA-developed replication products.
- Developing evaluation-related dissemination materials to describe the 2iS initiative and evaluation findings, such as manuscripts and professional conference presentations.
- Monitoring and informing the 2iS CCTA of data quality and completeness of data submissions.
- Training subawardee 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.

Overall project phases for 2iS CCTA (HRSA-21-076) and 2iS EC (HRSA-21-068)

As a lesson learned from the previous initiative for which this is a competing continuation (HRSA-17-044; HRSA-17-049), 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 2iS CCTA, the 2iS EC, and HRSA HAB on specific project activities.

Project Phases	2iS CCTA (HRSA-21-076)	2iS EC (HRSA-21-068)
Year 1, first quarter	<ul style="list-style-type: none"> • Convene with HRSA HAB and 2iS EC to develop joint work plan and timeline • Lead the identification and assessment of intervention strategies and implementation strategies • Develop and implement a process for selecting a subset of the identified intervention strategies and implementation strategies to be used for subawardee solicitation 	<ul style="list-style-type: none"> • Convene with HRSA HAB and 2iS EC to develop joint work plan and timeline • Support the 2iS CCTA in the identification, assessment, and selection of intervention strategies and implementation strategies • Finalize general approach/goals for the evaluation to inform intervention strategy selection

Year 1, second quarter	<ul style="list-style-type: none"> • Develop and implement a process for solicitation and selection of subawardees • Lead assessment of TA needs for selected subawardees • Develop a process for TA tracking and subawardee monitoring • Develop site visit plans for the implementation phase (years 2-3) 	<ul style="list-style-type: none"> • Support the 2iS CCTA to carry out solicitation and selection of subawardees • Support 2iS CCTA with assessment of TA needs based on evaluation goals
Year 1, third quarter	<ul style="list-style-type: none"> • Lead the development of implementation plans for each subawardee • Develop TA plans for each subawardee • Develop TA tools to support and monitor the subawardees • Support 2iS EC with developing data collection tools 	<ul style="list-style-type: none"> • Support the 2iS CCTA to develop implementation plans for each subawardee • Develop tailored and multi-site evaluation plans • Develop data collection systems and tools
Year 1, fourth quarter	<ul style="list-style-type: none"> • Finalize TA plans and tools • Support subawardees in staff recruitment and preparation for implementation • Provide TA to prepare for implementation • Develop dissemination materials • Lead development and implementation of intervention trainings for subawardees 	<ul style="list-style-type: none"> • Begin baseline data collection • Lead subawardee data collection systems trainings • Develop evaluation-related dissemination materials • Support the 2iS CCTA intervention trainings for subawardees
Year 2, first quarter	<ul style="list-style-type: none"> • Initiate subawardee implementation of intervention strategies • Provide technical assistance • Monitor subawardees 	<ul style="list-style-type: none"> • Continue baseline data collection • Continue subawardee data collection systems trainings • Continue subawardee data support and data monitoring

Years 2-3	<ul style="list-style-type: none"> • Continue subawardee implementation • Monitor subawardees • Provide technical assistance • Conduct biannual learning sessions (2 per year) • Support the 2iS EC to determine the feasibility of and implement any mid-implementation adjustments • Support the 2iS EC with each learning session evaluation • Develop dissemination materials • Produce quarterly TA tracking summaries (quantitative and qualitative) 	<ul style="list-style-type: none"> • Collect data • Continue subawardee data support and data monitoring • Conduct biannual learning session evaluation • Lead determining the feasibility of and implementing any mid-implementation adjustments • Produce biannual preliminary evaluation findings • Develop evaluation-related dissemination materials
Year 3, fourth quarter	<ul style="list-style-type: none"> • Closeout subawardee implementation period • Develop dissemination materials 	<ul style="list-style-type: none"> • Support subawardees to complete final data reporting • Develop evaluation-related dissemination materials
Year 4, first quarter	<ul style="list-style-type: none"> • Lead the assessment of dissemination plans for each intervention strategy based on TA tracking, learning sessions, and preliminary evaluation findings • Conduct learning session • Develop dissemination materials • Lead subawardee program integration planning 	<ul style="list-style-type: none"> • Collect data and perform client outcome evaluation • Support 2iS CCTA to assess dissemination plans for each intervention strategy based on TA tracking, learning sessions, and preliminary evaluation findings • Present preliminary evaluation findings • Develop evaluation-related dissemination materials

Year 4, second-third quarters	<ul style="list-style-type: none"> • Lead development and assessment of dissemination plans for each intervention strategy based on TA tracking, learning sessions, and preliminary evaluation findings • Develop tools for replication of intervention models • Develop implementation-related materials for dissemination • Conduct a final learning session 	<ul style="list-style-type: none"> • Support 2iS CCTA to develop and assess dissemination plans for each intervention strategy based on TA tracking, learning sessions, and preliminary evaluation findings • Conduct analyses of project data for implementation and client outcome evaluation • Develop evaluation-related materials for dissemination • Develop evaluation tools for replication products • Conduct final learning session evaluation
Year 4, fourth quarter	<ul style="list-style-type: none"> • Disseminate replication products and promote materials 	<ul style="list-style-type: none"> • Disseminate evaluation findings and promote materials

At least annually, the successful 2iS EC applicant should plan to collaborate with HRSA HAB to update existing work plans and, as needed, integrate new priorities during the funding period (e.g., through monthly strategy discussion calls, or other communication as needed).

2. Summary of Funding

HRSA estimates approximately \$1,050,000 to be available annually to fund one (1) recipient. The actual amount available will not be determined until enactment of the final FY 2021 federal appropriation. You may apply for a ceiling amount of up to \$1,050,000 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. Funding beyond the first year is subject to the availability of appropriated funds for the *Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV* program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

The period of performance is August 1, 2021, through July 31, 2025 (4 years).

If you are applying for funding under this announcement (HRSA-21-068) and under the companion Coordinating Center announcement (HRSA-21-076), you must be able to demonstrate the ability to administer multiple federal awards and to ensure adequate quality controls, staffing, and impartiality.

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

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include entities eligible for funding under RWHAP Parts A, B, C and D. These include but are not limited to: public and nonprofit private entities involved in addressing HIV-related issues at the regional or national level; 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.

2. Cost Sharing/Matching

Cost-sharing/matching is not required for this program.

3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in [Section IV.4](#) non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

The NOFO is also known as “Instructions” on Grants.gov. You must select “Subscribe” and provide your email address for each NOFO you are reviewing or preparing in the workspace application package 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, and abstract. You must submit the information outlined in the 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 *Application Guide* for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files included in the page limit may not exceed the equivalent of **80 pages** when printed by HRSA. 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-21-068, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, 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) Where you are unable to attest to the statements in this certification, 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](#).

ii. Project Narrative

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

Successful applications will contain the information below. Please use the following section headers for the narrative:

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

Briefly describe the purpose of the proposed project as it responds to the purpose outlined in this NOFO.

Provide a clear and succinct description of the roles and activities of the 2iS EC. Describe the 2iS EC's overall approach to how it will conduct the initial, interim, and final assessments and evaluations of the intervention strategies and implementation strategies used by subawardees in the four (4) focus areas:

- 1) Improving HIV health outcomes for people with substance use disorder
- 2) Improving HIV health outcomes for lesbian, gay, bisexual, transgender, and/or queer (LGBTQ+) youth
- 3) Improving HIV health outcomes for people who are justice system-involved and/or experiencing incarceration
- 4) Improving HIV health outcomes by using telehealth services

Briefly describe the applicant organization and your ability to conduct both multiple tailored evaluations simultaneously, as well as multi-site evaluations with common variables across sites.

- NEEDS ASSESSMENT -- Corresponds to Section V's Review [Criterion #1 Need](#)

Provide a summary of the literature that demonstrates a comprehensive understanding of issues regarding the role of innovative intervention strategies in reducing HIV-related health disparities and improving health outcomes, including improving retention in care, treatment adherence, and viral suppression in relation to the four focus areas. Discuss the four focus areas and provide a summary discussion, supported by the literature that demonstrates an understanding of the significance of each for ending the HIV epidemic.

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 effectively evaluate health care interventions aimed at improving health outcomes. Include examples of previous evaluation findings in this initiative's four focus areas.

- METHODOLOGY -- Corresponds to Section V's Review [Criteria #2 Response](#), [#3 Evaluative Measures](#), and [#4 Impact](#)

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

Intervention Strategy and Implementation Strategy Selection

- Describe what assistance you will provide to the 2iS CCTA and what approach you will use in determining which intervention strategies focused on the four areas will be identified, cataloged, and assessed.
- Describe the processes that you will employ to ensure that you can assess and evaluate the selected intervention strategies..

Needs assessment/baseline evaluation

Describe the approach(es) used and how the 2iS EC will:

- Support the 2iS CCTA to identify, catalog, and assess existing intervention strategies in the four focus areas and implementation strategies known to support the successful implementation/uptake and client outcome impact of HIV intervention strategies.
- Develop the multi-site evaluation including site-specific and cross-site components for each 2iS CCTA subawardee. The proposed evaluation plan must include, but is not limited to:
 - A review of relevant literature and identification of their theoretical basis
 - Evaluation components
 - Staffing and programmatic requirements
 - Costs
 - Existing resources, where available

Data collection

Describe the plan to develop, with input from the 2iS CCTA, a data collection tool for use by 2iS CCTA subawardees funded for this project to collect data at regular intervals in an electronic format.

Describe the organizational process for working directly with 2iS CCTA subawardees for collection of outcome and process data.

Discuss how the 2iS EC will assist the 2iS CCTA subawardees in data collection including the following:

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

Describe how the 2iS EC will collect evaluation data from the subawardees. 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 2iS CCTA.

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). Identify 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 2iS EC or the 2iS CCTA subawardees 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 subawardees 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 interventions by the subawardees, including improved health outcomes, at regular intervals, and at the conclusion of the period of performance.

Describe how you will evaluate complex and multi-faceted intervention strategies. Describe the variables that you will include to assess successful implementation and associated client health outcomes along the HIV care continuum. Those may include:

- Intervention exposure variables
- Organizational structure variables
- Contextual variables and barriers/facilitators
- HIV care continuum outcome variables based on medical record data
- Costing variables

You may propose the use of other measures, if applicable, from the NHAS measures, EHE measures, or other HAB measures. 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 subawardees 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 20 subawardee sites over the course of the cooperative agreement.

Mid-implementation adjustments assessment:

- Discuss a plan for assessment of learning session activities.
- Describe the approach to be used in assessing any mid-implementation adjustments that identified as needed to the intervention strategies and/or implementation 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 subawardee.
- Describe a process to provide support to the 2iS CCTA to ensure adaptations and improvements in implementation plans are measurable.

Dissemination

Describe a plan for the dissemination of evaluation information and lessons learned obtained as a result of this project to both subawardees of this project, RWHAP recipients/subrecipients, and other HIV providers not funded under this project to adapt the interventions and implementation strategies within their organizations. Describe specifically how you will fully carry out

dissemination plans within the boundaries of the 4-year funding period. In particular, describe how the evaluation findings will be available for dissemination within just 12 months (in project year 4).

- Describe a plan for disseminating project information, activities, and preliminary findings throughout the project period at national conferences.
 - Describe a plan to support the 2iS CCTA and subawardee 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](#)

Provide a work plan that delineates the 2iS EC's activities or steps that will be used to achieve each of the goals for the four-year period of performance. 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 2iS CCTA.

Describe the activities or steps that will be used to achieve each of the activities proposed during the entire period of performance in the Methodology section. The work plan should be presented in a table format and include (1) goals; (2) objectives that are specific, measurable, achievable, realistic, and time-framed (SMART); (3) action steps or activities; (4) staff responsible for each action step; and (5) anticipated dates of completion. Include all aspects of planning, implementation, and evaluation.

Write overall goals for the work plan for the entire proposed four-year period of performance, but only include objectives and action steps for the goals set for Year 1. Write objectives and key action steps in time-framed and measurable terms providing numbers for targeted outcomes where applicable, not just percentages. First-year objectives should describe key action steps or activities that you will undertake to implement the project. Consider including hiring appropriate staff, coordinating the development of the data portal, and addressing IRB and HIPAA requirements. Include the work plan as **Attachment 1**.

- RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review [Criterion #2 Response](#)

Discuss challenges that you are likely to encounter in designing, planning, and implementing the multi-site evaluation, data collection, and provision of evaluation-related technical assistance described in the work plan.

Describe strategies you expect to use to resolve challenges and how you will document these as part of the evaluation process. Specifically,

- Describe the challenges that you are likely to encounter in the evaluation of an innovative intervention strategy within varied medical settings serving racial and ethnic minority populations, and propose strategies that have been or that you may employ to overcome these challenges.
- Describe challenges to providing evaluation and data collection technical assistance to RWHAP recipients within a variety of settings, and 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 [#5 Resources and Capabilities](#)

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 and allow for changes so that maximum impact of the initiative is achieved.

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 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 2iS CCTA.

- ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review [Criterion #5 Resources/Capabilities](#)

Describe your organization's experience conducting multiple tailored or customized and multi-site evaluations assessing the effectiveness of intervention

strategies. Describe your organization's experience in research, evaluation, and dissemination of findings on issues related to engagement and retention in HIV primary care and improved HIV-related health outcomes for people with HIV. Describe how these all contribute to your organization's ability to successfully carry out project activities and meet the goals and objectives of this initiative.

Include a one-page project organizational chart as **Attachment 2** depicting the organizational structure of only the project (not the entire organization), and include contractors (if applicable) and other significant collaborators. If consultants and/or contractors will be used to provide any of the proposed services, describe their roles and responsibilities on the project. Signed letters of agreement, memoranda of understanding, and descriptions of proposed and/or existing contracts related to the proposed project should be included in **Attachment 3**.

Describe your organization's abilities to disseminate evaluation findings that resulted in increased engagement and retention in HIV primary care and improved HIV-related health outcomes, lessons learned, and other findings from multi-site evaluations. Describe the capacity of your organization's management information systems to support a comprehensive multi-site evaluation in the collection, reporting, and secure storage of client-level data.

Describe the experience of proposed key project staff (including any consultants and contractors) that demonstrates the necessary knowledge, experience, training, and skills for this project.

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 and how the work had a positive impact on the health outcomes of the people with HIV served by the organization.

Describe the proposed processes you will use, if funded, for oversight of contractors in the delivery of any project activities, and monitoring contractor performance.

Include in this section the roles of all personnel (including consultants and contractors) involved in each activity. Identify the personnel members who will manage and oversee the coordination of evaluation and evaluation-related technical assistance activities described in the Methodology section.

Include a staffing plan for proposed project staff and brief job descriptions to include the role, responsibilities, including who will manage/oversee the various project activities, and qualifications and include as **Attachment 4**. See *Section 4.1. of HRSA's [SF-424 Application Guide](#)* for additional information.

Include short biographical sketches of key project staff as **Attachment 5**. See *Section 4.1. of HRSA's [SF-424 Application Guide](#)* for information on the content for the sketches.

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 the 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 an 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 *Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Evaluation Center* program requires the following:

- Line Item Budget for Years 1 through 4: Submit line-item budgets for each year of the proposed period of performance as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs, as **Attachment 6**.

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 202 states, "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](#).

NARRATIVE GUIDANCE	
In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.	
Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response (3) Evaluative Measures and (4) Impact
Work Plan	(2) Response
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

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 limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Clearly label each attachment.**

Attachment 1: Work Plan (required)

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative.

Attachment 2: Project Organizational Chart (required)

Provide a one-page figure that depicts the organizational structure of the Evaluation Center.

Attachment 3: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific) (required, if applicable)

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 agreements should clearly describe the roles of the contractors and any deliverables. Letters of agreement must be dated.

Attachment 4: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's [SF-424 Application Guide](#)) (required)

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff.

Attachment 5: Biographical Sketches of Key Personnel (required)

Include biographical sketches for persons occupying the key positions described in Attachment 4, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 6: Line Item Budgets for Years 1 through 4 (required)

Attachment 7: Summary of known intervention strategies (required)

Include a summary table of known intervention strategies in the three (3) priority populations and one (1) area of opportunity to improve service delivery based on a comprehensive search of the published and grey literature. The summary table should include the intervention strategy name, brief description, focus area, and citations. Pay particular attention to intervention strategies that are feasible to implement in RWHAP settings and those that address known disparities and areas of greatest need. These may include but are not limited to race/ethnicity, aging, gender identity, sexual orientation, housing status, rurality, non-English language intervention strategies, a focus on retention-in-care, use of remote intervention delivery/telehealth, and use of social media for client recruitment and outreach. The summary table should prioritize innovative and timely intervention strategies, even if those have less published evidence. This summary will be shared with the 2iS CCTA and used as a baseline starting point for the identification of existing intervention strategies at the beginning of the initiative. Not included in the page limit.

Attachments 8-15: Other Relevant Documents (optional)

Include here any other documents that are relevant to the application, including letters of support. 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 pages: [Planned UEI Updates in Grant Application Forms](#) and [General Service Administration’s UEI Update](#).

You must also 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 the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR §

25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and 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 use that determination as to 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 (<http://www.dnb.com/duns-number.html>)
- System for Award Management (SAM) (<https://www.sam.gov>)
- Grants.gov (<http://www.grants.gov/>)

For further details, see Section 3.1 of HRSA's [SF-424 Application Guide](#).

[SAM.GOV](#) ALERT: For your SAM.gov registration, you must submit a [notarized letter](#) appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

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](#).

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 *March 8, 2021, 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

Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Evaluation Center is a program not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100. See Executive Order 12372 in the [HHS Grants Policy Statement](#).

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 four (4) years, at no more than \$1,050,000 per year (inclusive of direct **and** indirect costs). 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 A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) and Continuing Appropriations Act, 2021 and Other Extensions Act (P.L. 116-159) are in effect at the time this NOFO is posted. Please see Section 4.1 of HRSA's SF-424 Application Guide for additional information. Note that these or other restrictions will apply as required by law in subsequent appropriations acts for FY 2021.

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

- Provision of direct health care or supportive services
- To develop materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual
- Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (nPEP) medications or the related medical services [RWHAP Parts C and D recipients *may* provide prevention counseling and information to eligible clients' partners (see the [June 22, 2016, RWHAP and PrEP program letter](#))]
- 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.aids.gov/federal-resources/policies/syringe-services-programs/>
- Purchase or construction of new facilities or capital improvement to existing facilities
- Purchase of or improvement to land
- Purchase of vehicles
- International travel
- Cash payments to intended recipients of RWHAP services

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 the 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.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be 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 the objective review,

Review criteria are used to review and rank applications. The Program has six (6) review criteria. See the review criteria outlined below with specific detail and scoring points.

<u>Review Criteria</u>	<u>Points associated</u>
Criterion 1: Need	5 points
Criterion 2: Response	35 points
Criterion 3: Evaluative Measures	25 points
Criterion 4: Impact	10 points
Criterion 5: Resources/Capabilities	15 points
Criterion 6: Support Requested	10 points
TOTAL	100 points

Criterion 1: NEED (5 points) – Corresponds to Section IV’s [Introduction](#) and [Needs Assessment](#)

Introduction

- The strength and feasibility of the overall approach to conducting the initial, interim, and final assessments and evaluations of the intervention 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

- The extent to which the summary of the literature demonstrates a comprehensive understanding of issues regarding the role of intervention strategies to reduce HIV-related health disparities and improve health

- outcomes, including increasing retention in care, improving treatment adherence, and improving viral suppression, in relation to the four focus areas.
- The clarity of the discussion of the issues impacting the effective implementation of innovative intervention strategies.
 - The ability to effectively describe the role of an implementation science framework in the effective implementation and evaluation of innovative intervention strategies.
 - The clarity of the discussion of techniques used to effectively evaluate health care interventions among the initiative's four focus areas.

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

Methodology (15 points)

- The strength and feasibility of the plan for the implementation of the multi-site evaluation and data collection technical assistance.
- The strength, clarity, and feasibility of the methodology to support the 2iS CCTA's selection of intervention strategies and subawardees.
- The strength and clarity of the approach to develop a data collection tool for use by the subawardees.
- The strength and clarity of the approach to provide technical assistance to subawardees 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 extent to which the outline of a clear and comprehensive plan for monitoring data quality and data completeness, and communicating results to the 2iS CCTA.
- 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 subawardees regarding IRB approval.

Work Plan (15 points)

- The strength and clarity of the work plan and its goals for the four-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 4-year period of performance.

Resolution of Challenges (5 points)

- The strength and clarity of the described plan to address possible challenges

that are likely to be encountered during the design and planning of the multi-site evaluation.

- The clarity and feasibility of the approach, strategies, and techniques to resolve anticipated challenges.

Criterion 3: EVALUATIVE MEASURES (25 points) – Corresponds to Section IV's Evaluation section of [Methodology](#) and [Evaluation and Technical Support Capacity](#)

Methodology (20 points)

- The strength and effectiveness of the method proposed to support a needs assessment for each subawardee, to be led by the 2iS CCTA, particularly in terms of evaluation-related needs such as organizational capacity for data collection capacity.
- The strength and completeness of the plan for evaluating each subawardee intervention.
- 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 intervention strategies for each of the four focus areas.
- The strength and clarity of the proposed multi-site 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 likelihood of long-term sustainability/integration of interventions.
- The strength and feasibility of the proposed methods for measuring associated costs of implementing the intervention 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 subawardees.

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 Evaluation and Dissemination section of [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 2iS CCTA-led 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.
- The strength and clarity of the plans for the development of an evaluation toolkit.

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 intervention strategies.
- The extent of experience in research, evaluation, and dissemination of findings on issues related to engagement and retention in HIV primary 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 an award within available funding ranges. HRSA may also consider the assessment of risk and the other pre-award activities described in Section 3 below.

See Section 5.3 of HRSA’s [SF-424 Application Guide](#) for more details.

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

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 the 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 posed 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 issue the Notice of Award (NOA) prior to the start date of August 1, 2021. 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 Notice of Award, 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 Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

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 may copyright 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. 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 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.

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 a trimester basis. Further information will be available in the NOA.
- 2) **Preliminary Findings**. The recipient must submit a biannual preliminary evaluation findings report. Further information will be available in the NOA.

Please 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 H. Smith, M.H.S., R.R.T.
Senior 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:

Demetrios Psihopaidas, Ph.D., MA
Senior Health Scientist, Evaluation, Analysis, and Dissemination Branch
Division of Policy and Data, HIV/AIDS Bureau
Attn: Funding Program
HIV/AIDS Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 09N186B
Rockville, MD 20857
Telephone: (301) 443-1469
Email: dpsihopaidas@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, please 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 \(EHBs\)](#). 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
TTY: (877) 897-9910
Web: <http://www.hrsa.gov/about/contact/ehbhelp.aspx>

VIII. Other Information

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Wednesday, January 13, 2021
Time: 2 p.m. – 3:30 p.m. ET
Call-In Number: 1-800-779-5244
Participant Code: 3606454

Weblink: <https://hrsa.connectsolutions.com/hrsa-21webinar/>

The webinar will be recorded and should be available within 10 business days at <https://targethiv.org/library/nofos>. Answers to questions posed during and after the webinar will also be posted there.

Tips for Writing a Strong Application

See Section 4.7 of HRSA's [SF-424 Application Guide](#).