U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

HIV/AIDS Bureau
Office of Training and Capacity Development

Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Evaluation and Technical Assistance Provider

Funding Opportunity Number: HRSA-20-115 Funding Opportunity Type: New Assistance Listings (CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: June 15, 2020

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: April 15, 2020

MODIFICATION: MAY 15, 2020: anticipated available annual funding increased from \$700,000 to \$1,000,000; number of demonstration sites increased from 7 to 12; footnote #1 updated on page 1.

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Authority: Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, Title II and 42 U.S.C. § 300ff-101 (section 2691 of the Public Health Service (PHS) Act).

EXECUTIVE SUMMARY

Supported through funding from the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health Minority HIV/AIDS Fund (MHAF), the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau, Special Projects of National Significance (SPNS) Program is accepting applications for fiscal year (FY) 2020 for *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Evaluation and Technical Assistance Provider* (ETAP). The purpose of this cooperative agreement is to support a single organization to lead a multi-site evaluation and provide technical assistance (TA) to a cohort of up to 12 demonstration sites funded under a separate announcement number, HRSA-20-116: *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Demonstration Sites*.

The ETAP will provide TA and capacity building to the demonstration sites; work collaboratively with the sites to implement a comprehensive multi-site evaluation; and disseminate successful models, findings, best practices, and lessons learned for the Ryan White HIV/AIDS Program (RWHAP) community.

Funding Opportunity Title:	Improving Care and Treatment Coordination:	
	Focusing on Black Women with HIV –	
	Evaluation and Technical Assistance Provider	
Funding Opportunity Number:	HRSA-20-115	
Due Date for Applications:	June 15, 2020	
Anticipated Total Annual Available	Up to \$1,000,000	
FY 2020Funding:		
Estimated Number and Type of	1 Cooperative Agreement	
Award(s):		
Estimated Award Amount:	Up to \$1,000,000 per year subject to the	
	availability of appropriated funds	
Cost Sharing/Match Required:	No	
Period of Performance:	September 1, 2020 through	
	August 31, 2024	
	(4 years)	

Eligible Applicants:	Entities eligible for funding under Parts A – D of Title XXVI of the PHS Act, including public and nonprofit private entities, state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; community health centers receiving support under Section 330 of the PHS Act; faith-based and community-based organizations; and Indian Tribes or Tribal organizations with or
	based and community-based organizations; and Indian Tribes or Tribal organizations with or without federal recognition.
	See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility
	information.

Application Guide

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

Technical Assistance

HRSA strongly encourages all applicants to participate in a webinar for this funding opportunity to ensure the successful submission of the application. The purpose of the webinar is to assist potential applicants in preparing applications that address the requirements of the NOFO.

HRSA has scheduled the following technical assistance webinar:

Day and Date: Thursday, April 30, 2020

Time: 1:00 p.m. - 2:30 p.m. ET Call-In Number: 1-800-593-8953 Participant Code: 2516127

Weblink: https://hrsa.connectsolutions.com/hrsa-20-115-pre-app-ta/

The webinar will be recorded and should be available at <a href="https://www.targethiv.org/category/resource-type/training-resource-type/

Audio playback will be available as follows:

Playback Number: 1-800-879-4907

Passcode: 2156

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for fiscal year (FY) 2020 funding under the Improving Care and Treatment Coordination: Focusing on Black Women with HIV -Evaluation and Technical Assistance Provider (ETAP) program. Funding will be provided in the form of a cooperative agreement to support a single organization to lead a multi-site evaluation and provide technical assistance (TA) to a cohort of up to 12 demonstration sites funded under a separate announcement number, HRSA-20-116: Improving Care and Treatment Coordination: Focusing on Black Women with HIV -Demonstration Sites. The awarded ETAP organization will evaluate the implementation of the demonstration sites' bundled interventions and their outcomes on the HIV care continuum for future replication and scale-up in other Ryan White HIV/AIDS Program (RWHAP) provider organizations. These demonstration sites are supported for up to three years and tasked to design, implement, and evaluate the use of bundled interventions for Black women with HIV. Bundled interventions are a group of evidenceinformed practices put together into a package that when implemented together produces better health outcomes than when the practices are delivered separately.¹ Bundled interventions will address socio-cultural health determinants, expand the delivery and utilization of comprehensive HIV care and treatment services, support continuous engagement in care, and improve health outcomes for Black women with HIV in a culturally sensitive and responsive manner. HRSA will award grants under this funding announcement to entities in severely underserved areas that contain high populations of Black women with HIV.

The ETAP will also provide TA and capacity building to demonstration sites by facilitating peer-to-peer collaborative learning on the interventions. In addition, the ETAP will lead dissemination of evaluation findings, best practices and lessons learned, and promote the replication of successful bundled interventions in other Ryan White HIV/AIDS Program (RWHAP) providers and other health care settings.

Because award recipients under both NOFOs (HRSA-20-115 and HRSA-20-116) will need to work together to be successful, HRSA, HIV/AIDS Bureau (HAB) encourages you to read and familiarize yourself with the program expectations of the companion NOFO, HRSA-20-116 (Improving Care and Treatment Coordination: Focusing on Black Women with HIV –Demonstration Sites)

The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health MHAF project, authorized under Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, Title II, is also supported, in part, through SPNS, authorized under 42 U.S.C. § 300ff-101 (section 2691 of the PHS Act).

HRSA-20-115

¹ Huhman M. "Bundled Interventions." *Encyclopedia of Health Communication.* Ed. Teresa L. Thompson. Vol. 1. Thousand Oaks: SAGE Publications, Inc., 2014. 140-142. *SAGE Knowledge*. <u>Bundled Interventions Definition</u>.

Key Definitions:

For purposes of this announcement, HRSA uses "Black women with HIV" to describe the study population for inclusion in the Special Projects of National Significance (SPNS) multi-site evaluation. The actual evaluation project is intended to collect information only concerning Black women with HIV. However, individual programs are required to serve all people regardless of race, ethnicity, or gender. Additionally, in this initiative, a Black woman is described as a cisgender or transgender female who self-identifies as Black or African American or a combination of Black or African American and one or more of the other racial categories. This includes Black - Hispanic and Black - Not Hispanic.

For the purposes of this initiative, **evidence-informed interventions** are strategies, models, or approaches that have been proven effective or have shown promise as a methodology, practice, or means of improving the care and treatment of people with HIV. Evidence-informed should be understood as distinct from evidence-based. Evidence-informed interventions with strong evidence bases may meet evidence-based criteria established by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention (CDC). However, evidence-informed interventions may demonstrate the impact and strength of evidence without meeting AHRQ, CDC, or other criteria for being evidence-based.

For the purposes of this initiative, **HIV care services** are defined as all of the HIV clinical care and treatment services allowable through the RWHAP. For more information regarding RWHAP eligible services, refer to Policy Clarification Notice (PCN) #16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds.

Social determinants of health (SDOH) are conditions in which people are born, grow, live, work, and age. They include factors like socioeconomic status, education, neighborhood, and physical environment, community violence, employment, and social support networks, as well as access to health care. Intimate partner violence (IPV) is among these factors that can disproportionately affect underserved communities.

According to CDC, National Intimate Partner and Sexual Violence Survey (NISVS), intimate partner violence (IPV) describes physical violence, sexual violence, stalking, or psychological harm by a current or former partner or spouse, and can have direct and indirect effects on individual, family, and community health. In 2017, HRSA launched the HRSA Strategy to Address IPV, an effort to address this critical social determinant of health through agency-wide collaborative action. The Strategy includes four priority areas including (1) Training the nation's health workforce, (2) Building partnerships to raise awareness, (3) Increasing access to quality care, and (4) Addressing gaps in knowledge about IPV risks, impacts, and interventions. You are strongly encouraged to consider one or more of these priority areas, as relevant, in the development and measurement of your initiative.

2. Background

Disparity, which is defined as a lack of similarity or equality, inequality or difference,² is a word often used to characterize HIV health outcomes for Black women.³ The CDC shows a decline in new infections among Black women in the United States.⁴ However, the epidemic's disproportionate effect on Black people warrants the need to address some of the social and structural issues that hamper HIV prevention strategies in Black communities.

Black women with HIV have worse health-related outcomes than women of other racial and ethnic backgrounds ⁵ and face significant barriers to accessing, engaging, and staying in medical care. Decreased adherence to antiretrovirals (ART), increased missed medical appointments, and poorer mental health status are all in part impacted by socio-cultural factors like unstable housing, lack of transportation, and lack of trust in healthcare providers.^{6,7} For Black women with HIV, coping with a new health condition and navigating the health system can be a complex, multi-level process. Therefore, the women's adaptation and resilience is often based on the social, psychological, and/or cultural context and framing of their life with HIV (i.e., how they view their disease).

As reported in the 2018 Ryan White HIV/AIDS Program Annual Client-Level Data Report, 87.1 percent of clients who received HIV medical care reached viral suppression by 2018.8 The overall percentage of Black women who were retained in care was 82.5 percent and those virally suppressed were 85.7 percent. However, retention in care was lower for Black women ages 20–24 years (76.9 percent), 25–29 years (76.7 percent) and 30–34 years (76.7 percent).9 Additionally, percentages of viral suppression among Black women were lower among those in each of the 5-year age group ranging from 15–34 years (range: 69.6 percent–77.9 percent); for those with

² Disparity. (n.d.). Available at www.dictionary.com/browse/disparity .Accessed August 14, 2018

³ Bradley ELP, Geter A, Lima AC, Sutton MY, Hubbard McCree D. Effectively Addressing Human Immunodeficiency Virus Disparities Affecting US Black Women. Health Equity. 2018 Nov 16;2(1):329-333.

⁴ Centers for Disease Control and Prevention, "New HIV Diagnoses Among Women in the US and Dependent Areas, 2017", last modified, Jan. 21, 2020, https://www.cdc.gov/hiv/group/gender/women/index.html

⁵ Sullivan KA, Messer LC, and Quinlivan EB. Substance abuse, violence, and AIDS (SAVA) syndemic effects on viral suppression among HIV positive women of color. AIDS Patient Care STDs 2015; 29 (Suppl 1): S42–S48.

⁶ Schumann CL, Westergaard RP, Meier AE, et al. Developing a patient navigation program to improve engagement in HIV medical care and viral suppression: A demonstration project protocol. AIDS Behavior. 2019 Jan; 23(Suppl 1):5-13.

⁷ Watkin-Hayes et al

⁸ Ryan White HIV/AIDS Program Annual Client-Level Data Report. 2018, pg 6. https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2018.pdf

⁹ Ibid. pg. 7

perinatal acquired infection (70.8 percent); and those with temporary (80.3 percent) or unstable housing (73.6 percent).¹⁰

Women with HIV have various complex needs. Research shows that many Black women struggle with overlapping issues, such as physical and sexual violence and trauma or IPV, homelessness, mental health needs, and co-occurring STIs. 11,12 Likewise, the intersection of race, gender, social status, and sexuality impacts Black women's process of coping at varying levels of power and access to institutional and healthcare resources. 13,14 For some Black women with HIV, balancing care for self and for family, coming to terms with experiences that increased vulnerability to infection, and both internalized and external stigma, 15 provide significant barriers to accessing and remaining in HIV care. Thus innovative interventions to better understand and engage Black women are needed to improve health outcomes. A high prevalence of co-existing health concerns combined with low levels of patient engagement in HIV care shows the need for "comprehensive, multifaceted interventions to promote Black women's sustained engagement throughout the HIV care continuum." 16

Previous initiatives and interventions for women of color, including Black and Latina women, focused on general HIV health outcomes and disparities. However, gaps in HIV knowledge, education, interventions, cultural sensitivity, and comprehensive care for Black women still exist. To promote long-term health and stability for Black women with HIV, this MHAF initiative will support organizations to develop and implement innovative strategies for integrating comprehensive and culturally appropriate HIV care, social and behavioral health services, wellness coaching, and stigma reduction into a bundled intervention. The ETAP will monitor project outcomes to identify progress towards emerging or promising practices and intervention strategies focused on Black women. The initiative will also document challenges and opportunities resulting from these intervention strategies, and share lessons learned with MHAF recipients and the wider HIV, Women's health, and RWHAP communities.

¹⁰ Ibid.

¹¹ Sullivan KA, Schultz K, Ramaiya M, et al. Experiences of women of color with a nurse patient navigation program for linkage and engagement in HIV care. AIDS Patient Care STDs. 2015; 29: Suppl 1. S49-S54.:

¹² Sullivan, Messer, and Quinlivan, 2015

¹³ Ojikutu BO, Stone VE, and Bardeguez A. Women of Color and HIV/AIDS: Epidemiology, Clinical Aspects, and Management. In *HIV/AIDS in US Communities of Color*. 2009. Valerie Stone, Bisola Ojikutu, M. Keith Rawlings, and Kimberly Y. Smith, eds. Pp. 83–101. New York, NY: Springer.

¹⁴ Watkin-Hayes et al

¹⁵ Ibid

¹⁶ Sullivan, Schultz, Ramaiya, et al 2015, pg S52.

¹⁷ Mays, VM., Maas RM, Ricks J, and Cochran SD. HIV and African American Women in the U.S. South: A Social Determinants Approach to Population-Level HIV Prevention and Intervention Efforts. In *Handbook of Health Psychology 2nd ed.* 2012. Andrew Baum, Tracey A. Revenson and Jerome Singer, eds. Pp. 771–801. New York: Psychology Press.

Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration announced a new initiative, Ending the HIV Epidemic: A Plan for America. This 10-year initiative beginning 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 will focus 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. Across the United States, the initiative will promote and implement the 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).

National HIV/AIDS Strategy: Updated to 2020

The National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS 2020) is a 5-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. The RWHAP promotes robust advances and innovations in HIV health care using the National HIV/AIDS Strategy to end the epidemic as its framework. Therefore, to the extent possible, activities funded by RWHAP focus on addressing these 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 supports needed (e.g., mental health and substance use disorders services) to achieve HIV viral suppression

HIV Care Continuum

Diagnosing and linking people with HIV to HIV 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 "steps" or 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 2018 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2014 to 2018, 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 81.4 percent to 87.1 percent; additionally, racial/ethnic, age-based, and regional disparities have decreased. 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. 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.

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, needs assessments, unmet need estimates, reporting, quality improvement, the development of your 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.

Integrated HIV data sharing, analysis, and utilization approaches by state and territorial health departments can help further progress toward reaching the NHAS 2020 goals and improve outcomes on the HIV care continuum.

¹⁸ Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018. http://hab.hrsa.gov/data/data-reports. Published December 2019. Accessed December 2, 2019.

¹⁹ National Institute of Allergy and Infectious Diseases (NIAID). Preventing Sexual Transmission of HIV with Anti-HIV Drugs. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 Mar 29]. Available from: https://clinicaltrials.gov/ NCT00074581 NLM Identifier: NCT00074581.

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 and territorial 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.

Minority HIV/AIDS Fund from the HHS Secretary's Office (MHAF), HAB Technical Assistance, and Special Projects of National Significance (SPNS) Program
Through the MHAF and through HAB technical assistance (TA) cooperative agreements, HRSA has a number of projects that may be useful for RWHAP recipients to consider. Some select examples are:

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

Below are additional examples for specific populations, co-morbidities, and program areas: https://targethiv.org/help/ta-directory

Through HAB's SPNS Program, HRSA funds demonstration project initiatives focused on the development of effective interventions to respond quickly to emerging needs of people with HIV receiving assistance under the RWHAP. Through these demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health related outcomes of innovative treatment models, while promoting dissemination, replication and uptake of successful interventions. SPNS findings have demonstrated promising new approaches to linking and retaining into care underserved and marginalized people with HIV. All RWHAP recipients are encouraged to review and integrate a variety of SPNS evidence-informed tools within their HIV system of care in accordance with the allowable service categories defined in PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds as resources permit. SPNS related tools may be found at the following locations:

- Integrating HIV Innovative Practices (IHIP) (https://targethiv.org/ihip)
 Resources on the IHIP website include easy-to-use training manuals, curricula, case studies, pocket guides, monographs, and handbooks, as well as informational handouts and infographics about SPNS generally. IHIP also hosts TA training webinars designed to provide a more interactive experience with experts, and a TA help desk exists for you to submit additional questions and share your own lessons learned.
- Replication Resources from the SPNS Systems Linkages and Access to Care (https://targethiv.org/library/replication-resources-spns-systems-linkages-and-access-care)

There are Intervention manuals for patient navigation, care coordination, state bridge counselors, data to care, and other interventions developed for use at the state and regional levels to address specific HIV care continuum outcomes among hard-to-reach people with HIV.

• Dissemination of Evidence Informed Interventions (https://targethiv.org/library/dissemination-evidence-informed-interventions) The Dissemination of Evidence-Informed Interventions initiative runs from 2015-2020 and disseminates four adapted linkage and retention interventions from prior SPNS and the MHAF initiatives to improve health outcomes along the HIV care continuum. The end goal of the initiative is to produce four evidence-informed care and treatment interventions (CATIs) that are replicable, cost-effective, capable of producing optimal HIV care continuum outcomes, and easily adaptable to the changing healthcare environment. Manuals are currently available at the link provided and will be updated on an ongoing basis.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial programmatic involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

HRSA program involvement will include:

- Facilitating the availability and expertise of experienced HRSA HAB and HRSA OWH personnel as participants in the planning, development, and implementation of the project;
- Facilitating effective collaborative relationships with federal and state agencies, community-based and local organizations;
- Providing information resources, including TA resource centers and other entities of relevance to the initiative:

- Reviewing activities, procedures, measures, and tools to be implemented for accomplishing the program goals;
- Participating in the design and implementation of evaluation tools, evaluation plans, and other project material;
- Coordinating activities to address the evaluation-related training and TA needs of the demonstration sites; and
- Reviewing and participating in the dissemination of project activities, products, findings, best practices, evaluation data, and other information developed as part of this initiative to the broader health care, women's health, and RWHAP providers.

The cooperative agreement recipient's responsibilities will include:

- Designing and implementing a rigorous multi-site evaluation that includes outcome, process, and cost measures to assess the effectiveness of demonstration sites bundled interventions focused on Black women with HIV to improve their health outcomes along the HIV care continuum;
- Conducting focused evaluation studies on issues relating to the clinical, administrative financing, or public policy aspects of the initiative;
- Developing and maintaining a secure website, with both public and private password-protected access for the to serve as a data portal for the reporting of multi-site evaluation data by the demonstration sites and a communications nexus for the initiative;
- Coordinating the efforts of demonstration sites to assure the privacy and confidentiality of study participants in their health-seeking efforts;
- Assuring the appropriate review, approval, and renewal of all multi-site evaluation instruments and documents by an identified IRB;
- Providing TA on the adaptation, implementation, and evaluation of evidenceinformed interventions to demonstration sites through regular teleconferences, webinars, site visits, and in-person meetings for a range of needs over the course of the initiative;
- Coordinating and leading the logistics for two national multi-site meetings in each
 of the 3 years of the initiative with the demonstration sites in the Washington,
 DC/Metropolitan area;
- Conducting an annual site visit to each demonstration site for each year of the initiative;
- Leading and coordinating the publication and dissemination activities for the initiative, working in collaboration with the demonstration projects and HRSA staff:
- Assisting HRSA with information dissemination to constituencies upon request;
- Developing a final report highlighting the clinical, programmatic, and cost outcomes of the multi-site evaluation to facilitate future replication of successful models; and
- Collaborating with assigned HRSA project officers and other HRSA staff as necessary to plan, execute and evaluate the activities.

You are encouraged to collaborate with partner organizations, as needed, to conduct the recipient responsibilities and programmatic expectations to achieve the following four (4) goals:

1) Conduct a Rigorous Multi-Site Evaluation

The ETAP will design and implement a multisite evaluation plan to assess the effectiveness of the demonstration sites' bundled interventions. The evaluation plan proposed by the ETAP must include process and outcome measures, as well as assessing the cost of adapting and implementing the bundled interventions.

Key performance measures must include but are not limited to client retention, access to antiretroviral therapy, and viral suppression. The evaluation should also capture biomedical and behavioral health indicators, barriers and facilitators to retention in HIV medical care, and other measures proposed by the ETAP. Key performance measures must also include process analysis, cost analysis, and HAB Core Performance Measures:

- Process analysis will assess implementation of the bundled evidence-informed interventions, including but not limited to facilitators and barriers to implementation. The ETAP, in coordination with the demonstration sites, will develop the final core process methods.
- A cost analysis study (or cost-effectiveness study, if feasible) will measure the labor and programmatic costs and expenditures incurred by each demonstration site, to inform feasibility for future replication in RWHAP and other health care settings.
- HAB Core Performance Measures, ²⁰ specifically:
 - o Retention in HIV Medical Care
 - Percentage of patients, regardless of age, with a diagnosis of HIV who had at least two (2) encounters within the 12-month measurement year.
 - o Antiretroviral Therapy (ART) Among Persons in HIV Medical Care
 - Percentage of clients prescribed ART for the treatment of HIV infection in the 12-month measurement period
 - <u>Viral Suppression Among Persons in HIV Medical Care</u> Percentage of clients with a viral load <200 copies/mL during the last test in the 12month measurement period
- Additional HAB Core Performance Measures, ²¹ as needed
- Measurement of clients newly diagnosed

²⁰ HAB Performance Measures can be viewed at: https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf

²¹ HAB Performance Measures can be viewed at: https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf

- Measurement of individuals never in care
 - o People identified with HIV but have never entered care

Data Portal and Security: The ETAP will electronically receive, store, manage, and maintain de-identified client-level data to be collected and reported by demonstration sites. The demonstration sites will submit data to the ETAP through a secure data portal that the ETAP will design and maintain. The ETAP will coordinate efforts to assure the privacy and confidentiality of data submitted, collected, and stored. The ETAP will be responsible for monitoring data quality and completeness of submissions and interpreting evaluation results.

Website: In addition to a secure data portal, the ETAP will be responsible for developing and maintaining a project-specific website with both public access for communication of the initiative and private password-protected access for demonstration sites, ETAP, HRSA staff, and federal partners. The website will be expected to support TA resources for the multi-site evaluation; registration information for the national meetings of the initiative; recent findings of interest from outside the initiative; and links to relevant resources.

Institutional Review Board (IRB): Data to be collected and used in this initiative are classified as either public health data or client-level data. Public health data, such as HIV surveillance data and the Ryan White HIV/AIDS Program Services Report (RSR) treatment and support services data, are reported without disclosure of protected health information (PHI). The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) grants exemptions to covered entities that collect and report PHI for the purposes of communicable disease surveillance in public health activities and quality improvement in health care operations.²² IRB review will be required to determine where the Privacy Rule applies. Data that are PHI may not be submitted to HRSA/HAB, pursuant to section 2685 of the PHS Act.

Focused evaluation studies: In addition to the multi-site evaluation, the ETAP recipient will be responsible for conducting focused evaluation studies including but not limited to case studies or qualitative studies that focus on addressing issues and barriers specific to Black women with HIV that facilitate or impede access to, engagement, and retention in HIV clinical care and treatment. The ETAP, in collaboration with the demonstration sites, HRSA staff, and federal partners, will generate the specific topics for these focused studies.

2) Provide Evaluation and Implementation Technical Assistance

The ETAP will conduct an evaluation and provide TA to demonstration sites to support the implementation of the bundled interventions, designed to focus on Black women with HIV to improve their health outcomes. The ETAP will provide TA to the

²² See Summary of the HIPAA Privacy Rule at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html

demonstration projects in areas of intervention adaptation, implementation, and maintenance.

ETAP applicants, in designing their proposed evaluation and TA plans, should become familiar with the requirements for demonstration sites and the bundle of evidence-informed interventions that sites may implement under HRSA announcement number HRSA-20-116: *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Demonstration Sites.* For example, the demonstration sites will be funded to implement a minimum of three evidence-informed practices to offer a coordinated and comprehensive bundled intervention. The list of domains is provided in the companion NOFO, HRSA-20-116. The ETAP will provide training and other resources specifically tailored to the selected evidence-informed interventions for purposes of creating intervention manuals and tools for replication. The ETAP will assess demonstration sites' TA needs and will be responsible for the provision of evaluation-related TA to the demonstration sites. These overall TA goals will be achieved through regular face-to-face meetings, site visits, website resources, webinars, and teleconferences with the demonstration sites and designated HRSA program staff over the course of the project.

Intervention Manuals and Materials: The ETAP will coordinate with sites to adapt implementation tools and resources to provide competent and high-quality care for Black women with HIV, including bi-directional patient-provider education to establish better communication and coordination between HIV and ancillary and support service providers. These manuals and materials will be used by AIDS Education and Training Center (AETC) Programs to support uptake and replication of the successful models.

Site Visits: The ETAP will conduct, at minimum, one annual site visit with each demonstration site throughout the initiative, in coordination with federal staff, if available. The ETAP will develop a site visit protocol to guide the content and focus of these visits. Generally, the site visits will focus on the provision of TA as requested by the demonstration site or based on the ETAP's assessment. Site visit protocols should address TA needs in the areas of planning and project implementation, as well as data submission and data quality issues.

Grant Recipient Meetings: The ETAP will coordinate the logistics for two meetings with the demonstration sites during each year of the demonstration sites' 3-year period of performance. This activity includes but is not limited to meeting venue selection, logistics coordination, participant registration, development of meeting agendas, and meeting facilitation. While the ETAP is responsible for overall logistics and meeting costs, each demonstration site is responsible for its own travel costs, ground transportation, per diem and hotel accommodations for these meetings. All activities will be conducted in collaboration with HRSA staff, federal partners, and demonstration project staff. The meetings will take place in the Washington, DC metropolitan area.

3) Lead and Coordinate Dissemination of Findings

Dissemination: The ETAP, in coordination with HRSA staff, will lead the dissemination of findings and lessons learned from the bundled interventions designed to address the needs of Black women with HIV and improve their health outcomes along the HIV care continuum. The ETAP will be responsible for producing and disseminating TA toolkits, materials, and products to include intervention manuals. In collaboration with the demonstration sites, the ETAP will disseminate findings, including best practices and lessons learned to foster replication of these bundled interventions by other organizations that include patients who are Black women with HIV. This dissemination will include but is not limited to, intervention manuals that can be used by RWHAP and other organizations not funded under this project to adapt the bundled interventions within their organizations.

The ETAP will form a publication and disseminations committee, consisting of HRSA staff and demonstration site representatives, to generate research questions; topics for presentations and publications; concept sheets and analyses; and an overall dissemination plan for the initiative's products.

4) Promote Replication of Evidence-informed Interventions

The ETAP will develop intervention manuals and toolkits describing how to replicate bundled interventions proven effective in improving outcomes as well as best practices for implementation.

The ETAP will document challenges and opportunities of emerging intervention strategies and will share lessons learned with the demonstration sites and the wider HIV community. All materials will be disseminated to RWHAP and community health center programs.

The ETAP will also collaborate with national and regional AETC programs to optimize the potential for replication of these evidence-informed interventions and/or models of care. The network of AETC programs is uniquely positioned to help increase the capacity of HIV service providers to implement evidence-informed strategies for improving health outcomes of people with HIV. The AETC program provides education, training, and capacity-building resources to support its mission to offer timely, high quality, state-of-the-science information to health care professionals working with existing and emerging populations affected by HIV. AETC educational resources and events may be found at www.aidsetc.org.

2. Summary of Funding

HRSA estimates up to \$1,000,000 will be available annually to fund one (1) recipient. You may apply for a ceiling amount of up to \$1,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2024 (4 years). Funding beyond the first year is

subject to the availability of appropriated funds for *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Evaluation, and Technical Assistance Provider (ETAP)* in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. In addition, HRSA may reduce recipient funding levels beyond the first year if recipients are unable to fully succeed in achieving the goals listed in the application.

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

III. Eligibility Information

1. Eligible Applicants

Entities eligible for funding under Parts A – D of Title XXVI of the Public Health Service Act, including public and nonprofit private entities, state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; community health centers receiving support under Section 330 of the PHS Act; faith-based and community-based organizations; and Indian Tribes or Tribal organizations with or without federal recognition.

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. If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, 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 http://www.grants.gov/applicants/apply-for-grants.html.

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

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 may not exceed the equivalent of **60 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. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you 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 to be considered under this notice.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You, on behalf of the applicant organization, certify, 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 **Attachment 9**: 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.

In addition to the requirements listed in the <u>SF-424 Application Guide</u>, please list the following at the top of the page:

- Project Title
- Applicant Organization Name
- Address
- Proiect Director Name
- Contact Phone Numbers and Email Addresses

Using the following subheadings, include the following as part of the Project Abstract:

- Summary of the project: Include a brief summary description of the proposed project.
- Goals and Objectives: provide a brief description of the overall project goals and objectives.
- Overall multi-site evaluation questions
- Summary of Funding: Specify the funding amount requested for each year of the 4-year period of performance.

ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and well organized so that reviewers can understand the proposed project. Successful applications will contain the information below. Please use the following section headers for the narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion #1 (Need) This section should briefly describe the purpose of the proposed project. Provide a clear and succinct description of the roles and activities of the ETAP. Specifically, briefly describe how the ETAP will provide leadership in the implementation of the multi-site evaluation and dissemination activities, support replication, and assess TA needs and provide TA to the demonstration sites. Briefly describe the proposed multi-site evaluation plan and TA services that the ETAP will provide to the demonstration sites. Briefly describe your organization and any collaborating organizations.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 (Need) Provide a summary that demonstrates a comprehensive understanding of issues regarding the improvement of engagement and retention in HIV care focused on Black women. Additionally, provide a summary that demonstrates your understanding of the need to add to the field of implementation science evidence-informed bundled interventions that improve health outcomes for Black women with HIV. Discuss the client level, legal, technological, epidemiological, clinical, and systemic challenges that affect wider-scale adoption and/or optimal application of bundled interventions that improve health outcomes for Black women with HIV. Provide a discussion of the challenges associated with the evaluation, dissemination, and replication of evidence-informed strategies integrating behavioral health services into HIV care focused on Black women. When appropriate, corroborate your assessment with citations of literature and publications.
- METHODOLOGY -- Corresponds to Section V's Review Criterion #2 (Response)

The multi-site evaluation plan must include the longitudinal collection and reporting of relevant quantitative and qualitative outcome and process measures. Discuss anticipated evaluation questions for assessing the effectiveness and costs associated with the adaptation and implementation of the identified bundled evidence-informed interventions. At minimum, the evaluation plan must include the following elements:

- Patient survey to measure barriers and facilitators to retention and viral suppression;
- Clinical outcome measures;
- Qualitative process analysis to assess the barriers and facilitators to successful intervention implementation;
- o Quantitative process analysis to assess the intervention exposure; and
- Cost analysis to assess labor and programmatic costs incurred by the coordinated interventions across all phases – startup, implementation, and maintenance.

Describe a plan for conducting a rigorous, multi-site evaluation across demonstration sites to assess the bundling of evidence-informed interventions as a means to engage and retain Black women in HIV care. Describe the methodology for assessing the effectiveness and impact of bundled evidenceinformed interventions. Describe the methodology and theoretical framework that you will use to conduct the multi-site evaluation and provide the rationale for its selection. Describe the methodology for collecting, analyzing, and reporting relevant outcome and process measures for the interventions. Describe the set of proposed variables to be collected to evaluate the interventions' effectiveness. Describe your ability to use clinical and support services data. Provide a thorough rationale for any other data measures proposed that are relevant to the assessment of the interventions, specifying their sources and citing references in the literature that support their validation. You must propose the feasibility of collecting data elements based on the capacity of demonstration projects operating their interventions in real-world clinical settings, as is the case with RWHAPs.

Describe the design and implementation of a cost analysis study that will collect labor, training, structural, and other relevant costs the demonstration sites may incur. Describe the design and implementation of the proposed multi-site evaluation plan that reflect the dynamics of the demonstration projects' executing these types of interventions across provider service organizations in a changing health care environment.

Describe examples of potential focused studies of interest related to bundled interventions designed to include the care of Black women with HIV. Include a brief description, rationale, and possible impact of the special studies in addressing the goals and objectives of the initiative.

Describe your proposed approach to working collaboratively with the demonstration projects in leading data collection and reporting efforts for the multisite evaluation and additional focused evaluation studies. Describe a plan for the provision of TA to the demonstration sites over the course of the initiative, to include a routine means of TA needs assessment. Describe what kinds of TA needs are anticipated, and by what means they will be addressed, across the following: program development, implementation, sustainability, and program integration; multi-site evaluation; human research subjects' protection; IRB approval and renewal; and intervention manuals.

Describe how you will work with the demonstration sites in the provision of TA on IRB issues, including the provision of training to site staff to ensure proper management of IRB requirements and issues related to confidentiality of patient information.

In addition, describe your plan for creating a web portal and data repository system where information, multi-site data, and TA tools will be housed and available to the demonstration sites during the course of the initiative. Provide a

detailed plan for constructing and maintaining a secure website for the initiative to serve as a data portal for demonstration projects to report multi-site evaluation data. The website should also serve as a communications nexus for the initiative and have both public access for promotion of the initiative and private password-protected access for the demonstration project, ETAP, and HRSA staff. Additionally, the website will be expected to support TA resources for the multi-site evaluation; ongoing documentation of presentation, publication and dissemination efforts for the initiative; and a calendar of upcoming initiative events and national conferences with abstract submission deadlines. The website may also be used to disseminate recent findings of interest from outside the initiative; and links for relevant resources.

Describe your plan to conduct, at minimum, one site visit per year with demonstration site recipients to assess their intervention implementation and to deliver TA as needed. Describe the elements of a site visit protocol including timely documentation of all findings.

Describe your approach to leading and coordinating the semi-annual recipient meeting in each of the three years of the demonstration sites' period of performance in the Washington, DC metropolitan area, with the participation of the demonstration sites and the SPNS program.

Describe your approach in coordinating the publication and dissemination efforts for the initiative's findings and lessons learned in conjunction with the designated HRSA staff. Provide a brief discussion on the dynamics of the ETAP in coordinating the work of the publications and dissemination committee. Include a plan to disseminate reports, products, and/or project outputs to key target audiences.

Provide a dissemination plan identifying appropriate venues including the national and regional AETC program events and national conferences geared toward HIV primary care and social service providers and target audiences including, but not limited to, clinicians, program administrators, care providers, and policymakers. Include in your methodology proposed approaches for working with the AETC programs to integrate the evidence-informed strategies into clinical practice. The dissemination and replication plan should include lessons learned or best practices and help facilitate the replication of effective evidence-informed interventions into clinical practices.

Using the definitions for cultural sensitivity and cultural responsiveness provided below, describe your organizations' resources and capabilities to evaluate the provision of culturally and linguistically competent HIV care. Be specific in your description and where relevant provide examples of techniques, policies, and/or tools utilized and data to support and sustain successful outcomes.

- Cultural sensitivity is the ability to be appropriately responsive to the attitudes, feelings, or circumstances of groups of people that share a common and distinctive racial, national, religious, linguistic, or cultural heritage.²³
- Cultural responsiveness is a self and process-driven, lifelong commitment to a tailored, dialogue-based approach that responds to the needs being presented by the individual in front of the provider, within a contextual understanding of social/economic/political/linguistic disparities.²⁴

These include an understanding of integrated patterns of human behavior, including language, beliefs, norms, and values, as well as socioeconomic and political factors that may have a significant impact on psychological well-being and incorporating those variables into assessment, care, and services.

 WORK PLAN -- Corresponds to Section V's Review Criteria #2 (Response) and #4 (Impact)

Provide a work plan that delineates the ETAP's goals for the four-year period of performance. The work plan is to be used as a tool to manage the initiative by measuring progress, identifying necessary changes, and quantifying project accomplishments. The work plan should directly relate to your Methodology section and the program requirements of this announcement. Include all aspects of TA planning and provision; design and implementation of the multi-site evaluation; and publication and dissemination activities. The work plan should include written (1) goals for the entire proposed four-year period of performance; (2) objectives that are specific, time-framed, and measurable; (3) activities or action steps to achieve the stated objectives; (4) staff responsible for each action step (including consultants); and (5) anticipated start and completion dates.

Please note that goals for the work plan are to be written for the entire proposed four-year period of performance, but objectives and action steps are required only for the goals set for year one. First-year objectives should describe key action steps or activities that you will undertake to identify TA needs and implement the multi-site evaluation, including quality control mechanisms, IRB, and HIPAA requirements. Include the project's work plan as **Attachment 2**.

Logic Model

You must submit a logic model in **Attachment 2** for designing and managing the project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements.

²³ Office of Minority Health . National standards for culturally and linguistically appropriate services in health care. US Department of Health and Human Services; Washington, DC: 2001. p.131.

²⁴ National Alliance of State & Territorial AIDS Directors (NASTAD). Preparing Cultural Responsiveness in Health Care Delivery Setting. November 2015 https://www.nastad.org/sites/default/files/Cultural-Responsiveness-November-2015.pdf

While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:

- Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.);
- Inputs (e.g., organizational profile, collaborative partners, key personnel, budget, other resources);
- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a timeline used during program implementation; the work plan provides the "how-to" steps. You can find additional information on developing logic models at the following website: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

- RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion #2 (Response)
 - Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, logic model, and the proposed methods described in the Methodology section. Identify and describe the approaches that you will use to resolve such challenges.
- EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria #3 (Evaluative Measures), #4 (Impact), and #5 (Resources and Capabilities)

Describe your and your collaborating partner organization's (if applicable) capacity to conduct a comprehensive multi-site evaluation to assess the implementation and outcomes of the demonstration projects. Include evidence of experience, skills, training, and knowledge of proposed key project staff (including any consultants, sub-recipients, and contractors, if applicable) in achieving evaluation integrity in conducting a multi-site evaluation of national scope that will have maximum impact on practice and policy affecting engagement, access to, and retention in quality HIV medical care and ancillary services focused on Black women with HIV.

Describe how the proposed key personnel (including any consultants, sub-recipients, and contractors, if applicable) have the necessary knowledge, experience, training, and skills in designing and implementing public health program evaluations, specifically quantitative and qualitative outcome and process evaluations and cost studies of innovative and culturally appropriate HIV access and retention interventions.

Describe the capacity of the proposed project staff to provide TA to demonstration sites for the multi-site evaluation. Describe the experience of proposed project staff (including partner organization staff, if applicable) in providing TA to organizations that provide HIV and behavioral health care services. Include any experience with the provision of TA to organizations providing integrated care.

Describe the experience of proposed project staff (including partner organization staff, if applicable) in logistical planning and implementation of national meetings. Describe your knowledge of and experience with the submission of IRB materials and obtaining approvals and renewals for all client-level data collection instruments, informed consents, and evaluation materials. Describe any training in human subjects research protection by proposed project staff. Identify the IRB that will be responsible for the review, approval, and renewal of your multisite evaluation instruments.

Describe the experience of proposed key project staff (including any consultants and subcontractors) in collaborative writing and publishing study findings in peer-reviewed journals. Describe the experience of proposed key project staff in making presentations to local communities, state and national conferences, and to policymakers. Describe how the ETAP will provide the necessary training to the demonstration sites to ensure that each project fulfills the requirement of developing an intervention manual.

You must describe the systems and processes that will support your organization's multi-site evaluation requirements through effective tracking of performance outcomes, including a description of how the 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 current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery. You must describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

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

Describe your organization's mission, organizational structure, the quality and availability of facilities and personnel, and the scope of current activities. Describe how these all contribute to the organization's ability to successfully carry out a project of this magnitude and meet the goals and objectives of the initiative. You must demonstrate expertise in conducting program evaluation, in particular coordinating multi-site evaluations of demonstration projects across different geographical locations. You must demonstrate substantial expertise in the

implementation of research techniques including data management, statistical analysis, formulation of findings, and dissemination of findings through different publication venues.

Describe your experience conducting evaluations with racial/ethnic minorities, including Black women. Include information about your HIV experience, and expertise in identifying barriers and evaluating the facilitation of interventions to improve access, linkage, and retention in care for this population.

Describe the participation or inclusion of personnel with the necessary skills to communicate project findings to local communities, state and national conferences, and policymakers, and to collaborate in writing and publishing findings in peer-reviewed journals.

Include a staffing plan with job descriptions for key personnel (**Attachment 3**) that identifies staff credentials and commitments to the proposed project components. If you will use consultants and/or contractors to provide any of the proposed services, describe their roles and responsibilities on the project.

Include a project organizational chart as **Attachment 6**. The chart should be a one-page figure that depicts the project structure of the ETAP, not the entire organization. It should include sub-recipients, contractors and other significant collaborators, if applicable.

Describe the capacity of your organization's management information systems to support a comprehensive multi-site evaluation in the collection, reporting, and secure storage of client-level data. You must demonstrate that you have documented procedures for the electronic and physical protection of participant information and data. If you will use sub-recipients and/or contractors to provide services, describe their proposed roles and responsibilities. Include signed letters of agreement, memoranda of understanding, and descriptions of proposed and/or existing contracts related to the proposed project in **Attachment 5**.

Describe the ability of key personnel to successfully publish and disseminate findings about successful bundled interventions, lessons learned, and other findings from multi-site evaluations. Describe your experience in supporting the implementation of evidence-informed interventions. Describe the experience of proposed key project personnel (including any partner organizations) in collaborative writing and publishing study findings in peer-reviewed journals and in making presentations at conferences.

NARRATIVE GUIDANCE

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

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget
	section should include sufficient
	justification to allow reviewers to
	determine the reasonableness of the
	support requested.

iii. Budget

See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following the approved plan can 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) incurred by the recipient to carry out an HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the SPNS program requires the following:

Separate line-item budgets for each year of the four (4) year period of performance, using the Section B Budget Categories of the SF-424A and breaking down subcategorical costs as appropriate (**Attachment 1**).

The ETAP will conduct annual TA site visits with the demonstration sites, and lead

and coordinate the logistics for two meetings in each of the three years of the initiative with the demonstration sites. Costs for these activities should be included in the budget.

Key personnel includes the Principal Investigator, Project Director, and Evaluator. List each of these positions on the budget.

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, Title II, Sec. 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." Please see Section 4.1.iv Budget – Salary Limitation of HRSA's SF-424 Application Guide for additional information. Note that these or other salary limitations may apply in FY 2018, as required by law.

iv. Budget Narrative

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

In addition, the *Improving Care and Treatment Coordination for Black Women with HIV – ETAP* program requires the following:

Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of the proposed objectives. The budget period is for one year; however, you must submit projected one-year budgets for each of the subsequent budget periods within the requested period of performance (four years) at the time of application. The budget justification must clearly describe each cost element and explain how each cost contributes to meeting the project's objectives/goals.

For all staff listed on the budget identify what percentage of the FTE you will allocate to this award, the full salary amount and all other funding sources leveraged to account for the full salary. For subsequent budget years, the justification narrative should highlight the changes from year one or indicate that there are no substantive budget changes during the period of performance.

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. You must clearly label **each attachment**.

Attachment 1: Line Item Budgets Spreadsheet for Years 1 through 4, required. 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.

Attachment 2: Work Plan and Logic Model, required

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

Attachment 3: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's <u>SF-424 Application Guide</u>), required

Keep each job description to one page in length as much as possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

Attachment 4: Biographical Sketches of Key Personnel, required

Include biographical sketches for persons occupying the key positions described in Attachment 3, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

Attachment 5: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific), required

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

Attachment 6: Project Organizational Chart, required

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

Attachment 7: Tables, Charts, etc.

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

Attachment 8: Indirect Cost Rate agreement, if applicable (does not count toward page limit)

Attachments 9–15: Other Relevant Documents

Include here any other documents that are relevant to the application, including general 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 and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also HRSA-20-115

register with the System for Award Management (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)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is 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.

The Grants.gov registration process requires information in three separate systems:

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

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

<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 updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

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

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *June 15*, 2020 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

The Special Projects of National Significance Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to four years, at no more than up to \$1,000,000 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, title II and title V of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) apply to this program. Please see Section 4.1 of HRSA's SF-424 Application Guide for additional information. Note that these or other restrictions will apply in the following FY, as required by law.

You may not use funds under this notice for the following purposes:

- Charges that are billable to party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, HUD, etc.);
- To directly provide housing or health care services (e.g., HIV care, counseling, and testing);
- · Cash payments to intended RWHAP clients;
- Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (nPEP)
 medications or related medical services. (Please note that RWHAP recipients
 and providers may provide prevention counseling and information to eligible
 clients' partners see RWHAP and PrEP Program Letter, June 22, 2016);
- Syringe Services Programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy. See https://www.aids.gov/federal-resources/policies/syringe-services-programs/; or
- To develop materials designed to directly promote or encourage intravenous drug use or sexual activity, whether homosexual or heterosexual.
- Purchase or construction of new facilities or capital improvements to existing facilities:
- Purchase or improvement to land;

- Purchase vehicles: and/or
- International travel.

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

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

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

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

Review criteria are used to review and rank applications. The *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Evaluation and Technical Assistance Provider* (ETAP) has six (6) review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: Need	10 points
Criterion 2: Response	35 points
Criterion 3: Evaluative Measures	25 points
Criterion 4: Impact	10 points
Criterion 5: Resources/Capabilities	15 points
Criterion 6: Support Requested	5 points
Total	100 points

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

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

- Strength, clarity and relevance of applicant's brief description of the proposed Evaluation and TA structure, overall project goals, and overall multi-site evaluation questions.
- Extent to which the literature review demonstrates an in-depth understanding of the needs and issues related to providing coordinated care for Black women with HIV.
- Extent to which the applicant describes the need to evaluate the adaptation and implementation of care and treatment models that include HIV care, behavioral health services, and the impact of integrated or coordinated service models on the targeted population.
- Extent to which the applicant describes national incidence and/or prevalence rates of HIV infection among Black women using the most recently available data.
- Strength and clarity of the discussion of the issues that interfere with engaging and retaining people with HIV, including Black women, in quality HIV medical care and behavioral health treatment, and what strategies may be used to overcome them.

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

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

Methodology (15 points)

- Strength and clarity of described approach to working collaboratively with the demonstration projects in leading data collection and reporting efforts for the multi-site evaluation and additional focused evaluation studies.
- Strength, clarity, and feasibility of the proposed plan for the provision of TA to the demonstration projects over the course of the initiative, including a routine means of TA needs assessment.
- Strength, clarity, and feasibility of the applicant's description of the anticipated TA needs and the means by which they will be addressed.
- Feasibility of the proposed plan to review the demonstration projects' adaptation and implementation plans to safeguard the privacy and confidentiality of program participants, and their documented procedures for the electronic and physical

protection of study participant information and data, and a means to address deficits.

Work Plan (15 points)

- Strength, clarity, and feasibility of the work plan in achieving the ETAP's goals during the four-year period of performance (Attachment 2).
- Extent to which the goals of the work plan address the program requirements the applicant described in the Methodology section of the narrative.
- Evidence the objectives for year one are complete, specific to each goal, time-framed, and measurable.
- Evidence the work plan includes key activities associated with the design and implementation of the multi-site evaluation, TA provision, and dissemination of findings.
- Extent to which the work plan clearly identifies the staff responsible to accomplish each step, includes specific, time-framed, and measurable objectives and includes anticipated dates of completion.

Resolution of challenges (5 points)

• Extent to which the applicant clearly identifies possible challenges that are likely to be encountered during the planning and implementation of the TA and evaluation project and clearly describes realistic and appropriate responses to be used to resolve those challenges encountered.

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

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

- Strength, clarity, and feasibility of the proposed plan and methodology to conduct a rigorous multi-site evaluation and its rationale for selection.
- Extent to which the applicant clearly outlines the outcome, process, and cost
 elements of the multi-site evaluation and the possible measures to evaluate the
 client-level and process outcomes associated with adapting and implementing
 evidence informed models of care in an HIV treatment setting that incorporates
 behavioral health services.
- Strength and clarity of the elements for the outcome and process elements of the
 multi-site evaluation, including the patient survey to measure barriers and
 facilitators to retention and viral suppression; qualitative process analysis to
 assess intervention implementation; quantitative process analysis to assess
 intervention exposure; and cost analysis to assess labor and programmatic costs
 incurred by the bundled interventions.
- Extent to which the applicant describes the knowledge of and experience with training in human subjects research protection and submission of IRB materials

and obtaining approvals and renewals for all client-level data collection instruments, informed consents, and evaluation materials.

Criterion 4: IMPACT (10 points) –Corresponds to Section IV's Methodology, Work Plan, and Evaluation and Technical Support Capacity

The feasibility and effectiveness of plans for dissemination of project results, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

- Strength of the proposed approach, including committee involvement, in leading publication and dissemination efforts for the initiative's findings and lessons learned.
- Strength and feasibility of the proposed plan to develop timely and creative approaches to disseminating project findings, lessons learned about best practices.
- Strength and clarity of the proposed plan to develop dissemination products, including intervention manual and final report to target audiences including clinicians, program administrators, and policymakers. These dissemination products will be made available at venues such as national conferences geared toward HIV primary care and social service providers.
- Strength, clarity, and feasibility of the applicant's timeline for the development and release of the final report and other types of dissemination products.
- Strength, clarity and feasibility of the applicant's capacity to develop, understand and evaluate cultural sensitivity and responsiveness of the demonstration sites.

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

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

- i. Evaluation and Technical Support Capacity (10 points)
- Demonstrated capability of proposed key project staff in designing and implementing public health program evaluations, specifically quantitative and qualitative outcome and process evaluations and cost studies of innovative HIV access and retention projects.
- Evidence of specific experience in the design, implementation, and evaluation of programs serving people with HIV, including Black women, and strength of the applicant's capacity to conduct the required comprehensive multi-site evaluation
- Demonstrated capability to provide TA, especially in the areas of HIV medical care, behavioral health services, and the adaptation/replication of evidenceinformed interventions, to the demonstration sites during the implementation of their bundled interventions.

- Demonstrated capability of proposed project staff (to include consultants, subrecipients, and contractors, if applicable) in logistical planning and implementation.
- Strength and clarity of the staffing plan and job descriptions (Attachment 3).
- Strength and clarity of demonstrating the use and knowledge of cultural sensitivity and cultural responsiveness.

ii. Organizational Information (5 points)

- Demonstrated capacity of the applicant's management information system (MIS) to support a comprehensive multi-site evaluation in the collection, reporting, and secure storage of client-level data.
- Evidence of relevant organizational experience in providing TA on a national level.
- Strength of the applicant's knowledge of legislative and programmatic requirements of the RWHAP programs, current reporting protocols for the RWHAP, and the HIV care continuum.
- Demonstrated capability of proposed key project personnel (including any partner organizations) in collaborative writing, publishing, and disseminating study findings in peer-reviewed journals and in making presentations at conferences.
- Strength and clarity of the project organizational chart provided (Attachment 6).

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's budget, budget narrative, the line-item budget (Attachment 1), and the SF-424A

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

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable and relevant given the scope of work.
- The extent to which the narrative justification sufficiently justifies each line item.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- If applicable, the extent to which the applicant clearly describes sub-awards and/or contracts for proposed sub-recipients, contractors, and consultants in terms of scope of work; how costs were derived; payment mechanisms and deliverables are reasonable and appropriate.

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest-ranked applications receive consideration for an award within available funding ranges. HRSA may also consider an assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for award. See Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

Assessment of Risk

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

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

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

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

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

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2020. 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.

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 sub-recipients under awards. See 45 CFR § 75.101 Applicability for more details.

Data Rights

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

Human Subjects Protection

Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks. If you anticipate research involving human subjects, please review HRSA's SF-424 Application Guide to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application; if you do not have an assurance, you must indicate in the application that you will obtain

one from OHRP prior to award. In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following:

- develop all required documentation for submission of research protocol to IRB;
- communicate with IRB regarding the research protocol;
- · obtain IRB approval prior to the start of activities involving human subjects; and
- communicate about IRB's decision and any IRB subsequent issues with HRSA.

Client confidentiality requirements apply to all phases of the project. Prior to their IRB approval expiration, recipients must submit documentation from that IRB indicating the project has undergone an annual review and complies with all IRB requirements.

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:

- 1) **Progress Report**(s) The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be available in the NOA.
- 2) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR</u> part 75 Appendix XII.

VII. Agency Contacts

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

Beverly Smith
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857

Telephone: (301) 443-7065 Email: <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:

Adan Cajina, MSc
Chief, Demonstration and Evaluation Branch
Attn: SPNS-Black Women Initiative ETAP (HRSA-20-115)
Office of Training and Capacity Development, HIV/AIDS Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 9N108
Rockville, MD 20857

RUCKVIIIE, IVID 20057

Telephone: (301) 443-3180

Email: ACajina@hrsa.gov or SPNS@hrsa.gov

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

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: support@grants.gov

Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's 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: Thursday, April 30, 2020

Time: 1:00 p.m. - 2:30 p.m. ET Call-In Number: 1-800-593-8953

Participant Code: 2516127

HRSA-20-115

Weblink: https://hrsa.connectsolutions.com/hrsa-20-115-pre-app-ta/

The webinar will be recorded and should be available at https://www.targethiv.org/category/resource-type/training-resources.

Audio playback will be available as follows:

Playback Number: 1-800-879-4907

Passcode: 2156

Tips for Writing a Strong Application

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