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 - Coordinating Center

Funding Opportunity Number: HRSA-21-076 Funding Opportunity Type: 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

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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 – Coordinating Center. The purpose of this initiative is to use an implementation science framework to identify innovative intervention strategies in four (4) focus areas, pilot test the intervention strategies at subawarded sites and provide technical assistance (TA), and develop replication tools and products. 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 Coordinating Center for Technical Assistance (2iS CCTA). The 2iS CCTA will solicit and subaward up to 20 Ryan White HIV/AIDS Program (RWHAP)-funded recipients/subrecipients (approximately five sites per focus area) to serve as implementation sites where one (1) intervention strategy per site will be piloted. The piloted intervention strategies will be evaluated through the companion funding opportunity announcement titled Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Evaluation Center (2iS EC; HRSA-21-068). Ultimately, the 2iS EC's evaluation findings will determine dissemination plans for the replication tools developed by the 2iS CCTA. Please review this companion announcement for more information about the role of the 2iS EC.

Funding Opportunity Title:	Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Coordinating Center
Funding Opportunity Number:	HRSA-21-076
Due Date for Applications:	March 1, 2021
Anticipated Total Annual Available	\$4,825,000
FY 2021 Funding:	
Estimated Number and Type of Award(s):	Up to one (1) cooperative agreement
Estimated Award Amount:	Up to \$4,825,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	August 1, 2021, through
	July 31, 2025
	(4 years)

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 Public Health Service Act; faith-based and community-based organizations; and Indian Tribes or Tribal organizations with or without federal recognition.
	See <u>Section III.1</u> of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Wednesday, January 13, 2021 Time: 2 p.m. – 3:30 p.m. ET Call-In Number: 1-800-779-5244 Participant Code: 3606454 Weblink: <u>https://hrsa.connectsolutions.com/hrsa-21webinar/</u>

The webinar will be recorded and should be available within 10 business days at <u>https://targethiv.org/library/nofos</u>. 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	
II. AWARD INFORMATION	8
1. TYPE OF APPLICATION AND AWARD	
III. ELIGIBILITY INFORMATION	13
1. ELIGIBLE APPLICANTS 2. COST SHARING/MATCHING 3. OTHER	13
IV. APPLICATION AND SUBMISSION INFORMATION	14
 ADDRESS TO REQUEST APPLICATION PACKAGE. CONTENT AND FORM OF APPLICATION SUBMISSION Project Abstract. Project Narrative. Budget. Budget Narrative. Budget	14 15 23 23 24 ITION 25 26 26 26
V. APPLICATION REVIEW INFORMATION	
1. REVIEW CRITERIA 2. REVIEW AND SELECTION PROCESS	32
VI. AWARD ADMINISTRATION INFORMATION	33
1. AWARD NOTICES 2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS	33
VII. AGENCY CONTACTS	35
VIII. OTHER INFORMATION	36

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 – Coordinating Center. The purpose of this initiative is to use an implementation science framework¹ to identify innovative intervention strategies in four (4) focus areas, pilot test the intervention strategies at subawarded sites and provide technical assistance (TA), and develop replication tools and products. 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 Coordinating Center for Technical Assistance (2iS CCTA). The 2iS CCTA will solicit and subaward up to 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. The piloted intervention strategies will be evaluated through the companion funding opportunity announcement titled Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Evaluation Center (2iS EC; HRSA-21-068). Ultimately, the 2iS EC's evaluation findings will determine dissemination plans for the replication tools developed by the 2iS CCTA. Please review this companion announcement for more information about the role of the 2iS EC. You may also review the previous initiative for which this is a competing continuation (HRSA-17-044; HRSA-17-049).

2iS Focus Areas

This initiative will focus on three (3) priority populations and one (1) area of opportunity to improve service delivery. 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

To identify implementation sites to pilot test the intervention strategies identified across the four (4) focus areas, the 2iS CCTA will be responsible for soliciting, selecting, issuing, and monitoring subawards of up to \$190,000/year each for up to twenty (20) RWHAP recipients or subrecipients (hereafter referred to as "subawardees"), or up to five (5) per focus area. The 2iS CCTA will select subawardees based on a

¹ Psihopaidas D, Cohen SM, West T, et al.; 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 2020;17(11):e1003128. <u>https://doi.org/10.1371/journal.pmed.1003128</u>

demonstrated need and capacity to implement one intervention strategy from one focus area through a competitive application process. The 2iS CCTA will provide TA to the selected subawardees to support successful uptake of the intervention strategy and engagement of clients. The 2iS CCTA will also develop dissemination products that will support the rapid replication of intervention strategies found to be successfully implemented and effective at improving client outcomes in subawardee sites.

The companion 2iS EC cooperative agreement (HRSA-21-068) will evaluate the uptake, implementation and associated client outcomes of these intervention strategies at the subawarded sites. Please review the related 2iS EC (HRSA-21-068) 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. HRSA awards RWHAP funds 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, which include 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 <u>Psihopaidas et al. (2020)</u> 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

² ibid.

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 second component is an *implementation science evaluation* plan. The details of the evaluation are outlined in the 2iS EC companion announcement (HRSA-21-068).

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 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

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.

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 oxymorphone–Indiana, 2015. MMWR Morb Mortal Wkly Rep 2015; 64:443–4. <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm</u>

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. <u>https://doi.org/10.1080/08964289.2013.866540</u>

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

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.1 5.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). <u>https://doi-org.ezproxyhhs.nihlibrary.nih.gov/10.1007/s10935-018-0525-8</u>.

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}

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 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

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. <u>https://link.springer.com/article/10.1007/s11524-020-00428-8</u>

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. <u>https://www.ncbi.nlm.nih.gov/pubmed/30289811</u>

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

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. <u>https://pubmed.ncbi.nlm.nih.gov/30851042</u>

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. <u>https://pubmed.ncbi.nlm.nih.gov/30826803</u>

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). <u>https://doi.org/10.1007/s10461-020-02926-x</u>

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 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 <u>performance measures</u> 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 <u>2019 Ryan White Services Report (RSR)</u>, 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 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 <u>Data Security and Confidentiality</u> <u>Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and</u> <u>Tuberculosis Programs: Standards to Facilitate Sharing and Use of</u> <u>Surveillance Data for Public Health Action.</u>
- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

¹⁷ Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2019. <u>http://hab.hrsa.gov/data/data-reports</u>. Published December 2020. Accessed December 2, 2020.

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: <u>https://clinicaltrials.gov/</u> NCT00074581 NLM Identifier: NCT00074581.

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.

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 <u>https://targethiv.org/library/hrsa-hab-building-futures-supporting-youth-living-hiv</u>
- The Center for Engaging Black MSM Across the Care Continuum (CEBACC) at <u>https://targethiv.org/cebacc</u>
- 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 <u>https://targethiv.org/chw</u>

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 <u>PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds</u>. SPNS related tools may be found at the following locations:

Integrating HIV Innovative Practices (IHIP) (<u>https://targethiv.org/ihip</u>)

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 (<u>https://targethiv.org/library/replication-resources-spns-systems-linkages-and-access-care</u>)

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 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:

- Leading the identification and selection of intervention strategies and implementation strategies with support from HRSA HAB and the 2iS EC.
- Leading the solicitation and selection of subawardees and preparation for pilot testing with support from HRSA HAB and the 2iS EC.
- Collaborating with intervention strategy developers and training subawardee staff to implement the intervention strategy.
- Monitoring subawardees and providing TA to adapt and implement the intervention strategies and collect evaluation data.
- Developing and hosting learning sessions.
- Supporting the 2iS EC in carrying out their multi-site evaluation.
- Collaborating with the 2iS EC to assess the implemented interventions to inform dissemination plans.
- Developing dissemination materials to support rapid replication of intervention strategies, to describe the project, and to disseminate project findings, including implementation toolkits, manuscripts, and professional conference presentations.
- Anticipating and responding to the changes taking place in the health care environment as they impact or may impact the initiative and/or subawardees.
- 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	 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 	 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	 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) 	 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	 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 	implementation plans for each subawardee
Year 1, fourth quarter	 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 	 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	 Initiate subawardee implementation of intervention strategies Provide technical assistance Monitor subawardees 	 Continue baseline data collection Continue subawardee data collection systems trainings Continue subawardee data support and data monitoring
Years 2-3 Year 3, fourth	 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) Closeout subawardee implementation period 	 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 Support subawardees to complete final data reporting
quarter Year 4, first	 Develop dissemination materials Lead the assessment of dissemination 	 Develop evaluation-related dissemination materials Collect data and perform client
quarter	 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 	 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	 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 	 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	Disseminate replication products and promote materials	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 (i.e., through monthly strategy discussion calls, or other communication as needed).

2. Summary of Funding

HRSA estimates approximately \$4,825,000 to be available annually to fund one (1) recipient. You may apply for a ceiling amount of up to \$4,825,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. You should note that the award amount includes approximately \$3,800,000 to fund up to 20 subawardees at a ceiling amount of up to \$190,000 each. The actual amount available for this program will not be determined until the enactment of the final FY 2021 federal appropriation. 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* – *Coordinating Center* 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-21-076) and under the companion Evaluation Center announcement (HRSA-21-068), 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 any domestic organizations of the following category: 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.

Foreign entities are not eligible for these HRSA awards.

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 <u>Section IV.4</u> 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 <u>Grants.gov</u> using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

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 <u>SF-424 Application Guide</u> 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 <u>SF-424 Application Guide</u> 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. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-076, 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* # 7-15: Other Relevant Documents.

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

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (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 <u>Review Criterion #1</u>

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

Provide a clear and succinct description of the roles and activities of the 2iS CCTA. Describe the 2iS CCTA's overall approach to how it will select and monitor up to 20 subawardees, as well as conduct the TA activities to support the subawardees' implementation of innovative intervention strategies in the three (3) priority populations and one (1) area of opportunity to improve service delivery; together these make up 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, 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

Briefly describe your organization, your ability to provide TA, and your experience managing group learning activities (e.g., learning sessions).

NEEDS ASSESSMENT -- Corresponds to Section V's <u>Review Criterion #1</u>

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 (4) focus areas.

Discuss the issues impacting the effective implementation of innovative intervention strategies. Discuss the role of an implementation science framework in the effective implementation of intervention strategies. Discuss the issues impacting the provision of effective TA tailored to individual subawardees with a diversity of needs and resources, particularly as they relate to improving health outcomes. Include examples where TA has led to successful strategies to overcome barriers to HIV care engagement and subsequent improvements in health outcomes with specific attention to people with HIV who use telehealth services, people with substance use disorder, LGBTQ+ youth, or people who are justice system-involved and/or experiencing incarceration.

METHODOLOGY -- Corresponds to Section V's <u>Review Criteria #2, 3, and 4</u>

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

Intervention Strategy and Implementation Strategy Selection

- Propose an approach to identify and create an inventory of existing intervention strategies with evidence of effectiveness, as defined by HRSA HAB,¹⁹ for supporting rapid and successful implementation in HIV care and treatment, in the four focus areas. Include a discussion of how you will incorporate and expand upon the baseline list of intervention strategies developed by the 2iS EC (please see HRSA-21-068, Attachment 7).
- Propose an approach to filter the inventory of the identified intervention strategies to be selected for potential implementation by the subawardees. This approach should include a process that creates a subset of intervention strategies that are promising, innovative, and feasible within the RWHAP.
- Describe an approach to identify specific implementation strategies that show promise in improving uptake, integration, and impact of intervention strategies, specifically for HIV care and treatment outcomes.
- Describe an approach to integrate implementation strategies with intervention strategies to improve uptake, integration, and impact within the four focus areas. The approach should describe when the integration will

¹⁹ Psihopaidas D, Cohen SM, West T, et al.; 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 2020;17(11):e1003128. <u>https://doi.org/10.1371/journal.pmed.1003128</u>

take place and how to manage the potential need for multiple strategies and multiple combinations of strategies to adapt them to the particular intervention strategy and/or subawardee.

 Discuss the methods to collaborate with the 2iS EC to monitor and evaluate fidelity to the intervention strategy as originally described and as adapted for this project. Discuss the importance of fidelity in an implementation science project to ensure participants will experience similar outcomes to those found in the original intervention.

Site Selection

Propose a plan to solicit and select up to 20 subawardees to implement intervention strategies that address one of the four focus areas described earlier in this announcement. Describe the approach to create the subawardee selection criteria in collaboration with HRSA HAB to ensure a diverse and representative sample of sites that reflect providers across the RWHAP. Describe how the selection criteria will ensure the identification and participation of a diverse group of RWHAP-funded organizations while considering:

- The subawardee applicant's experience with providing HIV care in one of the four focus areas targeted by the intervention strategies
- The subawardee applicant's demonstrated need for support to implement the specific intervention strategy
- The subawardee applicant's size, capacity, performance level, number of clients served, number of HIV cases reported in the selected focus area
- The existence of a robust data system, preferably in an electronic format, for collecting client-level data

Technical Assistance

- Describe an approach to assess TA needs, in consultation with HRSA HAB and with the 2iS EC, for each subawardee.
- Discuss a proposed method to tailor the selected intervention strategies and implementation strategies, in collaboration with the 2iS EC, for each subawardee while maintaining fidelity to the core elements of the intervention strategy as originally described.
- Describe an approach to develop a TA plan for guiding each subawardee through the implementation of the intervention strategy. Describe the types of tools/materials needed to provide TA. Describe the methods that you will use to provide TA to subawardees. Describe the methods that you will use to monitor subawardees.
- Describe how you will track, organize, and summarize subawardee TA requests. Describe how you will synthesize and summarize this information in quarterly updates for the 2iS EC and HRSA HAB.
- Describe an approach to developing and maintaining a live file system to be accessible to HRSA HAB and the 2iS EC where all subawardee records will

be maintained and project team members can contribute to collaborative documents.

- Describe a plan and process for supporting the subawardes in understanding the intervention strategy they will implement in an implementation science framework, including: 1) the core elements of the intervention, 2) the tailorable or customizable components of the intervention strategy, 3) the implementation strategies used, 4) the determinants that the intervention strategy is intended to address, and 5) the mechanisms through which it is intended to address them.
- Describe a process for supporting sustainability planning for the subawardees throughout the implementation period in project years two and three and the beginning of project year four.

Learning Sessions

- Describe an approach to develop and facilitate two learning sessions per year during the second and third years of the project period, and one in the first half of the fourth year, to include all of the funded subawardees and the 2iS EC.
- Describe how the learning sessions will address different learning needs and assist subawardees with the implementation of innovative intervention strategies.
- Describe the components and structure of the learning session model and the steps that you will use to implement each session. The discussion should include a clear description of how the components and structure are grounded in the HRSA collaborative learning model, and what central role the subawardees will play in leading and facilitating discussions.
- Describe how you will work with the 2iS EC to identify expert facilitators and subawardee staff members to work together to engage in peer-led discussions and activities.
- Describe how you will work with subawardees to identify any potential midimplementation adjustments as a result of learning sessions, how you will collaborate with the 2iS EC and HRSA HAB to assess those proposed changes, and finally how you will work with the subawardees to integrate any approved adjustments.
- Describe the types of tools/materials needed for the provision of peer-topeer learning at the learning sessions.
- Describe how the learning sessions will be successfully carried out through an either in-person or virtual setting.

Evaluation

- Describe a plan for working collaboratively with the 2iS EC in the evaluation of both process and project outcomes, and assessment of midimplementation adjustments from the learning sessions.
- Describe a plan to work collaboratively with the 2iS EC to ensure that TA activities do not duplicate or undermine the evaluation.
- Describe a plan for integrating the findings of the evaluation with the TA tracking and subawardee monitoring reports in order to inform dissemination activities at the conclusion of project year four.

Dissemination

- Describe a plan for the development and dissemination of innovative and highly accessible tools and materials that describe the intervention strategies implemented in this initiative.
- Describe a plan for disseminating project information, activities, and findings throughout the project period at national conferences; include a discussion of how these presentations will include and highlight experiences and project insights of subawardee staff.
- Describe the key components of the replication products and tools for dissemination; include a discussion of how the tools are innovative beyond commonly used documents to describe intervention strategies, to maximize impact and accessibility.
- Describe how the replication products and tools for dissemination will incorporate the experiences of the subawardees funded through this initiative, including lessons learned from mid-implementation adjustments made by subawardees when applicable.
- Describe how the replication products and tools for dissemination will incorporate information regarding implementation strategies used, core components versus tailorable components of the intervention strategies, and implementation strategies.
- Describe the plan to disseminate information both to subawardees of this project and RWHAP grant recipients and subrecipients not funded under this project to adapt and rapidly replicate the intervention strategies within their organizations.
- Describe the plan for promoting materials/webinars using <u>TargetHIV</u> and the RWHAP Best Practices Compilation of four focus areas.
- Describe how you will ensure timely progress toward the creation of these materials such that they are ready for dissemination at the culmination of this project.

WORK PLAN -- Corresponds to Section V's <u>Review Criterion #2</u>

Provide a work plan that delineates your activities or steps to achieve each of the goals for the four-year project period. The work plan should be in table format and directly relate to the methods described in the Methodology section for this NOFO. The work plan is a tool to actively manage the project by including all aspects of planning and implementation of the intervention strategies.

The work plan must include clearly written (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.

You must clearly write overall goals for the entire proposed four-year project period. Provide objectives and action steps <u>only for the goals set for Year 1</u>. Write objectives and key action steps in time-framed and measurable terms, providing numbers for targeted outcomes where applicable, not just percentages.

Include key action steps or activities for your first-year objectives that you anticipate undertaking to implement the project. Consider including:

- Hiring appropriate staff,
- Developing an intervention strategy and site selection processes,
- Coordinating with the 2iS EC to determine the multi-site data components,
- Establishing quality control mechanisms and HRSA HAB review processes, and;
- Addressing Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPAA) requirements, as needed.

The work plan should be included as *Attachment 1*.

 RESOLUTION OF CHALLENGES -- Corresponds to Section V's <u>Review Criterion</u> <u>#2</u>

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

More specifically:

- Describe the challenges that are likely to occur in the implementation of an existing intervention strategy within varied program settings and propose potential strategies to overcome these challenges.
- Describe challenges to adapting existing intervention strategies for specific program settings and making mid-implementation adjustments to the implementation of those intervention strategies as needed, and propose potential strategies to overcome these challenges.
- Describe challenges to providing TA to and monitoring HIV service delivery organizations within a variety of settings, and techniques that you will use to address these challenges.

- Describe any anticipated challenges to the coordination of learning sessions and to managing peer-led group learning dynamics, and techniques that you will use to mitigate these challenges.
- EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's <u>Review Criteria #3 and 5</u>

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

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

Describe any experience in partnering with other entities for close collaboration as will be required in this initiative with the 2iS EC.

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

Describe your mission and structure, the scope of current activities, and experience in providing TA, especially to RWHAP and other HIV providers nationwide. Describe how these all contribute to your ability to successfully implement this project and meet the goals and objectives of this initiative. Describe your experience in providing TA for innovative intervention strategies to improve the delivery of HIV services to people with HIV. Describe an approach to providing TA without interfering with the replicability of the success demonstrated at the pilot sites.

 ORGANIZATIONAL INFORMATION -- Corresponds to Section V's <u>Review</u> <u>Criterion #5</u>

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 you plan to use consultants and/or contractors to provide any of the proposed services, describe their roles and responsibilities on the project. Include signed letters of agreement, memoranda of understanding, and descriptions of proposed and/or existing contracts related to the proposed project in **Attachment 3**.

Describe your organization's experience related to supporting innovative intervention strategies to improve linkage to and retention in care. Describe your level of experience in the area of developing intervention toolkits, specifically related to toolkits for HIV service delivery organizations or similar organizations. Describe your organization's experience in gathering data/information to determine the needs of health care providers or organizations related to the development and implementation of intervention strategies. Describe your organization's experience in tailoring intervention plans and strategies for specific organizations and subsequent adaptations of established intervention plans.

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

Describe the level and number of years of experience in supporting collaborative learning and TA projects, developing and disseminating informational materials, and providing TA to HIV-related organizations or similar organizations on a national level. Describe any experience in logistical planning and facilitation for learning sessions or other large meetings aimed at sharing information and expertise to build the knowledge and capacity of participants. Describe your organization's capacity to host webinars and webcasts, including platforms to be utilized.

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 past experience in the development of curricula, "How-To" manuals, implementation guides, or intervention toolkits including the topic areas and targeted audiences. Describe the experience in staying up-to-date on the latest, most innovative practices for the development of these materials.

If applicable, describe the proposed processes you will use for oversight of contractors in performance and delivery of any project activities. Include in this section the roles of all personnel (including consultants and contractors) involved in each activity.

Describe your organizational process to manage subawards that you will issue under this cooperative agreement. Include a description of your subaward process from initiation to approval, and your timeline for procurements. Describe the methodology for monitoring the subawardees including, among other items, the submission of invoices and reimbursement for services in a timely manner.

Include a staffing plan for proposed project staff and brief job descriptions to include the roles, responsibilities, including who will manage/oversee the various project activities, and qualifications and include as **Attachment 4**. *See Section 4.1. of* HRSA's <u>SF-424 Application Guide</u> 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 <u>SF-424 Application</u> <u>Guide</u> 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 a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Coordinating 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 <u>SF-424</u> <u>Application Guide</u> 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.

In addition to the requirements specified in the SF-424 Application Guide, the Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV program requires the following:

Subaward Budget Category: Include a description of funding for up to 20 RWHAP recipients or subrecipients (subawardees), at an amount of up to \$190,000/year each (up to \$3,800,000 total). The amount allotted for each subawardee must include sufficient funds to cover costs associated with the implementation of the intervention strategy as well as the collection and submission of evaluation-related data, travel to learning sessions if in-person, travel to present at national conferences if in-person, and the hiring of project-specific staff or allocation of existing staff.

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	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) 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 2iS CCTA project.

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 roles, 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)

Attachments 7 - 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: <u>Planned UEI Updates in Grant Application Forms</u> and <u>General Service</u> <u>Administration's UEI Update</u>.

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 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 (<u>http://www.dnb.com/duns-number.html</u>)
- System for Award Management (SAM) (<u>https://www.sam.gov</u>)
- Grants.gov (<u>http://www.grants.gov/</u>)

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

<u>SAM.GOV</u> ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> 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 annually through SAM located at <u>SAM.gov</u>.

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 <u>SF-424 Application Guide</u> for additional information.

5. Intergovernmental Review

Using Innovative Intervention Strategies to Improve Outcomes among People with HIV is a program not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 4 years, at no more than \$4,825,000 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. Awards will be made subsequent to enactment of the FY 2021 appropriation. The NOA will reference the FY

2021 appropriation act and any restrictions that may apply. 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:

- Charges that are billable to third-party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare)
- 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
- 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 <u>45 CFR § 75.307</u>.

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 Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Coordinating Center project has six (6) review criteria. See the review criteria outlined below with specific detail and scoring points.

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

Criterion 1: NEED (10 points) – Corresponds to Section IV's Project Narrative

Introduction (4 points)

- The strength and clarity of the description of the proposed project, including the approach to conducting TA activities to support the implementation of intervention strategies in the three (3) priority populations and one (1) area of opportunity to improve service delivery.
- The strength and clarity of the brief description of the organization's ability to provide TA.

Needs Assessment (6 points)

- The extent to which the summary of the literature demonstrates a comprehensive understanding of the role of intervention strategies on reducing HIV-related health disparities and improving health outcomes for people with HIV, including increasing retention in care, improving treatment adherence, and improving viral suppression, in relation to the three (3) priority populations and one (1) area of opportunity to improve service delivery.
- The extent to which the application demonstrates a thorough understanding of the roles and issues impacting implementation science in the effective implementation of innovative intervention strategies.
- The extent to which the application demonstrates a thorough understanding of challenges or barriers associated with the provision of effective TA tailored to individual subawardees with diverse needs and resources.
- The extent to which the application demonstrates a thorough understanding of the role of the evaluation in informing dissemination activities and the potential for TA provision to duplicate or undermine the evaluation and strategies to mitigate that.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's <u>Methodology</u>, <u>Work</u> <u><i>Plan</u>, and <u>Resolution of Challenges</u>

Methodology (15 points)

Intervention Strategy and Implementation Strategy Selection

- The strength, feasibility, and clarity of the approach to identify, filter, and select a subset of intervention strategies with evidence of effectiveness, as defined by HRSA HAB, for supporting rapid and successful implementation in HIV care and treatment, in the four focus areas.
- The strength, feasibility, and clarity of the approach to identify specific implementation strategies and the demonstrated understanding of the difference between implementation strategies and intervention strategies.
- The strength, feasibility, and clarity of the approach to integrate implementation strategies with intervention strategies to improve uptake, integration, and impact within the four focus areas.
- The strength, feasibility, and clarity of the methods to collaborate with the 2iS EC to monitor and evaluate fidelity to the intervention strategy as originally described and as adapted for this project.

Site Selection

- The strength and clarity of the plan to solicit and select up to 20 subawardees to implement intervention strategies.
- The strength and clarity of the proposed approach to develop site selection criteria that will ensure the identification of a diverse group of subawardees that ensures the identification of representative program sites, rather than program outliers with unusually strong capacity and/or resources.

Technical Assistance

- The strength and clarity of the approach to develop a TA needs assessment for each subawardee and use the findings to customize the selected intervention strategy and create a customized TA plan for each subawardee.
- The strength and clarity of the plan to track and synthesize TA requests from subawardees and subawardee monitoring reports to provide quarterly summaries to support the evaluation team.
- The strength and clarity of the discussion of how the provision of TA could duplicate and/or undermine the ability of other sites not funded through this initiative to replicate the success of the subawardees and clarity and specificity of described strategies to mitigate that risk.
- The strength and clarity of the plan to assess any proposed mid-implementation adjustments and support their integration where applicable while maintaining fidelity to the core elements of the intervention strategy.

Learning sessions

• The extent to which the application demonstrates a clear and compelling approach to develop and facilitate peer-led learning sessions in order to permit

subawardees to support and guide each other with the implementation of their intervention strategies.

- The strength and clarity of understanding of the components and structures of the HRSA collaborative learning model and how they will inform the learning sessions.
- The extent to which the application demonstrates the ability to work with the 2iS EC to identify expert facilitators to work with subawardee staff in peer-led discussion and activities.
- The extent to which the application demonstrates the ability to engage sites for peer-to-peer learning strategies to enhance communication across subawardee sites and to facilitate dialogue among staff within and across each focus area.

Work Plan (15 points)

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

Resolution of Challenges (5 points)

- The strength, clarity, and feasibility of the plan to identify challenges and propose solutions to adapting in-progress interventions in specific health care settings.
- The strength, clarity, and feasibility of the plan to identify challenges and propose solutions to providing TA to HIV service delivery organizations within a variety of settings.
- The strength, clarity, and feasibility of the plan to anticipate challenges to the coordination of collaborative and group learning dynamics and to describe techniques to address these challenges.
- The strength, clarity, and feasibility of the approaches, strategies, and techniques to resolve anticipated challenges.

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

Methodology (*Evaluation*; 5 points)

- The strength and clarity of the plan to support the 2iS EC and ensure close collaboration through every step of the project.
- The clarity and feasibility of the plan to support the 2iS EC in the multi-site evaluation of both process and project outcomes, and assessment of any mid-implementation adjustments from the learning sessions or other activities.

Evaluation and Technical Support Capacity (5 points)

• The extent to which the application's plan for the process evaluation clearly demonstrates how they will implement continuous quality improvement to monitor progress toward the goals and objectives of the project.

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

Learning sessions (5 points)

 The strength and clarity of the approach to assess and integrate any proposed mid-implementation adjustments identified by the subawardees and to capture the outcomes of the learning sessions and lessons learned in dissemination products.

Dissemination (5 points)

- The strength and clarity of the plan to develop highly innovative dissemination tools and materials to describe the intervention strategies and support their successful and rapid replication in other settings not funded through this initiative.
- The strength and clarity of the plan to collaborate closely with HRSA HAB and the 2iS EC to assess the intervention strategies implemented in this initiative, integrating TA tracking, site visit monitoring, and evaluation findings to inform dissemination plans.
- The strength and clarity of the plan to promote dissemination products.
- The strength and feasibility of the proposed methods for addressing the longterm sustainability of intervention strategies.

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV's <u>Evaluation and Technical Support Capacity</u> and <u>Organizational Information</u>

Evaluation and Technical Support Capacity (10 points)

- The extent to which the application demonstrates the capacity to provide implementation-related TA, including: proposed project personnel's knowledge, experience, training, and skills to provide implementation-related TA to HIV service delivery organizations serving people with HIV including in the four focus areas of this initiative.
- The extent to which the staffing plan (required in the application guide) and project organizational chart (*Attachment 2*) are consistent with the project description and project activities.

Organizational information (15 points)

- The extent to which the application demonstrates knowledge and experience conducting TA for innovative intervention strategies and models to improve linkage to care, retention in care, viral suppression rates, and the delivery of HIV services to people with HIV.
- The extent to which the application demonstrates knowledge of implementation science and its role in supporting efforts to end the HIV epidemic in the U.S.
- The extent to which the application demonstrates experience in gathering

data/information to identify needs and tailoring interventions according to specific organizations' needs.

- The extent to which the application clearly demonstrates experience and ability to collaborate with other agencies pertinent to the work of this project.
- The extent to which the application demonstrates experience in logistical planning and facilitation of learning sessions or other large meetings aimed at sharing information and expertise to build knowledge.
- The extent to which the application demonstrates experience in hosting webinars/webcasts and developing curricula, "How-To" manuals, implementation guides, and intervention toolkits related to HIV service delivery.
- If applicable, the strength and clarity of the plan to oversee and monitor the contractor's performance and delivery of project activities.
- The strength and appropriateness of the job descriptions for key staff based on the goals and objectives of this project (*Attachment 4*).
- The strength and appropriateness of the biographical sketches based on the goals and objectives of this project (*Attachment 5*).
- 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 extent to which the application demonstrates prior experience soliciting and managing subawards.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's <u>*Budget*</u> and <u>*Budget Narrative*</u>

- The extent to which costs outlined in the proposed budget are reasonable and appropriate for the project objectives.
- The strength and clarity of the budget narrative to support each line item budget.
- The extent to which contracts for proposed contractors or consultants are clearly described in terms of contract purposes; how costs are derived; and that deliverables are reasonable and appropriate, if applicable.
- The extent to which costs outlined in the proposed budget for the subawardees are reasonable and appropriate for project objectives.

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 the award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for the award. See Section 5.3 of HRSA's <u>SF-424 Application Guide</u> for more details.

3. Assessment of Risk

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

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 <u>Federal Awardee Performance and Integrity Information System (FAPIIS)</u>. 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 <u>FAPIIS</u> 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 (<u>45 CFR §</u> <u>75.212</u>).

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 <u>SF-424 Application Guide</u> for additional information.

2. Administrative and National Policy Requirements

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

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

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 <u>45 CFR § 75.101 Applicability</u> 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 (<u>45 CFR part 46</u>) 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 <u>SF-424 Application Guide</u> and the following reporting and review activities:

- Progress Report(s). The recipient must submit a progress report to HRSA on a trimester basis (i.e., three times per year). Further information will be available in the NOA.
- 2) **TA tracking.** The recipient must submit a quarterly update of tracked TA activities to HRSA HAB.

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: <u>bsmith@hrsa.gov</u>

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

Demetrios Psihopaidas, PhD, MA Senior Health Scientist, Evaluation, Analysis, and Dissemination Branch Division of Policy and Data, HIV/AIDS Bureau Attn: Using Innovative Intervention Strategies to Improve Health Outcomes among People with HIV – Coordinating Center HIV/AIDS Bureau Health Resources and Services Administration 5600 Fishers Lane, Room 09N-186B Rockville, MD 20857 Telephone: (301) 443-1469 Fax: (301) 443-8143 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: <u>support@grants.gov</u> Self-Service Knowledge Base: <u>https://grants-</u> <u>portal.psc.gov/Welcome.aspx?pt=Grants</u>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through <u>HRSA's Electronic Handbooks (EHBs)</u>.

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

The webinar will be recorded and should be available within 10 business days at <u>https://targethiv.org/library/nofos</u>. 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.