U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



HIV/AIDS Bureau Division of Policy and Data Special Projects of National Significance

Improving Sexually Transmitted Infection Screening and Treatment among People Living with or at Risk for HIV

Funding Opportunity Number: HRSA-18-040
Funding Opportunity Type: New
Catalog of Federal Domestic Assistance (CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: April 2, 2018

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!

Deadline extensions are not granted for lack of registration.

Registration in all systems, including SAM.gov and Grants.gov,

may take up to 1 month to complete.

Issuance Date: January 31, 2018

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Authority: Public Health Service Act, Section 2691 (42 USC § 300ff-101), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87); Public Health Service Act, Section 330, as amended (42 U.S.C. 254b)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Special Projects of National Significance program is accepting applications for a new three-year demonstration project entitled Improving Sexually Transmitted Infection Screening and Treatment for People Living with or at Risk for HIV. The purpose of this project is to support a single organization that will identify three service jurisdictions and fund a minimum of three and a maximum of five intervention sites within each jurisdiction to implement clinical and system-level interventions to improve screening and treatment of sexually transmitted infections (STIs) among low-income people living with HIV (PLWH) or at risk for HIV. The cooperative agreement recipient also will evaluate the implementation and outcomes of the interventions and disseminate the results to inform policy and practice, including the publication of successful models for future replication by other HRSA Ryan White HIV/AIDS Program (RWHAP) and Health Center Program award recipients. The FY 2018 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. You should note that this program may be cancelled prior to award recommendations.

Funding Opportunity Title:	Improving Sexually Transmitted Infection
	Screening and Treatment for People
	Living with or at Risk for HIV
Funding Opportunity Number:	HRSA-18-040
Due Date for Applications:	April 2, 2018
Anticipated Total Annual Available FY18	\$4,300,000
Funding:	
Estimated Number and Type of Award(s):	One (1) cooperative agreement
Estimated Award Amount:	Up to \$4,300,000 per year
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	September 30, 2018 – September 29,
	2021 (3 years)
Eligible Applicants:	Eligible applicants include entities eligible
	for funding under RWHAP Parts A, B, C
	and D of Title XXVI of the Public Health
	Service Act as amended by the Ryan
	White HIV/AIDS Treatment Extension Act
	of 2009. These include, but are not
	limited to: health centers receiving
	support under Section 330 of the Public
	Health Service Act; Federally Qualified
	Health Centers as described in Title XIX,
	Section 1905 of the Social Security Act;
	public and nonprofit private entities
	involved in addressing HIV/AIDS/STI
	related issues at the regional or national

level; state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; 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), formerly known as the funding opportunity announcement (FOA), 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. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

HRSA strongly encourages all applicants to participate in a technical assistance (TA) 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.

Day and Date: Tuesday, February 20, 2018

Time: 3 p.m. – 4 p.m.

Call-In Number: 1-888-324-9620 Participant Code: 8893019

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

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I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for a new three-year demonstration project entitled *Improving Sexually Transmitted Infection Screening and Treatment for People Living with or at Risk for HIV.* The purpose of this project is to support a single organization that will work collaboratively with Health Resources and Services Administration (HRSA) staff to promote clinical service and system-level interventions leading to an increase and/or improvements in the screening and treatment of sexually transmitted infections (STIs) among low-income people living with HIV (PLWH) or at risk for HIV who are served by HRSA's Ryan White HIV/AIDS Program (RWHAP) and/or Health Center Program. To promote these changes, the successful applicant will perform the following project activities:

- a. Identify three service jurisdictions within the United States and fund a minimum of three and a maximum of five intervention sites within each of the three jurisdictions to implement the interventions. The intervention sites will be subrecipients under the cooperative agreement. Among the intervention sites should be a local convener (such as a health department or university) to facilitate systems-level interventions between sites within a jurisdiction, and later assist with dissemination and program integration across the jurisdiction to nonintervention sites. The convener may or may not be a site of clinical intervention. You should select the service jurisdictions based on high incidence of STIs per the Centers for Disease Control and Prevention (CDC) 2016 Sexually Transmitted Diseases (STD) Surveillance report¹ in areas with high prevalence of HIV infection.² You should have existing relationships with the proposed intervention sites, and the sites must currently receive funding from HRSA's RWHAP and/or Health Center Program. The recipient should initiate and finalize formal written agreements (e.g., subawards, contracts, memoranda of understanding, letters of agreement) with the intervention sites to include a local convener for system level changes (such as a health department or university) within 90 days of award. Additionally, intervention sites must identify a change champion(s) to support both project and organizational change to help promote the interventions and build organizational support for system change.
 - In order to expedite selection and implementation of interventions and ensure uniformity across sites, HRSA will identify interventions based on insights gained from a federally convened Technical Experts Panel (TEP) conducted prior to the award. HRSA will select a total of five to seven interventions, and will notify the recipient of interventions selected. Examples of possible interventions may include, but are not limited to:
 - i. Innovative clinical interventions such as increasing extragenital testing, self-testing, express visits, integrating partner services,

¹ CDC. Sexually Transmitted Disease Surveillance 2016. Published 9-21-17. Accessed 10-23-17 from: https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf

² CDC. Sexually Transmitted Disease Surveillance 2016. Published 9-21-17. Accessed 10-23-17 from: https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf

- mobile clinic testing, health education, and risk reduction strategies.
- ii. System level interventions to increase STI screening and treatment across the jurisdiction, linkage to care (e.g., integration of public health surveillance and care teams), partnerships between clinical sites and local health departments, and policy development or changes affecting the service area.
- The recipient will draft intervention protocols for STI screening and treatment based on models identified by the TEP. The recipient should finalize these protocols within six months of award and will submit protocols to HRSA staff for review and approval.
- b. Provide training and technical assistance (TA) to the intervention sites to support their implementation of the screening and clinical interventions. Recipient project staff must:
 - possess expertise in both the diagnosis and treatment of STIs per the CDC STD Treatment Guidelines;
 - deliver TA to each intervention site; and
 - conduct site visits to each jurisdiction at least once annually and to each intervention site at least once during the implementation of the interventions.
- c. Conduct a multisite evaluation of the implemented interventions. Intervention sites will be required to collect and report relevant outcome, process and cost measures of their STI screening and treatment interventions to the cooperative agreement recipient.
- d. Disseminate findings, best practices, lessons learned, and provide an implementation toolkit to national and local audiences. Dissemination will include, but not be limited to, working with the RWHAP regional AIDS Education and Training Center (AETC) in its jurisdiction,³ national AETCs, CDC-funded Prevention Training Programs, Primary Care Associations (PCAs), the National LGBT Health Education Center, and the recipient's publication of successful interventions and strategies on the Technical Assistance Resources, Guidance, Education & Training (TARGET) Center website.⁴
- e. Provide assistance to intervention sites to implement changes and develop a sustainability plan for program integration across the jurisdiction by year three. Program integration is defined as the incorporation of these interventions into an organization's change management processes, which requires addressing cost and staffing requirements over the long term.

Recipients will work with selected intervention sites in geographic areas with high incidences of STI, as identified in the CDC 2016 STD Surveillance report,⁵ and high prevalence of HIV infection that are not currently and/or routinely utilizing the potential

³ See https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-f-aids-education-and-training-centers-aetc-program

⁴ See https://www.careacttarget.org/

⁵ CDC. Sexually Transmitted Disease Surveillance 2016. Published 9-21-17. Accessed 10-23-17 from: https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf

interventions listed above. Target populations for these screening and treatment interventions include low-income PLWH or at risk for HIV, but the multisite evaluation shall include a focused analysis of men who have sex with men (MSM) and transgender PLWH who are at an increased risk for acquiring an STI.

2. Background

HRSA's Special Projects of National Significance (SPNS) program is authorized by Section 2691 of the Public Health Service Act (42 USC 300ff-101), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87). The SPNS program supports the development of innovative approaches for HIV care to respond to the emerging needs of clients served by the RWHAP.⁶ The SPNS program also evaluates the effectiveness of these approaches' and/or interventions' design, implementation, utilization, cost, and health related outcomes, while promoting dissemination and successful replication.⁷

This project is also supported, in part, through HRSA's Health Center Program, authorized by Section 330 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254b). Through Service Area Competitions, organizations compete for Health Center Program operational support to provide comprehensive primary health care services to defined service areas and patient populations.

The Health Center Program funding targets the Nation's high need geographic areas and populations by currently supporting nearly 1,400 health centers that operate more than 10,400 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. More than 26 million patients, including medically underserved and uninsured or underinsured patients, receive accessible, affordable, quality primary health care services through the Health Center Program.

National Goals to End the HIV Epidemic

The RWHAP promotes robust advances and innovations in HIV health care using national goals to end the epidemic as its framework. Therefore, activities funded by the RWHAP focus on addressing these four goals:

- 1) Reduce new HIV infections:
- 2) Increase access to care and optimize health outcomes for PLWH;
- 3) Reduce HIV-related health disparities and health inequities; and
- 4) Achieve a more coordinated national response to the HIV epidemic.

To achieve these shared goals and priorities, recipients should align their organization's efforts, within the parameters of the RWHAP statute and program guidance, to ensure that PLWH are linked to and retained in care, and have timely access to HIV treatment and the supports needed (e.g., mental health and substance abuse services) to achieve

⁶ Information on the Ryan White HIV/AIDS Program Part F: Special Projects of National Significance Program can be found at: http://hab.hrsa.gov/abouthab/partfspns.html

⁷ Publications and products from various SPNS initiatives can be found at: http://hab.hrsa.gov/abouthab/special/spnsproducts.html AND https://careacttarget.org/library/integrating-hiv-innovative-practices-ihip

HIV viral suppression.

HHS utilizes the six principles of affordability, accessibility, quality, choices, innovation, and responsiveness in implementing HHS programs.

HIV Care Continuum

Diagnosing PLWH, linking PLWH to HIV primary care, and PLWH achieving 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 including 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 shows the proportion of individuals living with HIV or individuals diagnosed 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.

According to recent data from the 2016 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2010 to 2016, 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 69.5 percent to 84.9 percent, and racial/ethnic, age-based, and regional disparities have decreased.8 These improved outcomes mean more PLWH in the United States will live near normal lifespans and have a reduced risk of transmitting HIV to others.⁹ In a September 27, 2017 Dear Colleague letter, CDC notes that scientific advances have shown antiretroviral therapy (ART) preserves the health of PLWH. There is also strong evidence of the prevention effectiveness of ART. When ART results in viral suppression, it prevents sexual HIV transmission. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner. Such findings underscore the importance of supporting effective interventions for linking PLWH into care, retaining them in care, and helping them adhere to their ART.

RWHAP recipients are encouraged to assess the outcomes of their programs along this continuum of care. Recipients should work with their community and public health partners to improve outcomes across the HIV care continuum. HRSA encourages recipients to use the <u>performance measures</u> developed for the RWHAP at their local level to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

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⁸ Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016. http://hab.hrsa.gov/data/data-reports. Published December 2017. Accessed December 1, 2017.

⁹ National Institute of Allergy and Infectious Disease (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.

Sexually Transmitted Infections and HIV

According to the CDC, STI cases in the United States have reached record levels. More than two million cases of chlamydia, gonorrhea, and syphilis were reported in the United States in 2016, the highest number ever reported. The STI epidemic is accelerating among many groups, including women, infants, PLWH, and MSM. While chlamydia, syphilis, and gonorrhea can be cured with antibiotics, if left undiagnosed or untreated, these diseases have the potential to severely impact public health, including by perpetuating the spread of STIs, causing infertility, increased HIV transmission, and contributing to chronic pain. Additionally, undertreatment of STIs can result in possible increased risk of the development of bacterial resistance. Thus, maintaining and strengthening core STI prevention, screening, and treatment systems is essential to mounting an effective national response.

There is a high prevalence of HIV and STI co-infection, most notably among people with primary or secondary syphilis. The CDC 2016 STD Surveillance report notes a particularly high incidence of HIV and syphilis coinfection, especially among MSM. Among primary and secondary syphilis cases with known HIV status, 47 percent were MSM living with HIV. Co-infection of STIs in PLWH has been associated with decreased CD4 cell counts and increased HIV viral load, 12 which can lead to worse health outcomes for PLWH and a greater risk of transmitting HIV to a negative partner. The development and dissemination of innovative models to improve capacity to prevent, diagnose, and treat STIs are needed to address the rising incidence of STIs among PLWH or at risk for HIV.

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 programmatic involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

HRSA Program involvement will include:

- Providing the expertise of HRSA personnel and other relevant resources to the project.
- Prior to the award, convening the TEP to identify between five and seven interventions based on the information shared by national subject matter experts.
 - Examples of possible interventions may include:

¹⁰ CDC. Sexually Transmitted Disease Surveillance 2016. Published 9-21-17. Accessed 10-23-17 from: https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf

¹¹ Ventola, C.L. The antibiotic resistance crisis part 1: causes and threats. P.T. 2015, 40(4): 277-283.
¹² Jarzebowski W, Caumes E, Dupin N, et al. Effect of early syphilis infection on plasma viral load and CD4 cell count in human immunodeficiency virus- infected men: results from the FHDH-ANRS CO4 cohort. Arch Intern Med 2012; 172(16):1237–1243.

- Innovative clinical interventions such as increasing extragenital testing, self-testing, express visits, incorporating partner services, mobile clinic testing, health education, evaluation of testing frequency, and risk reduction strategies.
- System level interventions to increase STI screening and treatment across the jurisdiction, linkage to care (i.e., integration of surveillance and care teams), partnerships between care centers and the health department, and policy development or changes affecting the service area.
- Agreed upon interventions will be provided to the recipient at the time of the award.
- Reviewing the recipient-selected list of subrecipients.
- Ongoing review of activities, procedures, measures, and technical assistance tools to be established and implemented for accomplishing the goals of the cooperative agreement.
- Participating in the design and implementation of evaluation tools, evaluation plans, and other project material.
- Reviewing all information products prior to dissemination.
- Facilitating the dissemination of project findings, best practices, evaluation data and other information developed as part of this project to the broader network of providers.
- Anticipating and responding to the changes taking place in the health care environment and proposing adjustments to project activities accordingly.
- Collecting and analyzing data relative to national health issues, unmet need, marketplace conditions, special populations, and other key health indicators to guide current/future strategic planning, developmental efforts, and work plan activities.
- Facilitating access to education and training resources available through the
 national and regional AETCs, regional STD Prevention Training Centers (PTCs),
 the National STD Curriculum (https://www.std.uw.edu/), PCAs, the National LGBT
 Health Education Center, TARGET Center, and other HRSA supported resources.

The cooperative agreement recipient's responsibilities will include:

- Rapidly executing formal written agreements with three to five intervention sites
 within each of the three jurisdictions to include a local convener for system level
 changes (such as a health department or university) to implement interventions
 that address STI testing and treatment in PLWH or people at risk for HIV.
- Providing programmatic TA and work with the intervention sites to identify and select specific policies and procedures to operationalize interventions selected in conjunction with HRSA.
 - Conducting assessments of sites' TA needs, interpreting the results of assessments on the effectiveness of adjustments made (if any) to the interventions, and assessing the impact of the TA on intervention implementation.

- Additionally, coordinating TA with regional and/or national AETCs as well as regional STD PTCs to provide health education at the intervention sites.
- Designing, implementing, and conducting a rigorous multisite evaluation that includes outcome, process, and cost measures to assess the effectiveness of interventions and implementation strategies, implemented by intervention sites, in improving STI testing and treatment measures.
 - Working collaboratively with the intervention sites to ensure that proposed measures are appropriate to the selected interventions and overall goals of the project, and feasible given established electronic health records, management information systems (fiscal or clinical), or other data collection tools and systems.
 - Commencing the multisite evaluation at the start of the intervention implementation period (baseline data) of the project to assess each intervention by the sites.
 - Collecting outcome, process, and cost data from the intervention sites to evaluate the effectiveness of adapting interventions and implementation strategies in RWHAP and Health Center Program settings.
 - Monitoring and supporting the intervention sites to ensure data quality and completeness of submissions.
 - Constructing and maintaining a secure data portal through which the multisite evaluation data will be submitted by the intervention sites.
 - Coordinating efforts of the intervention sites to assure the privacy and confidentiality of data collected, submitted, and stored.
 - Providing evaluation-related TA to the selected sites through regular teleconferences, webinars, and in-person meetings over the course of the project.
 - Assuring Health Insurance Portability and Accountability Act (HIPAA) and human subjects research protections through Institutional Review Board (IRB) review and approval, where applicable, for the exchange and use of data.
- Conducting a two-day annual meeting with representation from all intervention sites and HRSA staff to discuss project updates, data sharing, and TA in the Washington, DC area.
- In collaboration with the intervention sites, disseminating findings, including best practices and lessons learned to foster rapid, efficient replication of these interventions by other organizations that treat people living with or at risk for HIV. This external dissemination will include, but is not limited to, tools and materials that can be used by RWHAP and Health Center Program award recipients, and other HRSA funded organizations not funded under this project to adapt the interventions within their own organizations.
 - Working with the TARGET Center as the primary web platform to disseminate information, materials, and products.
 - Collaborating with the national and regional AETCs, PCAs, the National LGBT Health Education Center, and other HRSA supported entities to disseminate findings.

Overall Preferred Project Timeline

Project Date	Tasks
Year 1, Months 1 – 3	Finalize site selection

Year 1, Months 4 – 12	 Complete formal written agreements (e.g., subawards, contracts, memoranda of understanding, letters of agreement) and other necessary documents with the intervention sites Adapt and implement selected interventions within sites Conduct assessment of TA needs and begin TA based on each site's needs Begin multisite evaluation data collection
Year 2	 Continue to adapt and implement selected interventions within sites Provide ongoing TA as needed Continue to collect multisite evaluation data Conduct process evaluation and make midintervention adjustments as needed Provide assistance to intervention sites and local convener to plan for and implement program integration across the jurisdiction by year three
Year 3, months 1 – 3	 Implementation/wrap-up interventions Continue to collect data, conduct outcome evaluation Continue to provide assistance to local convener with implementing program integration plan across the jurisdiction
Year 3, Months 4 - 9	 Continue to collect data, conduct outcome evaluation Continue to provide assistance to local convener with implementing program integration plan across the jurisdiction Develop tools for replication of intervention to HRSA's RWHAP and Health Center Program recipients/subrecipients
Year 3, Months 10 - 12	 Dissemination and promotion of materials

2. Summary of Funding

HRSA expects to have approximately \$4,300,000 available annually to fund one recipient. You may apply for a ceiling amount of up to \$4,300,000 total cost (includes both direct and indirect, facilities and administrative costs) per year of which up to \$500,000 per year may be directed to programmatic activities serving people at risk for HIV, and the remaining \$3,800,000 must be used for activities serving low-income PLWH. The recipient is expected to provide annual subawards to a minimum of three and a maximum of five intervention sites within each of the three jurisdictions to implement the interventions.

The actual amount available will not be determined until enactment of the final FY 2018 federal appropriation. The FY 2018 President's Budget does not request funding for

this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The project period/period of performance is September 30, 2018 through September 30, 2021 (three years). Funding beyond the first year is dependent on the availability of appropriated funds for this program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include entities eligible for funding under RWHAP Parts A, B, C and D of Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. These include, but are not limited to: health centers receiving support under Section 330 of the Public Health Service Act; Federally Qualified Health Centers as described in Title XIX, Section 1905 of the Social Security Act; public and nonprofit private entities involved in addressing HIV/AIDS/STI related issues at the regional or national level; state and local governments; academic institutions; local health departments; nonprofit hospitals and outpatient clinics; 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 applications that exceed the ceiling amount non-responsive and will not consider them for funding under this notice.

HRSA will consider applications that fail to satisfy the deadline requirements referenced in *Section IV.4* non-responsive and will not consider them 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 through Grants.gov. You must use the SF-424 application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

Effective December 31, 2017 - You **must** use the <u>Grants.gov Workspace</u> to complete the workspace forms and submit your application workspace package. After this date, you will no longer be able to use PDF application packages.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the NOFO (also known as "Instructions" on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. 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 Find Grant Opportunities* 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 your application in the English language and it must be 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 **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the application package do not count in the page limitation. 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

- The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is 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 the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in **Attachment 7**: 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), please include the following:

i. Project Abstract

In addition to the information required in Section 4.1.ix of HRSA's <u>SF-424 Application</u> <u>Guide</u>, include the following:

- Identify the three proposed service jurisdictions, and for each jurisdiction
 - The three to five proposed intervention sites, including
 - The local convener to facilitate systems-level interventions between the sites
 - The change champions to support both project and organizational change to help promote the interventions and build organizational support for system change

ii. Project Narrative

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

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

■ INTRODUCTION -- Corresponds to Section V's Review Criterion #1 Need

Briefly describe the purpose of the proposed project as it responds to the purpose set forth in this NOFO. Clearly identify the three proposed jurisdictions and three to five intervention sites within each jurisdiction to implement interventions that address STI testing and treatment in PLWH or people at risk for HIV, to include a local convener for system level changes (such as a health department or university). Identify the change champions to support both project and organizational change to help promote the interventions and build organizational support for system change. Provide a clear description of the roles and activities of your organization and partnering organizations. Describe the overall approach proposed to conduct the

initial, interim, and final assessments and evaluations of the potential interventions and implementation strategies to be used. Briefly describe your organization and its ability to evaluate multisite evidence informed interventions and provide TA to sites as necessary, toward improvements in the screening and treatment of STIs among PLWH or at risk for HIV.

NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 Need

Outline the needs of the proposed jurisdictions and intervention sites as they pertain to STIs in PLWH or at risk for HIV, and diagnosis and treatment of STIs in this population. Use and cite demographic and epidemiologic data whenever possible to support the information provided. Discuss any barriers affecting the effective implementation of interventions.

Describe the process to be used in conducting a needs assessment for each selected intervention site that will identify gaps in STI diagnosis and treatment in this population.

METHODOLOGY -- Corresponds to Section V's Review Criteria #2 Response, #3
 Evaluation Measures, and #4 Impact

Site Selection

Propose a plan for rapidly executing formal written agreements with three to five intervention sites within each of the three jurisdictions to include a local convener for system level changes (such as a health department or university) to implement interventions that address STI testing and treatment in PLWH or people at risk for HIV. The convener may or may not also be a site of clinical intervention. Additionally, intervention sites must identify a change champion(s) to support both project and organizational change to help promote the interventions and build organizational support for system change (**Attachment 4**). Describe site selection criteria that you used to ensure objective selection of appropriate sites and jurisdictions. Describe how the selection criteria ensured the identification and participation of a diverse group of HRSA's RWHAP and/or Health Center Program funded organizations. Selection criteria must include, but are not limited to, the following:

- The intervention sites and jurisdictions' demonstrated need for STI and HIV testing based on high incidence of STIs per the CDC 2016 STD Surveillance report in areas with high prevalence of HIV infection;
- The intervention sites' demonstrated experience with providing STI and HIV testing. Sites should not routinely or optimally utilize the potential interventions listed in the purpose section;
- The intervention sites' willingness to adopt interventions agreed upon with HRSA such as those listed in the purpose section;
- The intervention sites' size, capacity, performance level, number of PLWH or at risk for HIV served, number of STI cases reported in the selected focus area (e.g., Black MSM, transgender women, youth);

- The existence of a robust electronic data system or other mechanism at each site for collecting and reporting client level data, and capacity and experience with exporting data from the data system;
- The intervention sites' history of HRSA's RWHAP and/or Health Center Program funding (either as a direct recipient or a subrecipient);
- The interventions sites' experience working with a multi-component and multisite evaluation; and
- Your established relationship with the selected sites. Letters of commitment from all proposed intervention sites are required in this application (Attachment 3).
 Formal written agreements (e.g., subawards, contracts, memoranda of understanding, letters of agreement) should be finalized within 90 days of award including, as needed, data use agreements, IRB approvals, and partnership agreements.

Technical Assistance

Describe your approach to assess TA needs for each proposed intervention site. Discuss your planned method to customize selected interventions for each intervention site based on the site-specific needs assessments. Describe your approach to develop a TA plan for guiding each intervention site through the implementation of customized interventions. Describe the methods you will use to provide TA to the intervention sites.

Describe your plan to provide TA to the local convener in each jurisdiction to implement changes across the jurisdiction by year three. This plan should include the creation of a sustainability plan including budget projections for continued program integration and ongoing activities across the jurisdiction after the funding period ends.

Describe your approach to providing training and educational materials, if necessary, to fill gaps in existing resources; for example, using evidence-based best practices in distance-based education or learning when conducting webinars and collaborations with regional AETCs and STD PTCs.

Data Collection

Describe your plan to develop a data collection tool for use by intervention sites funded for this project to collect data at regular intervals in an electronic format.

Describe the organizational process for working directly with intervention sites for collection of outcome and process data.

Discuss how you will assist the intervention sites in data collection including the following:

- training intervention site staff in use of data collection instruments and web-based data entry portal,
- · regular monitoring of data collection and reporting efforts of intervention sites, and
- remedial action when necessary to ensure data collection is of the highest quality.

Describe how you will collect evaluation data from the intervention sites. Specifically include the structure, process, and vehicle to be used. Describe how you will monitor data quality and data completeness of regular data submissions.

Describe the procedures for the electronic and physical protection of participant information and data. Describe how you will identify any client-level data with the potential for disclosure of Protected Health Information (PHI). Identify your organization's IRB process for reviewing the multisite evaluation protocol and data collection instruments.

Multisite Evaluation

Describe your plan for a rigorous multisite evaluation across all intervention sites to assess the effectiveness of their selected interventions. Describe the theoretical basis for the multisite evaluation design, including the methodologies to be used, and provide the rationale for their selection. Describe all necessary components of the evaluation, to include process, outcome, and cost analyses.

Describe your process evaluation and process measures to document barriers and facilitators to the effective implementation of the selected interventions.

Outline the outcome design of the evaluation. Describe the STI diagnostic, treatment related, and other measures that will be utilized for the evaluation across intervention sites and jurisdictions. Provide a rationale for your outcome measures, specify their sources and cite references in the literature to support them.

Describe a cost analysis or cost-effectiveness study to collect labor and programmatic costs (but <u>not</u> evaluation-related costs) incurred by the sites in the implementation of their selected interventions.

Propose any additional focused studies of interest relating to diagnosis and treatment of STIs among PLWH or at risk for HIV. Describe the format of a regular report to HRSA describing the submission of all multisite evaluation data by the intervention sites, to include their IRB status (if applicable).

Describe your plan to provide TA to the intervention sites in the collection and reporting of evaluation data.

Describe the methods for assessing sustainable program integration of interventions within individual intervention sites and across jurisdictions including cost analysis.

Describe your approach to leading and coordinating the logistics for a two-day meeting in each of the three years of the demonstration project with the intervention sites. This activity includes but is not limited to site location and logistics, meeting registration, and the development of meeting agendas and presentations in collaboration with HRSA and intervention site staff. All meetings will take place in the Washington, DC metropolitan area, and you should allocate funds for the principal investigator and/or project director, the evaluator, and two other key staff members to attend these two-day meetings.

Dissemination

Describe your plan for the development and dissemination of tools and materials throughout the three-year implementation period. Describe your plan for generating manuscripts for peer-reviewed publication regarding outcomes of this project. Describe your plan to work with the local convener within each jurisdiction to facilitate implementation and program integration across the jurisdiction by year three. Describe your plan to disseminate information to intervention sites of this project, RWHAP and Health Center Program award recipients, and other HRSA funded organizations not funded under this project to adapt the interventions within their organizations. Describe your plan for promoting materials/webinars using the TARGET Center.

WORK PLAN -- Corresponds to Section V's Review Criterion #2 Response

Describe the activities or steps that you will use to achieve each of the components proposed during the entire project period/period of performance in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities. The work plan must include clearly written (1) goals; (2) objectives that are specific, measurable, achievable, realistic, and time-framed (SMART); (3) action steps or activities; (4) staff responsible for each action step; and (5) anticipated dates of completion. The work plan should be included as **Attachment 1.**

 RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion #2 Response

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

 EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria #3 Evaluation Measures, and #5 Resources and Capabilities

Describe your organization's capacity to conduct a comprehensive multisite evaluation of the proposed project. Describe the proposed staff's (including consultants' and contractors', if applicable) knowledge and expertise in conducting evaluations of HIV and STI primary care diagnosis and treatment interventions. Describe your experience and expertise in the three components of evaluation (process, outcome, and cost analysis). Provide evidence of experience, skills, training, and knowledge in achieving scientific excellence and evaluation integrity. Discuss any examples of previous projects that reflect the expertise of proposed staff, as well as proficiency in working collaboratively with similar demonstration projects. Describe the Human Subjects Research Protections training of proposed staff.

Describe how the proposed key project personnel have the necessary knowledge, experience, training, and skills to provide TA for innovative interventions to improve the delivery of STI services to PLWH or people at risk for HIV. Describe the proposed key project staff's (including any consultants' and contractors', if applicable)

experience in collaborative writing and publishing study findings in peer-reviewed journals and in making presentations at conferences. Describe any experience in logistical planning for national meetings. Describe any experience in the development and dissemination of web-based tools and materials.

 ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5 Resources and Capabilities

Describe your mission and structure, scope of current activities, and experience in providing TA, especially to HRSA's RWHAP and/or Health Center Program and other HIV providers nationwide. Describe your experience in working with systems of care that address the prevention, diagnosis, and treatment of STIs. Describe how these all contribute to your ability to successfully implement this project and meet the goals and objectives of this project. Describe your experience and expertise in data collection. Describe your experience and ability to successfully disseminate findings of interventions and lessons learned.

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

Describe your organization's experience conducting TA on interventions and implementation strategies to improve the delivery of STI services to PLWH or at risk for HIV. Describe your organization's level of experience in the area of developing intervention toolkits, specifically related to toolkits for HIV service delivery organizations. Describe your organization's experience in gathering data/information to determine the needs of medical providers or organizations related to the development and implementation of interventions. Describe your organization's experience in tailoring intervention plans and strategies for specific organizations, and subsequent adaptations of established intervention plans.

Describe collaborative efforts with other pertinent agencies that enhance your ability to accomplish the proposed project. Discuss any examples of previous projects that reflect the experience of proposed staff in working collaboratively with regional and/or national AETCs, regional STD PTCs, and HRSA's RWHAP and/or Health Center Program funded organizations.

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

Describe past experience in the development of curricula, "How-To" manuals, implementation guides, or intervention toolkits including the topic areas and targeted audiences.

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

Describe your organizational process for the monitoring of subrecipients under this cooperative agreement. Include a description of your subaward process from initiation to approval, and your timeline for procurements. Describe the methodology for monitoring the intervention sites including, among other items, the submission of invoices and reimbursement for services in a timely manner.

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

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

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.

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response, (3) Evaluative Measures, and
	(4) Impact
Work Plan	(2) Response
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget section
(below)	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. Please 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 the application is selected for funding, you will have a well-organized plan, and by carefully following the approved plan can avoid audit issues during the implementation phase.

The Consolidated Appropriations Act, 2017 (P.L. 115-31), Division H, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." Please see Section 4.1.iv Budget – Salary Limitation of HRSA's <u>SF-424 Application Guide</u> for additional information. Note that these or other salary limitations may apply in FY 2018, as required by law.

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 a 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, this program requires separate line item budgets for each year of the three (3) year period of performance, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate (**Attachment 6**). As a reminder, you may apply for a ceiling amount of up to \$4,300,000 per year of which \$500,000 per year may be directed to programmatic activities serving people at risk for HIV, and the remaining \$3,800,000 must be used for activities serving low-income PLWH. Your budget should include annual subawards to a minimum of three and a maximum of five intervention sites within each of the three jurisdictions to implement the interventions.

iv. Budget Narrative

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

In addition, this program requires the following:

Subaward Budget Narrative: Include a description of funding to be provided to three to five intervention sites in each of three jurisdictions identified by high incidence of STI as indicated by the CDC 2016 STD Surveillance report. The amount allotted for each site must include sufficient funds to cover projected costs associated with the implementation of interventions as well as the collection and submission of evaluation-related data, required travel to annual meeting, and partial or full time equivalent staff per jurisdiction. A revised budget may be required after the details of interventions to be implemented are provided.

v. Attachments

Please 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 (if applicable) will not count toward the page limit. You must clearly label each attachment.

Attachment 1: Work Plan (required)

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative. The work plan should include a description of measurable objectives for the three-year period. Also describe how your organization will ensure that subawarded or contracted funds are properly documented.

Attachment 2: Project Organizational Chart (required)

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

Attachment 3: Letters of Agreement, Memoranda of Understanding (MOU), and/or Description(s) of Proposed/Existing Contracts (project-specific) (required)
Include letters of commitment from all proposed intervention sites. Provide 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. Letters of agreement must be signed and dated.

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

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff, including the change champion identified from each intervention site. 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 5: Biographical Sketches of Key Personnel (required)
Include biographical sketches for persons occupying the key positions described in **Attachment 4**, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual whom you have not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 6: Line Item Budgets for Years 1-3 (required)

Submit line item budgets for each year of the proposed project period/period of performance as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs.

Attachments 7 – 15: Other Relevant Documents
Include here any other documents that are relevant to the application, including your current federally negotiated indirect cost rate agreement (if applicable).

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 SF-424 Application Guide.

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 April 2, 2018 at 11:59 p.m. Eastern Time.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 Application</u> Guide for additional information.

5. Intergovernmental Review

Improving Sexually Transmitted Infection Screening and Treatment for People Living With or at Risk for HIV is a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100. See Executive Order 12372 in the <a href="https://html.ncbi.nlm.nc

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

6. Funding Restrictions

You may apply for a ceiling amount of up to \$4,300,000 total cost (includes both direct and indirect, facilities and administrative costs) per year of which up to \$500,000 per year may be directed to programmatic activities serving people at risk for HIV, and the remaining \$3,800,000 must be used for activities serving low-income PLWH. The FY 2018 President's Budget does not request funding for this program. This program notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. 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.

Funds under this notice may not be used for the following purposes:

- Charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare)
- Purchase or construction of new facilities, or capital improvement to existing facilities
- Purchase of or improvement to land
- International travel
- Cash payments to intended recipients of RWHAP services
- To develop materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual
- Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (nPEP)
 medications or the related medical services [RWHAP Part C and D recipients
 may provide prevention counseling and information to eligible clients' partners
 (also see the June 22, 2016 RWHAP and PrEP program letter)]
- Syringe services programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy. See https://www.aids.gov/federal-resources/policies/syringe-services-programs/.

The General Provisions in Division H of the Consolidated Appropriations Act, 2017 (P.L. 115 - 31) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424 Application</u> <u>Guide</u> for additional information. Note that these or other restrictions will apply in FY 2018, as required by law.

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

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative(s) applied to the award(s) under the program will be addition. Recipients are responsible for ensuring that subrecipients have systems in place to account for program income, and for monitoring

to ensure that subrecipients are tracking and using program income consistent with RWHAP requirements. Please see <u>45 CFR § 75.307</u> for post-award requirements for program income for additional information.

V. Application Review Information

1. Review Criteria

HRSA has instituted procedures for assessing the technical merit of applications to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. HRSA has developed 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. See the review criteria outlined below with specific detail and scoring points.

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

Review criteria are used to review and rank applications. This program has 6 review criteria:

Criteria	Points
Criterion 1: Need	5
Criterion 2: Response	35
Criterion 3: Evaluation Measures	20
Criterion 4: Impact	10
Criterion 5: Resources/ Capabilities	20
Criterion 6: Support Requested	10
Total	100

Criterion 1: NEED (5 points) – Corresponds to Section IV's Introduction and Needs Assessment

- Strength of the proposed service jurisdictions based on high incidence of STIs per the CDC 2016 STD Surveillance report in areas with high prevalence of HIV infection.
- The extent to which the applicant demonstrates a comprehensive understanding of the needs of the proposed jurisdictions and intervention sites as they pertain to STIs in PLWH or at risk for HIV, and diagnosis and treatment of STIs in this population.
- The strength and clarity of the demographic and epidemiologic data used to demonstrate need.
- The strength and clarity of the applicant's process to be used in conducting a needs assessment for each selected intervention site that will identify gaps in STI diagnosis and treatment in PLWH or at risk for HIV.

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

Methodology (20 points)

Intervention Site Selection (6 points)

- The strength and clarity of the applicant's selection criteria to identify three to five intervention sites, including local conveners and change champions, in each of the three jurisdictions in relation to the required selection criteria set forth in section IV. 2. ii. and the purpose of the project set forth in section I. of this NOFO.
- The strength and appropriateness of the proposed intervention sites, local conveners, and change champions.
- The strength and feasibility of the applicant's plan to rapidly execute formal written agreements with the proposed intervention sites, local conveners, and change champions within each of the three jurisdictions.

Technical Assistance (7 points)

- The strength and clarity of the applicant's approach to assess TA needs for each intervention site and develop a TA plan based on those needs.
- The strength and feasibility of the applicant's proposed methods to provide TA to intervention sites.
- The strength and feasibility of the applicant's proposed methods to provide TA
 to the local convener in each jurisdiction to implement changes across the
 jurisdiction by year three to include a structured framework and budget for
 continued program integration after the funding period ends.
- The strength and clarity of the applicant's approach to providing training and educational materials to fill gaps in existing resources.

Data Collection (7 points)

- The feasibility of the applicant's plan to collect data for a multisite evaluation.
- The strength and clarity of the applicant's approach to develop a data collection tool for use by the intervention sites.
- The strength and clarity of the applicant's proposed organizational process for working directly with intervention sites for collection of outcome and process data.
- The strength and clarity of the applicant's approach to assisting the intervention sites in data collection, including proposed training, regular monitoring, and remedial action when necessary.
- The strength and clarity of the applicant's structure, process, and vehicle for data collection.
- The extent to which the applicant outlines a clear and comprehensive plan for monitoring data quality and data completeness.

Work Plan (10 Points)

• The strength and clarity of the applicant's work plan to achieve each of the components proposed in the Methodology section during the three-year project period/period of performance (Attachment 1).

• The extent to which the applicant's work plan includes clearly written: (1) objectives that are specific, measurable, achievable, realistic and time-framed (SMART); (2) action steps and activities; (3) staff responsible for each action step; and (4) anticipated dates of completion.

Resolution of Challenges (5 points)

- The extent to which the applicant clearly describes possible challenges that are likely to be encountered during the design and planning of the multisite evaluation plan.
- The clarity of the applicant's discussion of the barriers impacting the effective implementation of interventions.
- The clarity and feasibility of the applicant's approach, strategies, and techniques to resolve anticipated challenges.

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

Methodology (15 points)

- The strength, effectiveness, and feasibility of the applicant's plan for a rigorous multisite evaluation to assess the effectiveness of the selected interventions.
- The strength and clarity of the applicant's description of the theoretical basis and rationale for the evaluation design.
- The strength and clarity of the applicant's process evaluation to document barriers and facilitators to the effective implementation of the selected interventions.
- The strength and clarity of the applicant's outcome design and appropriateness of selection of outcome measures.
- The strength and clarity of the applicant's plan for a cost analysis or costeffectiveness study.
- The strength and clarity of the applicant's proposal for additional focused studies of interest relating to screening and treatment of STIs among PLWH or at risk for HIV.

Technical Support Capacity (5 points)

• The strength and clarity of the applicant's plan to provide TA to the intervention sites in the collection and reporting of evaluation data.

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

- The strength and clarity of the applicant's plan to promote replication and implementation of interventions.
- The strength and clarity of the applicant's approach for the development and dissemination of tools and materials throughout the implementation process, both to the intervention sites and HRSA RWHAP and Health Center Program recipients/subrecipients, and other HRSA funded organizations not funded under this project.
- The strength and clarity of the applicant's plan for promoting materials/webinars using the TARGET Center.
- The strength and feasibility of the proposed approach to create sustainability plans including budget projections for continued program integration and ongoing activities across the jurisdiction after the funding period ends.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

Evaluation and Technical Support Capacity (10 points)

- The strength of the applicant's capacity to conduct a comprehensive multisite evaluation of the proposed project.
- The extent to which the applicant demonstrates knowledge and expertise of proposed staff in conducting evaluations of HIV and STI primary care screening and treatment interventions.
- The extent to which the applicant demonstrates their experience, skills, training, and knowledge in achieving scientific excellence and evaluation integrity.
- The extent to which the applicant demonstrates how the proposed key project personnel have the necessary knowledge, experience, training, and skills to provide TA.
- The extent to which the applicant demonstrates experience in the development and publication of web-based tools and materials for evaluation-related dissemination activities.

Organizational Information (10 points)

- The extent to which the applicant demonstrates their experience, knowledge, and skill in data collection, reporting, and securing storage of client-level data.
- The extent to which the applicant demonstrates their experience, skills, knowledge, and ability to successfully provide implementation-related and evaluation-related TA.
- The extent to which the applicant demonstrates their experience in working with systems of care that address the prevention, diagnosis, and treatment of STIs.
- The extent to which the applicant demonstrates their experience and ability to successfully disseminate findings of interventions and lessons learned, and other findings from multisite evaluations.
- The extent to which the staffing plan is consistent with and appropriate for the project description, goal, and activities.
- The extent to which the applicant demonstrates their experience in gathering data/information to determine the needs of medical providers or organizations related to the development and implementation of interventions and tailoring intervention plans and strategies to these needs.
- The extent to which the applicant demonstrates their experience in leading collaborative efforts with other pertinent agencies and in supporting collaborative learning and TA projects.
- The extent to which the applicant demonstrates their experience in logistical planning and facilitation for large meetings and training sessions aimed at sharing information and expertise to build knowledge and capacity of participants.
- The strength and clarity of the organizational process for the monitoring of subrecipients under this cooperative agreement.

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

• 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 have adequate time devoted to the project to achieve project objectives.

2. Review and Selection Process

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's SF-424 Application Guide for more details.

3. Assessment of Risk and Other Pre-Award Activities

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

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

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

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Applicant 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 a determination that an applicant is not qualified to FAPIIS (45 CFR §

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing the award prior to the start date of September 30, 2018.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 30, 2018. See Section 5.4 of HRSA's <u>SF-424 Application Guide</u> for additional information.

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA's SF-424 Application Guide.

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 research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46). Guidance from the Office for Human Research Protections is available here: https://www.hhs.gov/ohrp/regulations-and-policy/index.html.

3. Reporting

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

- Progress Report(s). The recipient must submit a progress report to HRSA on a biannual basis, including progress towards meeting the stated outcomes. HRSA will provide further information in the award notice.
- Integrity and Performance Reporting. The Notice of Award will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45</u> <u>CFR part 75 Appendix XII</u>.

VII. Agency Contacts

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

Beverly H. 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 TA related to this NOFO by contacting:

Marlene Matosky Chief, Clinical and Quality Branch HIV/AIDS Bureau, Division of Policy and Data Telephone: (301) 443-0798

Fax: (301) 443-8143

Email: mmatosky@hrsa.gov

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

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, 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 strongly encourages all applicants to participate in a TA 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.

Day and Date: Tuesday, February 20, 2018

Time: 3 p.m. – 4 p.m.

Call-In Number: 1-888-324-9620 Participant Code: 8893019

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

IX. Tips for Writing a Strong Application

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