U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HIV AIDS Bureau
Office of Training and Capacity Development
Special Projects of National Significance

Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start for Improved Care Engagement in the Ryan White HIV/AIDS Program – Evaluation and Technical Assistance Provider

Funding Opportunity Number: HRSA-20-113
Funding Opportunity Type: New
Assistance Listings (CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: June 15, 2020

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
HRSA will not approve deadline extensions for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to 1 month to complete.

Issuance Date: April 15, 2020

MODIFICATION: MAY 15, 2020: total available annual funding increased from $700,000 to $1,000,000; number of implementation sites increased from 10 to 15.

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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 Act).

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2020 *Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program (RWHAP) – Evaluation and Technical Assistance Provider (ETAP)*. This program is supported by funding from the U.S. Department of Health and Human Services (HHS) Minority HIV/AIDS Fund (MHAF) and the HRSA HIV/AIDS Bureau (HAB) Special Projects of National Significance (SPNS) Program. The purpose of this program is to evaluate the implementation of rapid start interventions and their outcomes on the HIV care continuum for future replication and scale-up in other RWHAP provider organizations.

In support of the *Ending the HIV Epidemic (EHE): A Plan for America Initiative,*[1] HRSA will award a cooperative agreement to fund a single organization to conduct a rigorous multi-site evaluation on the implementation of rapid ART start interventions and facilitate technical assistance (TA) to up to 15 implementation sites. The implementation sites are being funded (under a separate announcement (HRSA-20-114)) to promote a "rapid start" connection or accelerated entry into HIV medical care and rapid initiation of ART for people with HIV who are newly diagnosed, new to care, or out of care. The target of the implementation project is to assist organizations that have the capacity and infrastructure to support rapid start implementation but have not yet been able to, with the goal of replicating and expanding successful rapid start models.

Funding Opportunity Title:	Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program – Evaluation and Technical Assistance Provider (ETAP)
Funding Opportunity Number:	HRSA-20-113
Due Date for Applications:	June 15, 2020
Anticipated Total Annual Available FY 2020 Funding:	Up to $ 1,000,000
Estimated Number and Type of Award(s):	Up to 1 cooperative agreement
Estimated Award Amount:	Up to $ 1,000,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020, through August 31, 2023 (3 years)

[1] U.S. Department of Health and Human Services. *Ending the HIV Epidemic: A Plan for America.* Available at: https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html

Eligible Applicants:	Eligible applicants include entities eligible for funding under Parts A - D of Title XXVI of the Public Health Service (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 Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Wednesday, April 29, 2020
Time: 3 p.m. – 4:30 p.m. ET
Call-In Number: 1-888-391-7047
Participant Code: 5501604
Weblink: https://hrsa.connectsolutions.com/hrsa-20-113
Playback Number: 1-888-566-0406
Passcode: 2156

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

Table of Contents

I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION....1

1. PURPOSE 1
2. BACKGROUND 1

II. AWARD INFORMATION 6

1. TYPE OF APPLICATION AND AWARD....6
3. SUMMARY OF FUNDING 11

III. ELIGIBILITY INFORMATION 11

1. ELIGIBLE APPLICANTS 11
2. COST SHARING/MATCHING....12
3. OTHER 12

IV. APPLICATION AND SUBMISSION INFORMATION....12

1. **ADDRESS TO REQUEST APPLICATION PACKAGE**....12
2. CONTENT AND FORM OF APPLICATION SUBMISSION 13
i. Project Abstract....*13*
ii. Project Narrative....*14*
iii. Budget....*20*
iv. Budget Narrative....*21*
v. Attachments....*21*
3. DUN AND BRADSTREET DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER AND SYSTEM FOR AWARD MANAGEMENT....22
4. SUBMISSION DATES AND TIMES 23
5. INTERGOVERNMENTAL REVIEW....24
6. FUNDING RESTRICTIONS 24

V. APPLICATION REVIEW INFORMATION....25

1. REVIEW CRITERIA 25
2. REVIEW AND SELECTION PROCESS....28
3. ASSESSMENT OF RISK 29

VI. AWARD ADMINISTRATION INFORMATION 29

1. AWARD NOTICES 29
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS 29
3. REPORTING 30

VII. AGENCY CONTACTS....31

VIII. OTHER INFORMATION 32

I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the *Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program – Evaluation and Technical Assistance Provider (ETAP)*.

In support of the *Ending the HIV Epidemic (EHE): A Plan for America Initiative*, the purpose of this program is to support a single organization that provides evaluation and technical assistance (TA) to up to 15 implementation sites (funded separately under announcement number HRSA-20-114). The awarded ETAP organization will evaluate the implementation of rapid start interventions and their outcomes on the HIV care continuum for future replication and scale-up in other Ryan White HIV/AIDS Program (RWHAP) provider organizations. HRSA anticipates that, through the implementation of rapid start and achievement of viral suppression as an effective strategy to prevent HIV transmission, rates of new HIV infections in areas of highest-burden will be reduced.

The ETAP will also provide TA and capacity building to up to 15 implementation sites by facilitating learning collaboratives and peer-to-peer exchanges on rapid start intervention processes and procedures, including sharing innovative and best practices with clinics and organizations that have already successfully implemented rapid start interventions. In addition, the ETAP will lead the dissemination of evaluation findings, best practices and lessons learned, and promote the replication of successful rapid start interventions in other Ryan White HIV/AIDS Program (RWHAP) providers and other health care settings. The expansion of successful rapid start interventions will further the goal of accelerating the period of time from new HIV diagnosis to entry into care, increasing faster linkage and engagement into care for those out of care, and achieving and sustaining viral suppression.

Because award recipients under both NOFOs (HRSA-20-113 and HRSA-20-114) will need to work together to be successful, HRSA, HIV/AIDS Bureau (HAB) encourages you to read and familiarize yourself with the program expectations of the companion NOFO, HRSA-20-114 (*Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program – Implementation Sites).*

2. Background

This program is funded through the Minority HIV/AIDS Fund, as authorized under the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, Title II. This initiative also is funded and administered by the HRSA HIV/AIDS Bureau (HAB) Special Projects of National Significance, as authorized by 42 U.S.C. § 300ff-101 (section 2691 of the PHS Act).

Of more than 1.1 million people with HIV, approximately 86 percent are aware of their HIV diagnosis, but only 64 percent of those aware are engaged in medical care.[2] Often, there is a delay between patients being notified of their HIV diagnosis and initiation of ART, due to difficulties in referring newly diagnosed individuals to appropriate HIV care providers, lack of availability of appointments, or other individual and structural barriers to care. Once a patient establishes HIV care, there are often additional delays before the initiation of ART can take place, including completing and filing paperwork for insurance coverage and pharmacy benefits resulting in the potential of patients to be lost to follow-up. Thus, some groups have proposed initiation of ART on the same day, next day or within a week of HIV diagnosis for newly diagnosed individuals or re-entry into care for people with HIV who are out of care as a strategy to streamline eligibility processes and improve engagement in care. Clinical studies have shown that reducing the delay between presentation to care and initiation of ART has led to substantially earlier linkage to care, earlier ART initiation, and a shorter time to viral suppression.[3]

Immediate linkage to care and rapid ART start leads to individual health benefits and can also lead to public health benefits because there is a reduced risk of transmission by individuals with viral suppression. In addition, immediate linkage to care and implementation of novel rapid start strategies, including the promotion of Undetectable = Untransmittable (U=U)[4] and reduction in a clinic or structural barriers, may make it more likely individuals stay engaged and retained in the care system. Thus, opportunities exist to accelerate rapid start strategies to increase the timeliness of linkage to care, increase retention in care, maintain sustained viral suppression, and reduce the number of new infections.

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).

[2] Centers for Disease Control and Prevention: https://www.cdc.gov/hiv/basics/statistics.html
[3] Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: http://aidsinfo.nih.gov/guidelines
[4] RW Eisinger, CW Dieffenbach, AS Fauci. HIV viral load and transmissibility of HIV infection: undetectable equals untransmittable. *Journal of the American Medical Association* DOI: 10.1001/jama.2018.21167 (2019).

National HIV/AIDS Strategy: Updated to 2020

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

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

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

HIV Care Continuum

Diagnosing and linking people with HIV to HIV primary care, and ensuring people with HIV achieve viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main "steps" or stages that include: HIV diagnosis, linkage to care, retention in care, antiretroviral use, and viral suppression. The HIV care continuum provides a framework that depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication. It also demonstrates the proportion of individuals with HIV who are engaged at each stage. The HIV care continuum allows recipients and planning groups to measure progress and to direct HIV resources most effectively. RWHAP recipients are encouraged to assess the outcomes of their programs along this continuum of care. Recipients should work with their community and public health partners to improve outcomes across the HIV care continuum. HRSA encourages recipients to use the 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.[5] These improved outcomes mean more people with HIV in the United States will live near

[5] 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.

normal lifespans and have a reduced risk of transmitting HIV to others.[6] Scientific advances have shown antiretroviral therapy (ART) preserves the health of people with HIV and prevents sexual HIV transmission. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner. Such findings underscore the importance of supporting effective interventions for linking people with HIV into care, retaining them in care, and helping them adhere to their ART.

Integrated Data Sharing and Use

HRSA and CDC's Division of HIV/AIDS Prevention support integrated data sharing, analysis, and utilization for the purposes of program planning, needs assessments, unmet need estimates, reporting, quality improvement, the development of your HIV care continuum, and public health action. HRSA strongly encourages RWHAP Part F recipients to:

- Follow the principles and standards in the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action.
- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated 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 territorial health departments may use CD4, VL, and nucleotide sequence data to identify cases, stage of HIV disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into and retention in HIV care, measure viral suppression, monitor prevalence of antiretroviral drug resistance, detect transmission clusters and understand transmission patterns, and assess unmet health care needs. Analyses at the national level to monitor progress toward ending the HIV epidemic can only occur if all HIV-related CD4, VL, and HIV nucleotide sequence test results are reported by all jurisdictions. CDC requires the reporting to the National HIV Surveillance System (NHSS) all HIV-related CD4 results (counts and percentages), all VL results (undetectable and specific values), and HIV nucleotide sequences.

[6] 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.

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

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

- **Replication Resources from the SPNS Systems Linkages and Access to Care (https://targethiv.org/library/replication-resources-spns-systems-linkages-and-access-care)**
  There are Intervention manuals for patient navigation, care coordination, state bridge counselors, data to care, and other interventions developed for use at the state and regional levels to address specific HIV care continuum outcomes among hard-to-reach people with HIV.

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

II. Award Information

1. Type of Application and Award

Type 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:

- Providing information and the expertise of HRSA personnel and other relevant resources in the planning, development, management, and technical performance of all phases of the project;
- Facilitating collaborative relationships between the ETAP, funded implementation sites, and other federal agencies and partners as needed;
- Providing an ongoing review of documents, activities, procedures, and tools to be established and implemented for accomplishing the goals of the cooperative agreement, including project information before dissemination to the broader network of RWHAP and other providers serving people with HIV;
- Participating in the design and implementation of evaluation tools, evaluation plans, and other project material; and
- Participating in the dissemination of best practices, lessons learned, and other information developed as part of this project to the broader network of HIV providers.

The cooperative agreement recipient's responsibilities will include:

- Working closely and concurrently with up to 15 implementation sites (funded separately through HRSA-20-114) to execute this initiative;
- Designing and implementing a rigorous multi-site evaluation that includes outcome, process, and cost measures to assess the effectiveness of rapid start models implemented at the implementation sites in improving early engagement, retention in care, and sustained viral suppression;

- Facilitating learning collaboratives and peer-to-peer learning on rapid start models including matching funded implementation sites with experienced sites that have already successfully implemented rapid start models to help build and increase the capacity of the implementation sites to implement rapid start approaches in the RWHAP setting for people with HIV;
- Providing TA on the adaptation, implementation, and evaluation of rapid start models to implementation sites through regular teleconferences, webinars, site visits, and in-person meetings if necessary for a range of needs over the course of the initiative;
- Leading and coordinating the dissemination and publication activities for the initiative, working in collaboration with the implementation projects and HRSA staff;
- Assisting HRSA with information dissemination to constituencies upon request;
- Developing a final report highlighting the clinical, programmatic, and cost outcomes of the multi-site evaluation to facilitate future replication of successful rapid start models;
- Developing and maintaining a secure website for the initiative, with both public and private password-protected access to serve as a data portal for the reporting of data by the implementation projects and a communications nexus for the initiative;
- Coordinating the efforts of implementation projects to assure the privacy and confidentiality of study participants in their health-seeking efforts;
- Assuring the appropriate review, approval, and renewal of all multi-site evaluation instruments and documents by an identified IRB.
- Coordinating and leading the logistics for annual national multi-site meetings in each of the 3 years of the initiative with the implementation sites in the Washington, DC/Metropolitan area; and
- Collaborating with assigned HRSA project officer and other HRSA staff as necessary to plan, execute, and evaluate the activities.

You are encouraged to collaborate with partner organizations, as needed, to conduct the recipient responsibilities and programmatic expectations to achieve the following three (3) goals:

1) Conduct a rigorous multi-site evaluation on the effectiveness of the implementation of rapid start models

The ETAP will work closely with up to 15 implementation sites (funded separately under HRSA announcement HRSA-20-114) to lead and conduct a multi-site evaluation that includes outcome, process, and cost measures to assess the effectiveness of rapid start models and outcomes along the HIV care continuum in the RWHAP setting. The multi-site evaluation seeks to answer, but is not limited to, the following evaluation questions:

- What factors influenced the adaptation and implementation of the selected rapid start interventions?

- How did implementation of the rapid start interventions affect the timing of early entry into care and initiation of ART?

- How were the implemented rapid start interventions associated with outcomes along the HIV continuum of care, including early linkage to care, rates of engagement, retention in care, and rapid ART initiation?

- Did the adaptation and implementation of the rapid start interventions result in increased viral suppression rates, a shorter period of time to viral suppression, and/or durable viral suppression?

- What were the estimated costs associated with adopting and implementing the selected rapid start interventions in RWHAP settings?

Outcome measures may include early engagement, retention in care, and sustained viral suppression and/or other outcomes on the HIV care continuum. The evaluation should also capture behavioral health indicators, barriers and facilitators to adopting rapid start interventions, and other measures proposed by the ETAP. To show the impact and contribution of rapid start interventions to the overall health of people with HIV, the evaluation plan must include key HAB performance measures[7] and the following MHAF performance measures:

- **Linkage to HIV Medical Care**
    - Percentage of clients linked to routine HIV medical care *within 30 days* of HIV diagnosis.
- **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 Load 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 core performance measures may also be proposed, subject to HRSA concurrence (Performance measures can be viewed at http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html)

The process evaluation will assess how the rapid start models/interventions are adapted and implemented at the implementation sites. It will include, but not be limited to, facilitators and barriers to implementation-associated processes. The ETAP, in coordination with the funded implementation sites, will develop the final core process evaluation methods.

The ETAP will also employ *qualitative methods* to better understand how the rapid start interventions are adapted at the implementation sites, and how the interventions affect a diverse set of stakeholders and beneficiaries, including patients and health care staff.

A *cost analysis study* will document the related costs, including the various funding streams and actual costs and expenditures incurred by each implementation site, to inform feasibility for future replication and expansion in RWHAP and other health care

[7] Health Resources and Services Administration, Ryan White HIV/AIDS Program, HIV/AIDS Bureau. Performance Measures Portfolio. Available at: https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio

settings. *Data Portal and Security:* The ETAP must demonstrate the capacity of their organizational information technology infrastructure to electronically receive, store, manage, and maintain de-identified client-level data to be collected and reported by implementation sites. The ETAP will coordinate efforts to assure the privacy and confidentiality of data submitted, collected, and stored. The ETAP will be responsible for monitoring data quality and completeness of submissions and interpreting evaluation results. Data use agreements with the funded implementation sites may be necessary to share data with the ETAP to evaluate progress toward meeting outcomes and objectives.

Website: In addition to a secure data portal, the ETAP will be responsible for developing and maintaining an initiative-specific website with both public access for communication of the initiative and private password-protected access for implementation sites, ETAP, HRSA staff, and federal partners. The website will be expected to support TA resources for the multi-site evaluation; registration information for the national meetings of the initiative; recent findings of interest from outside the initiative; and links to relevant resources. This website also serves as a repository of learning collaborative webinars, tools, and resources to share among the implementation sites.

The recipient will deliver interim evaluation results to HRSA HAB for ongoing monitoring and to support performance improvement feedback to funded implementation sites.

2. Provide and facilitate technical and capacity building assistance on the adaptation and implementation of rapid start models

The ETAP will implement and facilitate TA and capacity building assistance (CBA) to up to 15 clinical implementation sites on the adaptation and implementation of their rapid start interventions. The level and scope of TA and CBA provided to each clinic site will be based on a review of each site's needs assessments and determination of readiness including clinical capacity (e.g., staff, personnel, workforce trainings) and infrastructure (e.g., clinical system, procedures/workflows).

The ETAP will facilitate TA through learning collaboratives that allow groups working toward the same goal to learn from and assist one another during implementation,[8] including peer-to-peer exchange. The ETAP will seek experienced organizations that have successfully implemented rapid start programs to work and/or subcontract with to promote peer-to-peer learning with funded implementation sites. This will provide opportunities for engagement with subject matter experts to guide the development and implementation of rapid start approaches. The ETAP will match the implementation sites with experienced sites that are similar in geographic location, size of clinical settings, or available resources.

The ETAP will establish and support a rapid start-focused learning collaborative and provide a virtual platform, utilizing available technology that facilitates the rapid exchange of information and ideas for participating clinics. This will further capacity development, advance the knowledge of existing providers, and expand the provider

[8] Planning and Implementing a Successful Learning Collaborative. Available at https://targethiv.org/sites/default/files/file-upload/resources/Plan_Implement-Learning_Collaborative_2008.pdf

base of personnel skilled in administering rapid start while the recipient focuses on implementation and evaluation of models.

The ETAP will also provide other trainings and CBA to the implementation sites. This may include facilitating team-based provider training on patient screening, baseline laboratory assessments, recommended regimens for immediate ART, and follow-up with a review of contraindications or special considerations to improve immediate patient linkage and overall retention in care and related activities. The ETAP may coordinate training in collaboration with the RWHAP AIDS Education and Training Centers (AETCs) Program or other TA entities in the region to further build capacity around rapid start implementation.

The ETAP will work with each implementation site to support the development and finalization of an implementation protocol specific to the selected rapid start interventions. This will include a step-by-step guide of all aspects of rapid start service delivery, from receipt and intake of new clients, through eligibility and processing, clinical provider visits, follow-up schedule, and any additional services provided by support staff. The protocol may be revised and updated as needed during the implementation period. The ETAP may use the AETC-developed guide titled *"Immediate ART Initiation: Guide for Clinicians"*[9] to facilitate the development of the implementation protocols.

3. Identify and collect best practices and lessons learned of effective rapid start models for the purposes of dissemination and replication

The ETAP will work collaboratively with the implementation sites to identify successful rapid start interventions, promising and best practices, and lessons learned that can be disseminated to the RWHAP community. The ETAP will also work collaboratively with the implementation sites in the development of these dissemination materials to support further replication and expansion.

The ETAP will be responsible for producing and disseminating TA toolkits, materials, and products to include an implementation manual. Mechanisms of dissemination may include websites (the initiative website and the TargetHIV website), presentations via webcasts, conferences, meetings, or national forums. In addition, the ETAP will lead to developing and producing an implementation manual by the end of the period of performance for replication and expansion to the rest of the RWHAP community. The implementation manual should reflect evidence-informed practices for adapting and implementing rapid start services at RWHAP sites describing the different resources and program considerations needed for clinical settings with varying resources.

The ETAP and implementation sites will work with the TargetHIV **(https://targethiv.org/)** (website for hosting tools, webcasts, trainings, and other resources to assist RWHAP-funded programs) as the web forum to disseminate information, materials, and products. The ETAP shall make all files, including captioning, audio descriptions, videos, tables, graphics/pictures, registration forms, presentations (both audio and video) or other types of proprietary format files – e.g.,

[9] AETC National Coordinating Resource Center. Immediate ART Initiation: Guide for Clinicians. Available at: https://aidsetc.org/blog/immediate-art

Adobe Portable Document Format (.pdf), Microsoft Office PowerPoint (.ppt) and Microsoft Excel (.xls), fully accessible to members of the public with disabilities. Technical and functional standards for accessibility are codified at 36 CFR Part 1194 and may be accessed through the Access Board's Web site at http://www.access-board.gov.

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

The ETAP, in coordination with HRSA staff, will lead the dissemination of evaluation results, findings, and lessons learned from rapid start implementation to improve early engagement, retention in care and sustained viral suppression.

3. Summary of Funding

HRSA estimates approximately up to $ 1,000,000 to be available annually to fund one ETAP recipient. You may apply for a ceiling amount of up to $ 1,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2023 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for *Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start for Improved Care Engagement in the Ryan White HIV/AIDS Program – Evaluation and Technical Assistance Provider (ETAP)* in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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 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, Indian Tribes or Tribal organizations with or without federal recognition.

2. Cost Sharing/Matching

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

3. Other

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

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

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once before 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 Grants.gov using the SF-424 workspace application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package 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 *SF-424 Application Guide* provides instructions for the budget, budget narrative, staffing plan, and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

Application Page Limit
The total size of all uploaded files 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 8** Other Relevant Documents.

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

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (including the budget, budget narrative, staffing plan, and personnel requirements, assurances, certifications, and abstract), include the following:

i. Project Abstract
See Section 4.1.ix of HRSA's *SF-424 Application Guide*. In addition to the requirements listed in the SF424 Application Guide, the abstract must include the following information:

- Brief description of the proposed ETAP structure
- Overall project goals
- Overall multi-site evaluation questions
- Overall TA and CBA approaches

The project abstract must be single-spaced and limited to one page in length.

ii. Project Narrative

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

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

- *INTRODUCTION -- Corresponds to Section V's Review Criterion #1 (Need)*
  This section should briefly describe the purpose of the proposed project and how the ETAP will execute the project to respond to the three (3) goals required by the initiative. Briefly describe your organization and any collaborating organizations that will help to meet the goals of the project.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 (Need)*
  Provide a brief summary of the literature that demonstrates a comprehensive understanding of successful strategies that have been utilized to implement rapid start in similar populations. Describe the existing barriers regarding the access to rapid start and timely linkage to HIV care of the target population.

  Discuss technical, programmatic, clinical capacity, and infrastructure issues in the implementation of rapid start administration, identifying salient challenges and possible strategies to address those challenges. Discuss barriers to access to rapid start, adherence, retention in care, and achieving viral suppression for people with HIV, including policy, financial, capacity, and structural issues that impact the deployment of rapid start activities.

- *METHODOLOGY -- Corresponds to Section V's Review Criteria #2 (Response), (3) Evaluative Measures, and (4) Impact*
  Propose methods that you will use to meet the program expectations in this NOFO.

  For the multi-site evaluation:

  Describe a plan for conducting a rigorous multi-site evaluation of the effectiveness of implementation of rapid start models at the implementation sites. Take into consideration the following items in the development of the plan:

  Discuss the evaluation approach you will use to gather information to answer the evaluation questions stated under *Section II, Goal 1* of this NOFO. Note that you may add additional elements to your evaluation. The evaluation approach must

include the theoretical framework that you will use to design the multi-site evaluation. Provide the rationale for its selection.

Describe your methodology, tools, and instruments that you will use to collect evaluation data and how these data collection methods align with evaluation questions as well as steps taken to ensure that the measurements of outcomes are reliable and valid.

The multi-site evaluation plan must include the collection and reporting of relevant quantitative and qualitative outcomes and process measures as well as costs associated with the implementation of the rapid start interventions to measure their effectiveness. At a minimum, the evaluation plan must include the following descriptions:

- Elements or domains of process surveys (qualitative and/or quantitative and/or mixed methods) and their analyses to assess factors, including barriers and facilitators influencing the adaptation and implementation of the rapid start interventions;
- Elements or domains of outcome surveys (qualitative and/or quantitative and/or mixed methods) and their analyses to assess how the adapted rapid start interventions affect the timing of early entry into care and initiation of ART;
- Elements or domains of clinical and/or patient outcome surveys (qualitative and/or quantitative and/or mixed methods) and their analyses to assess outcomes on the HIV care continuum associated with the implementation of the rapid start interventions; and
- Elements of a cost analysis to assess labor, programmatic, and structural costs associated with implementing the rapid start models and interventions at the implementation sites.

The evaluation plan should also contain descriptions of the following components:

- The analysis and interpretation plan for each data source. The data analysis techniques used should be appropriate and provide the results needed to answer the proposed evaluation questions.

- The feasibility of collecting data elements based on the capacity of implementation projects operating their rapid start interventions in real-world clinical settings.

- Your approach to working collaboratively with the implementation sites as well as other stakeholders in leading data collection and reporting efforts for the multi-site evaluation.

- Your approach to leading and coordinating the annual grantee meeting in each of the 3 years of the initiative in the Washington, DC metropolitan area, with the participation of the implementation sites and the SPNS program.

For the TA:

- Your plan for the provision and facilitation of TA to a cohort of up to15 implementation sites based on the needs assessment results. Include a detailed methodology to customize the provision of TA to each implementation site according to their varying degrees of readiness and capacity to implement rapid start interventions over the course of the initiative. Describe how you will help each implementation site with the development and finalization of an implementation protocol for rapid start services provision.

- The approach to implementing and facilitating TA and capacity building for the implementation sites through learning collaboratives such as a rapid start-focused peer-to-peer learning collaborative platform to share best practices, challenges, and lessons learned while adapting and implementing rapid start interventions. Describe the plan (if applicable) for coordinating and collaborating with other TA entities and programs such as the AETCs to fulfill Goal 2 of the initiative. Describe other types of TA that you will incorporate that may be helpful for the implementation sites.

- Your plan to develop effective tools for information sharing/dissemination among implementation sites. Include a plan to disseminate reports and project information to key target audiences, including dissemination of best practices via the TargetHIV website and the RWHAP community.

- Your plan for creating and maintaining a secure website, web portal, and data repository system where information, multi-site data, TA tools and resources, as well as dissemination and publication will be housed and available to the implementation sites during the initiative. The website should also serve as a communications nexus for the initiative, accommodating both public access for the initiative promotion and private password-protected access for the demonstration project, ETAP, and HRSA staff.

- A dissemination, replication, and expansion promotion plan identifying appropriate venues including the National and Regional AETC Programs and target audiences including, but not limited to, clinicians, program administrators, policymakers, and national conferences geared toward HIV primary care and social service providers. The dissemination and replication plan should include lessons learned or best practices, and help facilitate the replication of effective rapid start interventions into clinical practices.

- *WORK PLAN -- Corresponds to Section V's Review Criteria #2 (Response) and #4 (Impact)*
  Develop a work plan to describe the steps used to achieve each of the activities proposed during the period of performance in the methodology section. The work plan should be time-framed with specific dates to actively manage the project by

measuring progress and quantifying accomplishments. In chronological order, list the major elements/tasks/ activities to be performed during the period of performance. Identify proposed staff members (in-kind and cooperative agreement supported) responsible for each activity.

The work plan should be presented in a table format and include (1) goals for an entire 3-year period of performance; (2) objectives that are specific, time-framed, realistic, and measurable; (3) action steps; (4) staff responsible for each action step; and (5) anticipated dates of completion. Among key activities that you may address in the timeline include, but are not limited to, start-up activities, multi-site evaluation activities, peer-to-peer learning collaboratives facilitation, dissemination to the RWHAP community and HIV providers, and replication and expansion promotion activities. The work plan should be included as **Attachment 1**.

You must submit a logic model for designing and managing the project as **Attachment 7**. 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).

- *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/innovations 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/Capacities)*
  Describe your capacity to carry out the following activities:
  - You and your collaborating partner organization's (if applicable) capacity to conduct a rigorous multi-site evaluation to assess the implementation and outcomes of the implementation projects. Include evidence of experience, skills, training, and knowledge of proposed key project staff (including any consultants, subrecipients, and contractors, if applicable) in achieving evaluation integrity that will have maximum impact on practice and policy affecting early engagement, retention in care, and sustained viral suppression.

- How your knowledge of legislative and programmatic requirements of the RWHAP programs, current reporting protocols for the RWHAP, and the HIV care continuum meet the objectives and expectations of this initiative.

- How the proposed key personnel (including any consultants, sub-recipients, and contractors, if applicable) have the necessary knowledge, experience, training, and skills in designing and implementing public health program evaluations to successfully carry out the required activities and meet the expectation of the initiative.

- The capacity of the proposed project staff to provide TA to implementation sites for the rigorous multi-site evaluation. Describe the experience of proposed project staff (including partner organization staff, if applicable) in providing and facilitating TA and CBA to the implementation sites that provide HIV care and clinical services.

- Describe your knowledge of and experience with the submission of IRB materials for review and obtaining approvals and renewals for all data collection instruments, informed consents, and evaluation materials. Describe any training in human subjects research protection by proposed project staff.

- The experience of proposed project staff (including partner organization staff, if applicable) in logistical planning and implementation of annual meetings and other necessary events if needed.

- The experience of proposed key project staff (including any consultants and subcontractors) in collaborative writing and publishing study findings in peer-reviewed journals. Describe the experience of proposed key project staff in making presentations to local communities, at state and national conferences, and to policymakers.

You must describe the systems and processes that will effectively support tracking your organization's performance outcomes including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5 (Resources and Capabilities)*
  Describe your organization's mission and structure, the scope of current activities, the quality, and availability of facilities and personnel. Include information on all partnering organizations' current mission and structure, and scope of current activities. Describe how these all contribute to the organization's ability to successfully carry out a project of this magnitude and meet the goals and objectives of this initiative.

Describe your organization's capacity to conduct the rigorous multi-site evaluation, and to provide and facilitate TA and capacity building assistance activities described earlier in this announcement.

Provide information on your organization's ability to lead and coordinate the dissemination of best practices, lessons learned, and other findings from the multi-site evaluation.

Describe the capacity of your organization to build and maintain the project website as described earlier.

Provide a one-page figure that depicts the organizational structure of the project, including collaborating organizations, contractors and other significant collaborators as **Attachment 5**. Do not provide a standard organization chart for the entire organization.

Provide a staffing plan (**Attachment 2**) that identifies staff credentials and commitments to the proposed project components.

If applicable, describe the roles and responsibilities of any consultants and/or contractors who will carry out aspects of the proposed project. Any current and/or proposed collaborating organizations, consultants and/or contractors must demonstrate their commitment to fulfill the goals and objectives of the project through written letters of support or memoranda of agreement or understanding. Include any such letters or memoranda, and descriptions of any existing or proposed contracts relating to the proposed project, as **Attachment 4**.

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

NARRATIVE GUIDANCE To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.	
Narrative Section	**Review Criteria**
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response, (3) Evaluative Measures and (4) Impact
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 *SF-424 Application Guide*. 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, this program requires the following:

- 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 noted, the ETAP will lead and coordinate the logistics for annual meetings in each of the 3 years of the initiative with the implementation sites. Proposed costs for these activities should also be included in the budget.

- Key personnel includes, at a minimum, the Principal Investigator, Project Director, and Evaluator, and you must list each of these positions on the budget.

- Please also include travel to the biennial National Ryan White Conference on HIV Care and Treatment, to be held in the Washington, DC/Metropolitan area. The next conference will be held in 2022.

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 *Building Capacity to Implement Rapid ART Start for Improved Care Engagement in RWHP – Evaluation, and Technical Assistance Provider (ETAP)* program requires the following:

Provide a budget narrative that explains the amounts requested for each line of the budget in Section B. 6. Object Class Categories. The budget narrative should specifically describe how each item will support the achievement of the proposed objectives. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year 1 or indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

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

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. It also includes 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 *SF-424 Application Guide)*

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

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length per person. If 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

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

Attachment 6: Line Item Budgets Spreadsheet for Years 1 through 3

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 7: Logic Model

Provide a one-page diagram to present the conceptual framework to explain the links among program elements.

Attachments 8 – 10: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number 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 to the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

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

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

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

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

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the 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 *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The Program *Building Capacity to Implement* R*apid Antiretroviral Therapy (ART) Start for Improved Care Engagement in the Ryan White HIV/AIDS Program - Evaluation and Technical Assistance Provider* 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 $ 1,000,000 per year (inclusive of direct **and** indirect costs). Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division A, title II and title V of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in the following FY, as required by law.

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

1) Any charges that are billable to third-party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare);
2) To directly provide medical or support services (e.g., HIV care, counseling and testing) that supplant existing services;
3) Cash payments to intended recipients of RWHAP services;
4) Purchase, construction of new facilities or capital improvements to existing facilities;
5) Purchase or improvement to land;
6) Purchase vehicles;
7) Fundraising expenses;
8) Lobbying activities and expenses;
9) Reimbursement of pre-award costs; and/or
10) International travel

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

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

V. Application Review Information

1. Review Criteria

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

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

Review criteria are used to review and rank applications. The Building Capacity to Implement Rapid ART Initiation for Improved Care Engagement – Evaluation and Technical Provider (ETAP) has six review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's Abstract, Introduction and Needs Assessment
The extent to which the application demonstrates the problem and associated contributing factors to the problem.

- Strength, clarity and relevance of the applicant organization's brief description of the proposed project, including the overall project goals, overall proposed multi-site evaluation plan and activities, and TA provision and facilitation activities.
- The extent to which the literature review demonstrates a comprehensive understanding of successful strategies that have been utilized to implement rapid start.
- The extent to which the applicant describes the need to evaluate the implementation of rapid start interventions in the RWHAP setting to improve early engagement, retention in care, and sustained viral suppression.
- Strength of and clarity with which the applicant describes barriers to access to rapid start, engagement, retention in care, and achieving viral suppression for people with HIV, including policy, financial, capacity, and structural issues that impact the rapid start interventions.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges.
The extent to which the proposed project responds to the "Purpose" included in the program description. The extent to which the activities described in the application are capable of addressing the problem and attaining the project objectives.

Methodology (15 points)

- Strength, clarity, and feasibility of the methods that the applicant uses to meet the program expectations in this NOFO. Strength, clarity, and feasibility with which the applicant describes the evaluation approach(es) and plans for conducting a rigorous multi-site evaluation.

- Strength and clarity of the applicant's approach to providing and facilitating TA and capacity building with the implementation sites through learning collaboratives such as a rapid start-focused peer-to-peer learning collaborative platform to share best practices, challenges, and lessons learned while implementing rapid start interventions.
- Strength and clarity of the applicant's plan for provision and facilitation of TA and capacity building to a cohort of up to 15 implementation sites, including a detailed methodology to customize the provision of matching the implementation sites with the more experienced sites that are similar in geographic location, size of a clinical setting, or available resource to promote peer-to-peer learning collaboratives.
- Strength and clarity of the applicant's plan for reviewing the needs assessments prepared by each implementation site and determining the adequate level of TA and capacity building required to support their needs, including development and finalization of their implementation protocol to provide rapid start services.

Work Plan (10 points)

- The extent to which the applicant's work plan describes the steps used to achieve each of the activities proposed during the period of performance, including but not limited to start-up activities, multi-site evaluation activities, peer-to-peer learning collaboratives facilitation, dissemination to the RWHAP community and HIV providers, and replication and expansion promotion activities. The work plan should be included as **Attachment 1**.
- The extent to which the applicant's work plan lists the major elements/tasks/ activities to be performed during the period of performance identifies proposed staff members responsible for each activity and is time-framed with specific dates to actively manage the project by measuring progress and quantifying accomplishments.
- The strength and clarity of the applicant's proposed logic model to design and manage the project.

Resolution of Challenges (5 points)

- The extent to which the applicant discusses the programmatic, clinical capacity, and infrastructural issues in the adaptation and implementation of rapid start interventions.
- The extent to which the applicant identifies possible challenges that are likely to be encountered in planning and implementing a multi-site evaluation, and providing and facilitating TA and capacity building for the implementation sites and other activities proposed in their work plan.
- Extent and clarity of the proposed approaches that the applicant will use to resolve such challenges.

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

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

- Strength, clarity, and feasibility of the proposed plan and methodology to conduct a multi-site evaluation and its rationale for selection.
- Strength and clarity of the applicant's plan for utilizing data to identify and collect successful models/interventions of implementation of rapid start, best practices, and lessons learned for replication purposes among the RWHAP community.
- Strength, clarity, and feasibility of the applicant's description of how they will monitor and evaluate the effectiveness of the TA provision, including peer-to-peer TA facilitation and matching implementation sites with the sites already successfully implemented rapid start programs.
- The extent to which the applicant describes the knowledge of and experience with training in human subjects research protection and submission of IRB materials and obtaining approvals and renewals for all data collection instruments, informed consents, and evaluation materials.

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

- Extent and strength of the applicant's plan to develop effective tools for information sharing/dissemination among implementation sites.
- Strength and clarity of the applicant's plan to disseminate reports and project information to key target audiences, including dissemination of best practices to the RWHAP community, utilizing inputs from the sites and the data obtained from the multi-site evaluation to identify the best practices for the implementation of rapid start services in HIV care settings at various levels of readiness and resources.
- Extent and strength of the applicant's proposed plan to gather components for the implementation manual to include methods, resources, successful rapid start interventions and detailed implementation protocol in implementing rapid start interventions for the replication and expansion purposes, and lessons learned for use by the RWHAP community and HIV providers at the end of the period of performance.
- Strength and clarity of the applicant's plan for providing and facilitating TA and capacity building among providers of rapid start services at the implementation sites.
- The extent to which the applicant describes their plan for collaborations with the AETC Program to integrate the evidence-informed strategies into clinical practice.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information
The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and

the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

- Demonstrated capability of proposed key project staff in designing and implementing public health program evaluations to successfully carry out the required activities and meet the expectation of the initiative.
- Demonstrated capability of the proposed key project personnel to have the necessary knowledge, experience, training, and skills to promote learning collaboratives, including peer-to-peer exchange.
- Strength, clarity, and feasibility of the applicant organization's ability to lead dissemination of best practices, lessons learned, and other findings from the multi-site evaluation.
- Extent and strength of the capacity of the organization to build and maintain the project website and other electronic systems needed as described earlier.
- Strength and clarity of the project organizational chart provided (**Attachment 5)**. Clarity of the staffing plan (**Attachment 2**) that identifies staff credentials and commitments to the proposed project components, including information on all partnering organizations' current mission and structure, and scope of current activities.
- If applicable, extent and clarity of the applicant organization's description of the roles and responsibilities of any consultants and/or subcontractors who will carry out aspects of the proposed project as demonstrated in **Attachment 4**.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Budget, Line Item 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 the narrative justification sufficiently justifies each line item
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- If applicable, the extent to which the applicant clearly describes sub-awards and/or contracts for proposed sub-recipients, contractors, and consultants in terms of scope of work; how costs were derived; payment mechanisms and deliverables are reasonable and appropriate.

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest-ranked applications receive consideration for an award within available funding ranges. HRSA may also consider an assessment of risk and the other pre-award activities described in Section 3 below. See Section 5.3 of HRSA's *SF-424 Application Guide* 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 (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

If you anticipate research involving human subjects, please review HRSA's SF-424 Application Guide to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application; if you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award. In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following:

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

3. Reporting

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

1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be available in the NOA.

2) **Minority HIV/AIDS Fund Report.** The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be available in the NOA.

3) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

VII. Agency Contacts

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

Beverly Smith
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-7065
Email: 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: Rapid Antiretroviral Therapy (ART) Implementation in the Ryan White HIV/AIDS Program - Evaluation and Technical Assistance Provider (HRSA-20-113)
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
Fax: (301) 594-2511
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 the following technical assistance:

Webinar

Day and Date: Wednesday, April 29, 2020
Time: 3 p.m. – 4:30 p.m. ET
Call-In Number: 1-888-391-7047
Participant Code: 5501604
Weblink: https://hrsa.connectsolutions.com/hrsa-20-113
Playback Number: 1-888-566-0406
Passcode: 2156

Tips for Writing a Strong Application

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