U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



HIV/AIDS Bureau Office of Training and Capacity Development

Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Demonstration Sites

Funding Opportunity Number: HRSA-20-116 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

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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, Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Demonstration Sites. This funding opportunity announcement will fund up to seven demonstration sites to design, implement, and evaluate bundled interventions, a group of evidence-informed practices put together into a package that when implemented together produces better health outcomes than when the practices are delivered separately. 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.

Funding Opportunity Title:	Improving Care and Treatment
	Coordination: Focusing on Black Women
	with HIV – Demonstration Sites
Funding Opportunity Number:	HRSA-20-116
Due Date for Applications:	June 15, 2020
Anticipated Total Annual Available	\$2,170,000
FY 2020 Funding:	
Estimated Number and Type of Award(s):	Up to seven cooperative agreement(s)
Estimated Award Amount:	Up to \$310,000 per year subject to the
	availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020, through
	August 31, 2023
	(3 years)

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*. http://sk.sagepub.com/reference/download/encyclopedia-of-health-communication/n52.pdf

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 without federal recognition.

See <u>Section III.1</u> of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA 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: 3:00 p.m. – 4:30 p.m. ET Call-In Number: 1-888-469-3347 Participant Code: 6672543

Weblink: https://hrsa.connectsolutions.com/ta_webinar_hrsa20_116/

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

Playback Number: 1-888-566-0693

Passcode: 2516

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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 – Demonstration Sites.* Funding awarded under this announcement will support up to seven cooperative agreements for up to three years to design, implement, and evaluate the use of bundled interventions for Black women with HIV. Bundled interventions are a group of evidence-informed practices put together into a package that when implemented together produces better health outcomes than when the practices are delivered separately.² 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 is publishing this NOFO in conjunction with *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Evaluation, and Technical Assistance Provider (ETAP)*. All demonstration sites funded under this announcement will be required to collaborate with the ETAP, (to be funded separately under announcement number HRSA-20-115), which will facilitate technical assistance (TA) and lead a multi-site evaluation to measure the effectiveness of the bundled interventions and impact in the Ryan White HIV/AIDS Program (RWHAP). HRSA encourages you to read the companion announcement number HRSA-20-115, as applicants under both NOFOs are required to work together to ensure the success of the implementation and evaluation/technical assistance initiatives.

Key Definitions

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

² Huhman M. "Bundled Interventions." *Encyclopedia of Health Communication.* Ed. Teresa L. Thompson. Vol. 1. Thousand Oaks: SAGE Publications, Inc., 2014. 140-142. *SAGE Knowledge*. http://sk.sagepub.com/reference/download/encyclopedia-of-health-communication/n52.pdf

(PCN) #16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds.³

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.

Additional resources to assist you in determining how to effectively address intimate partner violence in your HRSA-funded programs may be found via the references included in the <u>HRSA Strategy to Address IPV</u>.

2. Background

This Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health Minority HIV/AIDS Fund (MHAF) project, is authorized under Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, Title II, supported, in part, through Special Projects of National Significance (SPNS), and authorized under 42 U.S.C. § 300ff-101 (section 2691 of the Public Health Service (PHS) Act).

Disparity, which is defined as a lack of similarity or equality, inequality or difference⁴, is a word often used to characterize HIV health outcomes for Black women.⁵ The CDC shows a decline in new infections among Black women in the United States.⁶ 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.

³ PCN# 16-02 can be viewed at https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters

⁴ Disparity. (n.d.). Available at <u>www.dictionary.com/browse/disparity</u>. Accessed August 14, 2018

⁵ 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.

⁶ 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

Black women with HIV have worse health-related outcomes than women of other racial and ethnic backgrounds⁷ 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, such as unstable housing, lack of transportation, and lack of trust in health care providers.^{8,9} For Black women with HIV, coping with a new health condition and navigating the health system can be a complex, multi-level process. Therefore, women's adaptation and resiliency are 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 2018.¹⁰ 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).¹¹ Additionally, percentages of viral suppression among Black women were lower among those in each of the 5-year age groups ranging from 15–34 years (range: 69.6 percent –77.9 percent); for those with perinatal acquired infection (70.8 percent); and those with temporary (80.3 percent) or unstable housing (73.6 percent).¹²

Women with HIV have various complex needs. Research shows that many women, particularly Black women, struggle with overlapping issues such as physical and sexual violence and trauma or IPV, homelessness, mental health needs, and co-occurring STIs. 13,14 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 health care resources. 15,16 For some Black women with HIV, balancing care for self and for family, coming to terms with past experiences that increased vulnerability to

⁷ 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.

⁸ 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.

⁹ Watkin-Hayes et al

¹⁰ 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

¹¹ Ibid, pg. 7

¹² Ibid.

¹³ 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.

¹⁴ Sullivan KA, Messer LC, and Quinlivan EB, 2015

¹⁵ 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.
¹⁶ Watkin-Hayes et al

infection, and both internalized and external stigma, ¹⁷ can 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 and overcome health disparities. 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". ¹⁸

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. ¹⁹ 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. This initiative 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.

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

 $^{^{17}}$ Ibid

¹⁸ Sullivan, Schultz, Ramaiya, et al 2015, pg S52.

¹⁹ 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.

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 performance measures developed for the RWHAP at their local level to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

According to recent data from the 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.²⁰ 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.²¹ 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

²⁰ 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.

²¹ 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.

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>
 Surveillance Data for Public Health Action.
- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated 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.

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 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 Minority HIV/AIDS Funds (MHAF) from the HHS Secretary's Office initiatives to improve health outcomes along the HIV care continuum. The end goal of the initiative is to produce four evidence-informed care and treatment interventions (CATIs) that are replicable, cost-effective, capable of producing optimal HIV care continuum outcomes, and easily adaptable to the changing healthcare environment. Manuals are currently available at the link provided and will be updated on an ongoing basis.

II. Award Information

1. Type of Application and Award

Type of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial 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 OWH personnel, as participants in the planning, development, and implementation of the project;
- Facilitating effective collaborative relationships with federal and state agencies and 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 on an on-going basis;
- 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:

- Completing the proposed initiative work plan activities within the three year project period;
- Collaborating with HRSA on review of activities, procedures, and budget items, including timely communication with project officer;
- Ensuring proposed activities are based on documented need, targeted for maximum impact on HIV care continuum outcomes, and designed to reach, engage, and retain Black women with HIV in care;
- Coordinating the activities with existing RWHAP entities and identified partnering agencies, when applicable;
- Collaborating with the ETAP on the development and implementation of a multisite evaluation;
- Participating in on-site and remote learning opportunities as coordinated and conducted by the ETAP;
- Developing and implementing a methodology, including proposed metrics, to measure the impact of proposed activities, as well as reporting on outcomes;
- Participating in all aspects of the multi-site evaluation and communicating with the ETAP. Cooperative agreement recipients must comply with requests for data

and information in accordance with specified timelines of the ETAP. Required multi-site evaluation activities will include, but are not limited to:

- Attending two SPNS multi-site recipient meetings per year. Travel to attend SPNS multi-site recipient meetings is limited to no more than three staff participants. Prior approval from the Project Officer is required for exceptions.
- Collecting and reporting multi-site evaluation data, as specified by the ETAP. Collect and submit data to the ETAP measuring the impact of the bundled interventions for HIV care of Black women with HIV.
- Documenting implementation processes, including action steps taken, lessons learned, and successes and barriers encountered.
- Cooperating with the ETAP to conduct focused evaluation studies of interest to the initiative, such as exploring case studies, cost analysis (including cost-effectiveness, if feasible), impact and/or policy issues pertaining to the goals and objectives of the project.
- Developing a sustainability and integration plan to support successful strategies following the conclusion of the cooperative agreement;
- Modifying activities as necessary to ensure relevant outcomes for the project;
 and
- Participating in the dissemination of project findings, best practices, and lessons learned, including adherence to MHAF and HRSA guidelines pertaining to acknowledgment and disclaimer on all products produced by MHAF and HRSA award funds.

Implementation of Bundled Interventions

HRSA will fund demonstration sites to adopt the delivery of multiple interventions focused on Black women with HIV. When delivered simultaneously, such interventions can produce better health outcomes, (i.e., improved engagement, higher retention, and improved viral suppression), than when these elements are delivered separately. Applicants must propose a minimum of two evidence-informed interventions to offer a coordinated and comprehensive bundled intervention to be delivered simultaneously. Interventions should include at least one of the following domains listed below, with the remaining being of the applicant's choice but related to the goals of the initiative:

- 1. Enhanced patient navigation, enhanced case management, or peer engagement;
- 2. Red Carpet Care Experience,²² which provides support and addresses barriers to accessing HIV care including such services as transportation, food/nutrition, housing, employment, mental health, or social support, among others:
- 3. Stigma reduction intervention that can speak to social determinants of health (e.g., address stigma and the environment, use media to show HIV has a human face, engage the community, help institutions recognize stigma, educate about stigma and HIV);

²² Crider, P and Karpen, C. Red Carpet Care: Breaking Down Barriers to Care. MetroHealth. https://dsas.cuyahogacounty.us/pdf dsas/en-US/2017RedCarpetCare.pdf, accessed Feb 19, 2020

- 4. Use of trauma-informed interventions, provider and/or organizational training on guiding principles to a trauma-informed approach;²³
- 5. Self-efficacy, health literacy or resiliency, and;
- 6. Interventions for IPV, physical and sexual violence, or other behavioral health needs (e.g. provider and /or organizational training on IPV, physical and sexual violence prevention, or behavioral health and care coordination with other community-based services).

As part of the bundled intervention design, these efforts must focus on Black women who are aware of their HIV status and who have fallen out of care, never entered into care, or are at high risk of falling out of care. Additionally, efforts will focus on Black women who are newly diagnosed or in care and not virally suppressed. Interventions should include coordination with local and partnering agencies that serve Black women, including but not limited to, social, cultural, behavioral, and community-based organizations. Addressing SDOH, such as IPV, is an HRSA objective to improve the health and well-being of individuals and the communities in which they reside.

HRSA HAB developed this initiative in collaboration with staff from HRSA's Office of Women's Health (OWH) to ensure the program design supports interventions that are culturally sensitive, inclusive, and empowering while providing care to women who are geographically isolated or economically or medically vulnerable. This project not only furthers HRSA's *Ending the HIV Epidemic: A Plan for America* initiative (EHE) goals related to addressing social determinants of health and reducing health disparities, but enhances the OWH's goals related to improving programs and carrying out initiatives to achieve health equity for underserved women. HRSA will use MHAF resources to foster the development of bundled interventions of comprehensive HIV care and treatment to improve health outcomes particularly for retention in care and the attainment of viral suppression. These efforts will add to the literature and the field of implementation science to address effective care and treatment for Black women with HIV.

Finally, demonstration sites will be required to participate with the ETAP in the development of an intervention manual to document the implementation methodology of their project for purposes of replication. The manual will include, at minimum, the following: 1) a description of the intervention and key considerations and 2) recommendations for other programs looking to replicate the model.

Multi-Site Evaluation Requirements

Demonstration sites will be expected to work collaboratively with the ETAP in all aspects of the multi-site evaluation. Sites must have the ability to collect and report quantitative and qualitative data to the ETAP. In order to facilitate adherence to the evaluation protocol, the ETAP will provide TA to all demonstration sites over the course of the entire project. This initiative provides a unique opportunity for HRSA HAB and OWH to examine how bundled interventions promote increased linkage to HIV care, higher retention in care, improved viral suppression, and overall enhanced quality of health for Black women with HIV. By creating an integrated structural intervention that

²³ Centers for Disease Control and Prevention, Center for Preparedness and Response. Infographic: 6 Guiding Principles To A Trauma Informed Approach. https://www.cdc.gov/cpr/infographics/6 principles trauma info.htm. Accessed March 4, 2020.

addresses significant social determinants of health, the federal partners expect to see the following system-level outcomes:

- Improved ability to address socio-cultural determinants of health and unmet needs:
- Enhanced coordinated care models and better tools to help providers build capacity around patient-centered and culturally sensitive and responsive care.

HRSA expects the following health outcomes for Black women with HIV participating in this project:

- Improved engagement, reengagement, and adherence to care
- Stigma reduction
- Achievement and maintenance of viral suppression

Recipients must demonstrate the ability to work among partner organizations. Additionally, recipients must collect and report data to the ETAP related to HIV health outcomes. Performance measures must include the outcomes of Black women with HIV participants, along the HIV care continuum²⁴ including:

- HAB Core Performance Measures, 25 specifically:
 - 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
 - Viral Suppression Among Persons in HIV Medical Care
 - Percentage of clients with a viral load <200 copies/mL during the last test in the 12-month measurement period
- Additional HAB Core Performance Measures,²⁶ as needed

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

²⁴ For more information on the HIV Care Continuum go to https://www.aids.gov/federal-resources/policies/care-continuum/

²⁵ HAB Performance Measures can be viewed at:

https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf

²⁶ HAB Performance Measures can be viewed at:

https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf

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.

2. Summary of Funding

HRSA anticipates approximately \$2,170,000 to be available annually to fund up to seven recipients. You may apply for a ceiling amount of up to \$310,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2023 (3 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 – Demonstration Sites* 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 e-mail 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 10: 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 <u>SF-424 Application Guide</u>. 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
- Project Director Name
- Contact Phone Numbers and Email Addresses

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

- **Summary of project**: Provide a brief summary description of the proposed project, including the minimum three (3) proposed bundled interventions to be implemented, specific sites where the activities will take place, and collaborating entities.
- **Target population(s):** Provide a brief description of the geographic area(s) to be served by the proposed project and the demographic characteristics of the target population to be served.
- Goals and Objectives: Describe overall project goals and proposed services.
- **Summary of Funding:** Specify the funding amount requested for each year of the 3-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) Provide a clear and succinct description of the proposed bundled intervention strategies to expand the delivery and utilization of comprehensive care and treatment services for Black women with HIV. Include information about how the interventions will improve health outcomes along the HIV care continuum for members of the identified racial/ethnic minority community. Provide a clear and succinct description of your and any partnering organizations' capacity to implement and provide services to clients within the first year of the award.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 (Need) The purpose of this section is to demonstrate the care and service needs of Black women with HIV who reside in the proposed jurisdictions or communities, existing gaps and other unmet needs in services, and collaborations needed to engage in care and achieve viral suppression.

Identify and briefly describe the demographics of the population(s) you will serve, (e.g., young Black women, older Black women, pregnant Black women, cisgender Black women, transgender Black women). Include information about the incidence and prevalence rates of HIV infection in the identified population(s) as

well as issues specific to your service area that interfere with engaging and retaining the identified population(s) in HIV care.

Utilizing relevant local and national data and published research, identify and discuss the existing unmet HIV care and service needs experienced in the identified population(s), including services to address SDOH, as relevant. Include a description of the health disparities affecting the identified population(s), and indicate how these disparities put them at risk for poor HIV health outcomes. If applicable, identify and describe any unmet needs or gaps in behavioral health and other social support services for Black women with HIV. This may include but is not limited to, emotional, mental, or spiritual health services, self-efficacy, health literacy education, and resilience.

Identify the geographic area to be served. Describe the existing HIV care infrastructure including clinical, social, behavioral, community, or faith-based programs currently available to meet the needs of the identified client population, and any relevant gaps or barriers in the service area that the project plans to address.

In 1997, the Office of Management and Budget (OMB) revised standardized racial and ethnic classifications to provide common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. The revised standards contain five minimum categories for race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White and two categories for ethnicity: "Hispanic or Latino" and "Not Hispanic or Latino." In 2020, these standards are still commonly used for federal data collection, medical and clinical research, and program evaluation. For the purpose of this initiative, a *Black woman is* described as a cisgender or transgendered 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. However, this does not preclude the provision of services under this grant to persons of any race, ethnicity, sex or gender, although the collection of evaluation data is limited to the study population.

• METHODOLOGY -- Corresponds to Section V's Review Criterion #2 (Response) Provide a description of your proposed bundled set of interventions, including any innovative methods and strategies, and the rationale for their use. Describe how the proposed bundle of interventions address key unmet HIV care and other unmet needs experienced in your service area, including, but not limited to, transportation, unstable housing, stigma, IPV services, and socio-cultural factors as identified in your data and literature research. Include how your proposed methodology addresses identified barriers within the service area limiting access to, and retention in care, for Black women with HIV.

A key component of this initiative is the coordination and delivery of bundled evidence-informed interventions simultaneously. Provide detailed information on

²⁷ The Office of Minority Health. OMB Standards for Data on Race and Ethnicity. https://obamawhitehouse.archives.gov/omb/fedreg 1997standards

how you intend to implement the proposed bundle of interventions you will use to address the stated needs described in the needs assessment section. Highlight innovative methods you propose as part of your interventions that address any socio-cultural factors, gaps, unmet HIV care or service needs, and barriers at the structural, provider and individual levels identified in the needs assessment. For example, an innovative structural-level intervention could entail a 'woman-responsive' approach to quality HIV care with emphasis on meaningful participation of people with HIV, including Black women, in the planning, designing, implementation, and evaluation of HIV programs and using evidence-informed curricula to address intimate partner violence, among others. Also describe plans for systematically assessing needs in order to target the intervention(s) at particular times when the woman is especially at risk for not engaging in or falling out of care. Additionally, describe plans for developing acuity scales to determine the intensity of the intervention required in order to divert a threat to a person's ability to engage and remain in quality HIV care.

The project period for this award is three years; therefore, successful applicants must be able to implement the bundled interventions effectively and quickly. At a minimum, HRSA expects you to begin the implementation of the proposed bundled interventions within 6 months of the award. Describe your timeline for the first year for adapting and implementing the bundled set of evidence-informed HIV interventions to better impact the delivery of HIV care for Black women. Include information about how you will assist Black women with HIV with adherence and engagement in proposed intervention components, and how you will identify and re-engage clients who do not remain engaged in these intervention components.

Describe how Black women with HIV who are newly diagnosed, diagnosed and have fallen out of care, never entered into care, or are at high risk of falling out of care will be identified and referred to your organization to participate in this initiative, and how you will assess the impact of the delivery of bundled interventions on improvements in the HIV care continuum focused on Black women. Describe your organization's collaborations, partnerships, or affiliation with sites that provide HIV testing and case finding, and how these and any other relationships will be a source of newly identified and out of care Black women with HIV. Describe the proposed referral and linkage networks to your organization, including referral activities from community stakeholders or collaborations.

Describe how your proposed bundled intervention supports engagement and retention strategies to optimize medication adherence and proactively address barriers to increase retention. Describe your organization's plan to utilize clinic, community, and social support service resources, and provide health literacy education to support retention in care after the project is complete.

Include a description of your plan to develop policies and procedures that ensure the privacy and confidentiality of clients participating in the proposed intervention. This description must indicate what types of data sharing agreements partner agencies must have in place in order to access required data and how the agencies will ensure that these agreements are in place within the first six (6) months of the award. Include a description of procedures for the electronic and

physical protection of study participant information and data, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and human subjects protections regulations. Describe your plan to obtain and submit documentation of local IRB approval on all evaluation and data collection instruments for both local and multi-site evaluation activities.

Funded demonstration sites will be required to create and finalize an intervention manual detailing the methodology, protocols, and procedures used and outcomes of the bundled interventions. The ETAP will provide additional TA to develop site-specific protocols as needed. Describe your plan to develop an Intervention manual in order to guide potential replication in the future.

Collaboration and Coordination: Describe how you will collaborate and/or coordinate with organizations to implement the proposed bundled interventions and address the barriers identified in the needs assessment section. Describe how you will build, expand and/or maintain effective strategic partnerships with new and existing key providers and organizations within your community that serve and support the target population, in order to carry out the proposed activities. Identify the tasks each partner proposes to perform and the amount of funding, if any, you expect to allocate to the partner. Describe how Black women with HIV, who represent the target population and/or organizations that represent them, will be engaged in the implementation of this project, including decision-making activities. Include letters of support and/or letters of commitment from each partner and/or collaborating entity stating their concurrence with the proposed project as **Attachment 4**.

<u>Sustainability:</u> Describe how you will continue successful aspects of the interventions after the period of federal funding ends. Include a description of how you will balance efforts to have immediate impact with efforts to establish longer-term and more sustainable coordination strategies. In addition, describe how you intend to share or disseminate strategies or services and interventions that have been effective and that have led to improved outcomes in the target population.

Using the definitions for cultural sensitivity and cultural responsiveness provided below, describe your and your partnering organizations' resources and capabilities to support 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.²⁸

Cultural Responsiveness is a self- and process-driven, lifelong commitment to a tailored, dialogue-based approach that responds to the needs being presented by

²⁸ 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

the individual in front of the provider, within a contextual understanding of social/economic/political/linguistic disparities.²⁹ This includes an understanding of integrated patterns of human behavior, including language, beliefs, norms, and values, as well as socioeconomic and political factors that may have 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 steps for implementing and assessing the innovative intervention. If awarded, you will use the work plan as a tool to actively manage the project by measuring progress, identifying necessary changes, and quantifying accomplishments. The work plan should directly relate to the program components described in the Methodology section as well as the program requirements and expectations detailed in this NOFO.

Describe the activities or steps you will use over the life of the award to achieve each of the strategies proposed in the Methodology section. Additionally, identify meaningful support and collaboration with key stakeholders and partners in planning, designing, and implementing all activities, including the extent to which these contributors reflect the cultural, racial, linguistic, and geographic diversities of the populations and communities served.

The work plan should include (1) goals for the entire proposed three year project period; (2) objectives that are specific, time-framed, and measurable; (3) activities or action steps to achieve the stated objectives with anticipated start and completion dates; and (4) staff responsible for each action step. Include all aspects of planning, implementation, and evaluation, along with the role of key personnel involved in each activity.

Define goals as broad statements of what the program seeks to accomplish, and for whom. Focus the objectives on the most critical organizational issues and outcomes that need to be addressed to achieve the stated goals.

First-year objectives should describe key action steps or activities that you will undertake to implement the intervention and the evaluation protocol. Objectives may include but are not limited to hiring appropriate staff, developing and implementing client assessment tools, outreaching to the intended population, coordinating with ETAP on the development of multi-site data components, establishing quality control mechanisms, as well as addressing IRB and HIPAA requirements. Clearly indicate the anticipated start date of the intervention, and provide numbers for targeted outcomes where applicable, not just percentages. Be sure that the work plan clearly indicates how you will ensure service delivery for Black women with HIV and the implementation of data collection processes within the first six (6) months of the award. Include the project's work plan in

²⁹ 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

Attachment 1. This section is often best presented and/or summarized in a chart format.

Logic Model

You must submit a logic model in **Attachment 1** 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. 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. Identify any potential need for TA from the ETAP, as described in HRSA-20-115. Also, describe any proposed resolutions to the barriers, as described in the Needs Assessment section.

If applicable, include information about initiating, managing, and sustaining communication, including data collection and reporting among multiple partner organizations. Be sure to discuss strategies the project will employ to identify and address barriers clients may experience in remaining in the intervention components.

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

Describe the current or prior experience of proposed key personnel, (including any consultants, partner organization staff, sub-recipients, and contractors) in implementing innovative models of care and treatment for Black women with HIV. Include a description of key personnel's experience with participation in a multi-site evaluation of national scope. Describe the experience of proposed key project personnel, (including any consultants, partner organization staff, sub-recipients, and contractors), in writing and publishing study findings in peer-reviewed journals and in disseminating findings to local communities, national conferences, and to policymakers.

Describe the systems and processes that will support your organization's performance management requirements through effective tracking of client level, clinical, and process 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 clinical and 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.

Funded demonstration sites must collect and report relevant quantitative and qualitative outcomes, process, and cost measures data for their interventions and/or models of care as part of the national multi-site evaluation. These data may include, but are not limited to:

- Client demographic characteristics
- Biomedical indicators
- Utilization of core medical and support services, (e.g., substance abuse, mental health, housing assistance)
- Barriers to accessing treatment and services
- Medication adherence measures; and other outcome measures as defined by ETAP

As such, the demonstration sites must be able to report these indicators, either as a direct clinical provider or through the execution of partnership agreements with a medical clinic for HIV health care services. Include supporting documentation of medical record availability as **Attachment 8**. Describe how you will collect and manage data, including using any electronic medical record or electronic health record (EMR/EHR) or data management software that allows for accurate and timely reporting of performance and implementation outcomes. Describe how you will ensure data collection and reporting per the requirements for the multi-site evaluation as outlined in Section 1 of the NOFO. Include a timeline for developing

processes for collecting client-level data from all of the partnering agencies associated with implementing the selected evidence-informed interventions and/or models of care to the ETAP. This description must indicate what types of data-sharing agreements with partner agencies you currently have or plan to put in place in order to access required data.

Identify any barriers to meeting these requirements including, but not limited to, lack of data sharing agreements, concerns about client confidentiality, and coordinating disparate data systems (e.g., EMRs). Describe how you plan to address these barriers in the designated timeframes.

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

You must demonstrate the ability to serve Black women with HIV at high risk for poor health outcomes. Succinctly describe your organization's current mission and structure, scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Discuss how your organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings.

Describe your experience serving racial/ethnic minorities, including Black women. Include information about your HIV experience, and expertise in identifying and addressing barriers associated with access, linkage, and retention in care for this population. These barriers may include, but are not limited to, issues such as lack of consistent HIV care, the lack of HIV service provider education, the lack of diagnosis and treatment of co-morbidities such as mental illness, lack of trust in health care providers, behavioral health issues, physical or sexual violence or IPV, or competing sustenance needs. Include a description of the services currently available to assist the identified population(s) and the funding sources for those services. Describe how these all contribute to your ability to conduct the proposed project and meet program expectations. Provide information on your resources and capabilities to support the proposed project.

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.

Provide a staffing plan (Attachment 2) that identifies staff credentials and commitments to the proposed project components. Include information on all partnering organizations' current mission and structure, scope of current activities, service delivery experience, and expertise in serving Black women with HIV at risk for poor health outcomes. Describe how the organizational staff and collaborating partners will contribute to the ability of the project to conduct the proposed intervention and/or model of care and meet program expectations. If applicable, provide information on the partnering organizations' resources and capabilities to support the proposed project. Describe how you and your partnering organizations, if applicable, routinely assess and address the unique needs of

Black women with HIV.

Describe the capacity of your information technology and management information system (MIS) to support the comprehensive evaluation including data collection, reporting, and secure storage of client-level data. Because of the data requirements of the project, program recommends that proposed staffing plans include, at a minimum:

- A 10 percent full-time equivalent Evaluator (.10 FTE) to oversee the implementation of the multi-site evaluation activities conducted by ETAP, and
- A 25 percent full-time equivalent (.25 FTE) Data Manager to assist in data collection and reporting.

Include a project organizational chart as **Attachment 5.** The organizational chart should be a one-page figure that depicts the organizational structure of only the project, not the entire organization, and it should include subrecipients, contractors, partner organizations, and other significant collaborators.

If you will use consultants, sub-recipients, and/or contractors to carry out aspects of the proposed project, describe their roles and responsibilities. Current and proposed collaborating organizations and individuals must demonstrate their commitment to fulfill the goals and objectives of the project through signed and dated letters of agreement, memorandums of agreement (MOAs), or memorandums of understanding (MOUs). If applicable, include any such letters or memoranda, and descriptions of any existing or proposed contracts relating to the proposed project, as **Attachment 4**.

NARRATIVE GUIDANCE

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

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

Budget and Budget Narrative	(6) Support Requested – 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 *Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Demonstration Sites* program requires the following: Separate line-item budgets for each year of the 3-year project period, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate (Attachment 7).

The demonstration sites will implement the multi-site evaluation plan and send up to three key personnel to attend required meetings twice a year in Washington D.C. Include costs for these activities in 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." See Section 4.1.iv Budget – Salary Limitation of HRSA's SF-424 Application Guide for additional information. Note that these or other salary limitations may apply in the following FY, 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: Focusing on Black Women with HIV – Demonstration Sites* 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 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 project period (three 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 clearly indicate that there are no substantive budget changes during the project period.

v. Attachments

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. You must clearly label **each attachment**.

Attachment 1: 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>. Also include the required logic model in this attachment. If you will make sub-awards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's <u>SF-424 Application Guide</u>), required

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

Attachment 3: Biographical Sketches of Key Personnel, required

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

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

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

Attachment 5: Project Organizational Chart, required

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

Attachment 6: Tables, Charts, etc.

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

Attachment 7: Line Item Budgets Spreadsheet for Years 1 through 3, 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 8: Medical Record Availability Documentation.

Please provide documents to demonstrate that you have access, (either directly or through a formal, written agreement), to clients' medical records to verify the use of and retention in medical care and to collect health outcome information.

Attachment 9: Indirect Cost Rate agreement, if applicable (does not count toward page limit)

Attachments 10 – 15: Other Relevant Documents [15 is the maximum number of attachments allowed.]

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 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 <u>SF-424 Application Guide</u>.

<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

Improving Care and Treatment Coordination: Focusing on Black Women with HIV – Demonstration Sites is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 3 years, at no more than \$310,000 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 cannot use funds under this notice for the following purposes:

- Charges that are billable to third party payers, (e.g., private health insurance, prepaid health plans, Medicaid, Medicare);
- To directly provide medical or support services, (e.g., HIV care, counseling and testing) that supplant existing services;
- Cash payments to intended recipients of RWHAP services;
- Purchase, construction of new facilities or capital improvements to existing facilities;
- Purchase or improvement to land;
- Purchase vehicles;
- Fundraising expenses or lobbying activities and expenses;
- 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/;
- To develop materials designed to directly promote or encourage, intravenous drug use or sexual activity, whether homosexual or heterosexual;
- Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (nPEP) medications or related medical services. (Please note that RWHAP recipients and sub-recipient providers may provide prevention counseling and information to eligible clients' partners see <u>June 22, 2016, RWHAP and PrEP program letter</u>); 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 objective review.

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

Criterion 1: Need	15 points
Criterion 2: Response	30 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 (15 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 and clarity of the proposed bundled intervention strategies to expand
 the delivery and utilization of comprehensive care and treatment services for
 Black women with HIV, and the description of how the bundled interventions will
 improve HIV health outcomes for the identified community along the HIV care
 continuum.
- Strength and clarity of the description of the applicant and any partnering organizations' capacity to implement and provide services to clients within the first year of the award.
- Extent to which the applicant demonstrated knowledge of the racial/ethnic population to be served including information about the incidence and prevalence rates of HIV and issues within the service area that interfere with engaging or retaining the identified population in HIV care.
- Extent to which the applicant used relevant local and national data and published research to discuss the existing unmet HIV care and other needs experienced in the identified racial/ethnic minority population, including services to address SDOH, as relevant.
- If provided, strength and clarity of description of any unmet needs or gaps in behavioral health and other social support services for Black women with HIV.
- Strength and clarity of the applicant's description of the health disparities affecting the identified population and a demonstrated understanding of how these disparities put the population at risk for poor health outcomes.
- Extent to which the applicant identified the geographic area to be served and the
 existing HIV clinical, social, behavioral, and community-based programs currently
 available in the service area to meet the needs of the identified client population,
 and any relevant gaps or barriers in the service area that the project plans to
 address.

Criterion 2: RESPONSE (30 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:

i. Methodology (10 points)

- Strength and clarity of the proposed bundled intervention, including its innovative methods and strategies, and the rationale for their use.
- Extent to which the proposed bundled intervention addresses key factors leading to unmet HIV care and other needs, as identified in the data and research, as well as barriers within the service area limiting access to and retention in care for Black women with HIV.
- Extent to which the applicant described strategies to assist Black women with HIV with adherence and engagement in proposed intervention components and to identify and re-engage clients who do not remain engaged in these intervention components.
- Strength, clarity, and feasibility plan for the identification and referral of Black women with HIV for participation in the identified bundle of interventions.
- Extent to which proposed collaboration and/or coordination with organizations to implement the proposed bundled interventions addresses the barriers identified in the needs assessment section.

ii. Work Plan (15 points)

- Strength, clarity, and feasibility of the applicant's work plan and its goals for each year of the 3-year project period (**Attachment 1**).
- Extent to which the applicant's work plan delineates steps for implementing and assessing the intervention described in the Methodology section of the Narrative.
- Extent to which the applicant identified key stakeholders and partners in planning, designing and implementing all activities, including the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversities of the populations and communities served.
- Evidence the applicant's objectives for the three year project period are specific to each goal, time-framed, and measurable.
- Strength and clarity of the work plan indicating how the applicant will ensure service delivery to Black women with HIV and implementation of data collection processes within the first 6 months of the award. This includes planning, implementation, and evaluation activities including adherence with IRB and HIPAA requirements, the staff responsible to accomplish each step, and anticipated dates of completion.
- Strength and clarity of logic model (Attachment 1) for designing and managing the proposed project.

iii. Resolution of Challenges (5 points)

- Extent to which the applicant identifies possible challenges that are likely to be encountered in designing and implementing the activities described in the work plan.
- Extent to which the applicant identifies barriers clients may experience in remaining in the HIV intervention components.
- Extent to which the applicant identifies realistic and appropriate responses for resolving identified challenges.

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

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

- Strength and clarity of plan to ensure data collection and reporting per requirements for multi-site evaluation with the ETAP, as outlined in Section I of the NOFO, including a timeline for developing processes for collecting client-level data for partnering agencies associated with implementing selected interventions and/or models of care to the ETAP and identifying barriers to meeting requirements, including, but not limited to lack of data sharing agreements, concerns about client confidentiality, and coordinating disparate data systems (e.g., EMRs).
- Strength of the experience of proposed key project personnel, (including any consultants, partner organization staff, sub-recipients, and contractors), in implementing innovative models of care and treatment for Black women with HIV, including a description of key personnel's experiences participating in a multi-site evaluation of national scope.
- Strength of the experience of proposed key project personnel, (including any consultants, partner organization staff, sub-recipients and contractors), in writing and publishing study findings in peer-reviewed journals and in disseminating findings to local communities, national conferences, and to policymakers.
- Strength and clarity of the applicant's plan to collect and manage data, including any EMR or EHR, or data management software, that allows for accurate and timely reporting of performance and implementation outcomes, as well as information about how the agency will collect and share data among the partners and agencies providing leveraged resources.
- Strength and clarity of the evaluation for a bundled intervention approach and methods to determine the cost-effectiveness of implementing a bundled intervention.

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

The extent to which the proposed project has a public health impact and the project will be effective if funded. This may include the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the

degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

- Strength of the proposed plan to develop an Intervention manual for the purposes of replication.
- Strength and clarity of the sustainability and program integration plan or strategy including how the applicant will work with the ETAP and community partners to sustain the project after the project period ends.
- Extent to which the applicant demonstrated the potential for replicating the proposed intervention strategy and the ways other providers might implement similar innovative models in their service settings.
- The feasibility and effectiveness of plans for dissemination of project results, and the extent to which project results may be national in scope.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity, Organizational Information
The extent to which project personnel is 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.

- Extent to which the applicant's and partner organizations' current mission and structure, scope of current activities, HIV experience, and expertise including the current service portfolio demonstrates expertise in serving racial/ethnic minority communities, including Black women at risk for poor health outcomes and will ensure the coordination of HIV health care and services.
- Relevance of the organization's experience in implementing and managing HIV care services, coordination, and evaluation, including programs serving marginalized and hard-to-reach populations.
- Strength of the capacity of the applicant organization's management information system (MIS) to support comprehensive data collection, reporting, and secure storage of study participant data.
- The extent to which the staffing plan (Attachment 2) and project organizational chart (Attachment 5) are consistent with the project description and, proposed activities, and include the roles and responsibilities of any partnering organizations.
- The extent to which the applicant demonstrated the inclusion of consumers in the agency's operations, including the formulation of the proposal and the incorporation of consumer issues and preferences into the service delivery model.
- The extent to which the applicant demonstrated, with specific examples and data, the resources and capabilities to support the provision of culturally and linguistically competent HIV care and services.

 Extent to which the applicant described any partnerships developed to ensure the coordination of HIV care and services, and whether the applicant included any relevant MOUs or contractual agreements to define these partnerships (Attachment 4).

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's Budget and Budget Narrative

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

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.
- The extent to which key personnel has adequate time devoted to the project to achieve project objectives.
- Strength and clarity of the applicant's budget justification narrative for each year
 of the three year project period and its appropriateness to the proposed work
 plan.
- If applicable, the extent to which sub-awards and/or contracts for proposed subrecipients, contractors, and consultants are clearly described in terms of scope of work, how costs were derived, and payment mechanisms and deliverables are reasonable and appropriate.
- Evidence that the budget allocates sufficient resources to implement the multisite evaluation plan and for three key personnel to attend required annual meetings in Washington D.C.

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 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 <u>SF-424 Application Guide</u> for more details.

3. Assessment of Risk

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (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 *SF-424 Application Guide* 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 (<u>45 CFR part 46</u>) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

3. Reporting

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

- Progress Report(s). The recipient must submit a progress report to HRSA on an annual basis. Further information will be available in the NOA. NCC renewal will be submitted separately.
- 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> <u>part 75 Appendix XII</u>.

VII. Agency Contacts

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

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

Telephone: (301) 443-7065 Email: BSmith@hrsa.gov You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Adan Cajina, MSc

Chief, Demonstration and Evaluation Branch

Attn: Improving Care and Treatment Coordination: Focusing on Black Women with

HIV – Demonstration Sites (HRSA-20-116)

Office of Training and Capacity Development, HIV/AIDS Bureau

Health Resources and Services Administration

5600 Fishers Lane, Room 9N108

Rockville, MD 20857

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: 3 p.m. – 4:30 p.m. ET Call-In Number: 1-888-469-3347 Participant Code: 6672543

Weblink: https://hrsa.connectsolutions.com/ta_webinar_hrsa20_116/

The webinar will be recorded and should be available at

https://www.targethiv.org/category/resource-type/training-resources

Playback Number: 1-888-566-0693

Passcode: 2516

Tips for Writing a Strong Application

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