

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**



**Health Resources & Services Administration**

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 – Implementation Sites***

**Funding Opportunity Number: HRSA-20-114**  
**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 annual funding increased from \$2,000,000 to \$3,075,000; award ceiling amount increased from \$200,000 to \$205,000; 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 – Implementation Sites*. This program is supported with 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.

In support of the *Ending the HIV Epidemic (EHE): A Plan for America Initiative*,<sup>1</sup> this program will fund up to 15 organizations interested in the implementation and evaluation of “rapid start” or the accelerated entry into HIV medical care and rapid initiation of antiretroviral therapy (ART) for people with HIV who are newly diagnosed, new to care, or out of care. This funding opportunity will support 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 – Implementation Sites
Funding Opportunity Number:	HRSA-20-114
Due Date for Applications:	June 15, 2020
Anticipated Total Annual Available FY 2020 Funding:	Up to \$3,075,000
Estimated Number and Type of Award(s):	Up to 15 grants
Estimated Award Amount:	Up to \$205,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020, through August 31, 2023 (3 years)

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<sup>1</sup> 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:	<p>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.</p> <p>See <a href="#">Section III.1</a> of this notice of funding opportunity (NOFO) for complete eligibility information.</p>
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## **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: 1 p.m. – 2:30 p.m. ET

Call-In Number: 1-888-391-7047

Participant Code: 5501604

Weblink: <https://hrsa.connectsolutions.com/hrsa-20-114>

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

<b>I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION.....</b>	<b>1</b>
1. PURPOSE .....	1
2. BACKGROUND .....	2
<b>II. AWARD INFORMATION .....</b>	<b>6</b>
1. TYPE OF APPLICATION AND AWARD .....	6
2. SUMMARY OF FUNDING .....	6
<b>III. ELIGIBILITY INFORMATION .....</b>	<b>7</b>
1. ELIGIBLE APPLICANTS .....	7
2. COST SHARING/MATCHING.....	7
3. OTHER .....	7
<b>IV. APPLICATION AND SUBMISSION INFORMATION.....</b>	<b>7</b>
1. ADDRESS TO REQUEST APPLICATION PACKAGE.....	7
2. CONTENT AND FORM OF APPLICATION SUBMISSION .....	8
<i>i. Project Abstract</i> .....	9
<i>ii. Project Narrative</i> .....	9
<i>iii. Budget</i> .....	18
<i>iv. Budget Narrative</i> .....	19
<i>v. Attachments</i> .....	19
3. DUN AND BRADSTREET DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER AND SYSTEM FOR AWARD MANAGEMENT .....	20
4. SUBMISSION DATES AND TIMES .....	21
5. INTERGOVERNMENTAL REVIEW.....	21
6. FUNDING RESTRICTIONS .....	21
<b>V. APPLICATION REVIEW INFORMATION.....</b>	<b>22</b>
1. REVIEW CRITERIA .....	22
2. REVIEW AND SELECTION PROCESS.....	27
3. ASSESSMENT OF RISK .....	27
<b>VI. AWARD ADMINISTRATION INFORMATION .....</b>	<b>28</b>
1. AWARD NOTICES .....	28
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS .....	28
3. REPORTING .....	29
<b>VII. AGENCY CONTACTS.....</b>	<b>29</b>
<b>VIII. OTHER INFORMATION .....</b>	<b>31</b>

# 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 – Implementation Sites*. In support of the *Ending the HIV Epidemic (EHE): A Plan for America Initiative*, the purpose of this program is to fund up to 15 organizations interested in the implementation and evaluation of “rapid start” or the accelerated entry into HIV medical care and rapid initiation of antiretroviral therapy (ART) for low income and underserved people with HIV who are newly diagnosed, new to care, or out of care, especially racial and ethnic minorities.

This program will fund organizations that have the capacity (e.g., staff, personnel, workforce trainings) and infrastructure (e.g., clinical system, procedures/workflows) to support rapid start implementation, but have not yet been able to, with the goal of replicating and expanding successful rapid start models. The funding will support sites in leveraging their existing staffing and clinical infrastructure to launch and implement rapid start interventions with the goal of improving engagement in care, including accelerating the period of time from new HIV diagnosis to entry into care, increasing faster linkage and re-engagement into care for those out of care, and achieving and sustaining viral suppression.

The main objective of this initiative is to improve the timeliness and rates of access, linkage, and retention to HIV care, and viral suppression through the implementation of rapid start interventions for individuals newly diagnosed and aware of their HIV status, and people with HIV not currently engaged in HIV care.

In addition to the implementation of rapid start interventions, a main goal of this initiative is to evaluate the effectiveness of rapid start models in improvements in early engagement, retention in care and sustained viral suppression in the RWHAP. Finally, this initiative will facilitate technical assistance (TA) to increase the capacity of health care organizations to implement rapid start interventions and provide high quality, comprehensive care and treatment in the RWHAP setting for people with HIV, especially for racial/ethnic minorities living in areas with the highest HIV burden.

All implementation sites funded under this announcement will be required to collaborate with an evaluation and technical assistance provider (ETAP) (to be funded separately under HRSA-20-113) who will lead a multi-site evaluation to measure the effectiveness of rapid start models and impact in the RWHAP, and provide and facilitate TA through different venues including peer-to-peer learning.

Award recipients under both NOFOs (HRSA-20-113 and HRSA-20-114) will need to work together to be successful. Therefore, HRSA encourages you to read the companion announcement and be familiar with all program expectations within both NOFOs.

It is anticipated that through implementation and scale-up of rapid start interventions, earlier viral suppression rates will increase and could thereby make an impact to help reduce new HIV infections within the areas of highest HIV burden, especially among low income and racial/ethnic minority populations.

## 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 is also funded and administered by the HRSA HAB SPNS Program, as authorized by 42 U.S.C. § 300ff-101 (section 2691 of the PHS Act).

Of an estimated more than 1.1 million people with HIV in the United States, approximately 86 percent are aware of their HIV diagnosis. Only about 64 percent of those who are aware of their diagnosis are engaged in medical care.<sup>2</sup> 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 followup. 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 the offer to initiate ART has led to substantially earlier linkage to care, earlier ART initiation, and a shorter time to viral suppression.<sup>3</sup>

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)<sup>4</sup> 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.

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<sup>2</sup> Centers for Disease Control and Prevention: <https://www.cdc.gov/hiv/basics/statistics.html>

<sup>3</sup> Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: <http://aidsinfo.nih.gov/guidelines>

<sup>4</sup> 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).

## Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration announced a new initiative, [Ending the HIV Epidemic: A Plan for America](#). This 10-year initiative beginning FY 2020 seeks to achieve the important goal of reducing new HIV infections in the United States to fewer than 3,000 per year by 2030. The first phase of the initiative will focus on 48 counties, Washington, D.C., San Juan, PR, and 7 states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the initiative, the U.S. Department of Health and Human Services (HHS) plans to reduce new HIV infections by 75 percent within five years. Across the United States, the initiative will promote and implement the four Pillars to substantially reduce HIV transmissions – Diagnose, Treat, Prevent, and Respond. The initiative is a collaborative effort among key HHS agencies, primarily HRSA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

### National HIV/AIDS Strategy: Updated to 2020

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

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

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

### HIV Care Continuum

Diagnosing and linking people with HIV to HIV primary care, and ensuring people with HIV achieve viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main "steps" or stages that include: HIV diagnosis, linkage to care, retention in care, antiretroviral use, and viral suppression. The HIV care continuum provides a framework that depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication. It also demonstrates the proportion of individuals with HIV who are engaged at each stage. The HIV care continuum allows recipients and planning groups to measure progress and to direct HIV resources most effectively. RWHAP recipients are encouraged to assess the outcomes of their programs along this continuum of care. Recipients should work with their community and public health partners to improve outcomes across the HIV care continuum. HRSA encourages recipients to use the [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.<sup>5</sup> These improved outcomes mean more people with HIV in the United States will live near-normal lifespans and have a reduced risk of transmitting HIV to others.<sup>6</sup> 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 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

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<sup>5</sup> 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.

<sup>6</sup> 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.

resistance, detect transmission clusters and understand transmission patterns, and assess unmet health care needs. Analyses at the national level to monitor progress toward ending the HIV epidemic can only occur if all HIV-related CD4, VL, and HIV nucleotide sequence test results are reported by all jurisdictions. CDC requires the reporting to the National HIV Surveillance System (NHSS) all HIV-related CD4 results (counts and percentages), all VL results (undetectable and specific values), and HIV nucleotide sequences.

### **Minority HIV/AIDS Fund from the HHS Secretary's Office (MHAF), HAB Technical Assistance, and Special Projects of National Significance (SPNS) Program**

Through the MHAF and through HAB technical assistance (TA) cooperative agreements, HRSA has a number of projects that may be useful for RWHAP recipients to consider. Some select examples are:

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

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

Through 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 grant.

### 2. Summary of Funding

HRSA estimates up to \$3,075,000 to be available annually to fund up to 15 recipients. You may apply for a ceiling amount of up to \$205,000 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 the *Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start for Improved Care Engagement in the Ryan White HIV/AIDS Program – Implementation Sites* Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. Also, HRSA may reduce funding levels beyond the first year if recipients are unable to fully succeed in achieving the goals listed in the application.

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

### III. Eligibility Information

#### 1. Eligible Applicants

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

#### 2. Cost Sharing/Matching

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

#### 3. Other

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

HRSA will consider any application that fails to satisfy the deadline requirements referenced in [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 notice of funding opportunity (NOFO) following the directions provided at <http://www.grants.gov/applicants/apply-for-grants.html>.

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

## **2. Content and Form of Application Submission**

Section 4 of HRSA’s [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 7: 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](#).

- List at the top of the page:
  - Project Title
  - Applicant Organization Name
  - Address
  - Project Director Name
  - Contact Phone Numbers and Email Address
- Describe overall project goals and proposed services.
- Include a brief summary description of the proposed project, including how the organization will implement a rapid start intervention into their existing clinical operations and HIV care service delivery.
- Specify the funding amount requested for each year of the three-year period of performance.

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)***

Briefly describe the purpose of the proposed project. Discuss your organization's need for funds to improve capacity to initiate rapid start activities. Include a description of your organization's capacity and infrastructure to provide direct HIV care and treatment services.

Describe how this funding will improve the ability of your organization to initiate a rapid start program as an intervention in response to the goals to improve the timeliness of access, linkage, and retention to quality HIV primary care services for low income, uninsured, and underserved people with HIV, especially racial and ethnic minorities.

- **NEEDS ASSESSMENT** -- *Corresponds to Section V's Review Criterion #1 (Need)*  
This section will help reviewers understand the community and/or organization that you will serve with the proposed project.

Describe the incidence and/or prevalence rates of HIV infection in your area. Use and cite the most recent available relevant local and/or national data and published research whenever possible to support the information provided.

Describe the existing HIV medical care and support services currently available in your service area, including any relevant gaps or barriers in engaging, linking, and retaining people with HIV into care.

Provide a summary that demonstrates a comprehensive understanding of issues regarding the need for improvement in timeliness of linkage, retention, and viral suppression among people with HIV. Include information specific to the implementation of rapid start that the project hopes to overcome.

Clearly describe the client populations in your service area who could benefit from a rapid start intervention, including those who are newly identified or recently diagnosed, people with HIV who are engaged in care but were never provided ART, and/or people with HIV who are out of care. Describe the racial and/or ethnic minority population(s) you will serve. Focus populations of interest may include populations with health disparities, including African American and Latino men and women, gay and bisexual men, transgender women, and other populations hardest hit by the HIV epidemic.

Describe your organization's capacity and specific need for project funding in order to successfully implement a rapid start intervention. Describe how the proposed project builds upon the current standard of care activities and furthers the objectives of your organization in maximizing impact. Post-award, HRSA will share this needs assessment with the ETAP and it will be used to determine the level of TA needed.

- **METHODOLOGY** -- *Corresponds to Section V's Review Criteria #2 (Response), #3 (Evaluative Measures), and #4 (Impact)*

#### Rapid Start Interventions

Describe the proposed rapid start intervention that your organization will implement based on your needs assessment. Describe the rationale for your proposed rapid start methodology.

To accelerate and improve the timely linkage to care and rapid initiation of ART, applicants must propose rapid start interventions with the following core components:

- On-site or partnership with, direct referral, or warm handoff from currently established testing programs (e.g., local health departments, HIV testing sites, emergency departments, or primary care centers) to identify newly diagnosed people with HIV;

- Expedited linkage to HIV care (i.e., same day, next day, or within one week) for individuals newly diagnosed with HIV, new to care or out of care; and
- Rapid initiation of ART, including starter packs of ART administered within the same day, next day or within the week (the time period defined as “rapid start”)  
*Note: Purchase of starter packs of ART can be supported through this funding initiative if alternative mechanisms of payment (including RWHAP or the AIDS Drug Assistance Program (ADAP) is not available).*

Since rapid start interventions may be resource-intensive and require coordination and consolidation of multiple steps of testing, counseling, patient transportation, clinical provider evaluation, intake, accelerated insurance coverage, and initiation of ART, you may likely need clinic and other structural changes to improve rapid linkage to care and ART initiation.

Thus, you may propose rapid start activities that can include, but are not limited to:

- Connection with outreach workers or early intervention staff for immediate referral/direct linkage into HIV care, including escorting/transportation into care services or assistance in making appointments
- Improvements to the current capacity and infrastructure of your organization by leveraging existing staff and core medical services (e.g., outreach worker, case manager, or outpatient ambulatory care) to design and implement a rapid start intervention
- Team-based models of care (physician, nurse, counselor, care coordinator, intake staff, social worker, pharmacist, laboratory staff, insurance specialist, peer navigator, etc.) and on-site multi-disciplinary services (including social support, HIV education, mental health counseling, medical evaluation, prescription of ART, pharmacy services, etc.) to support immediate linkage and treatment services
- Streamlined enrollment procedures, e.g., adding priority appointment slots to obtain lab work, or expediting the first provider visit to begin treatment
- Restructuring of staff or clinic workflows to implement rapid start interventions, including consolidating paperwork requirements, counseling, laboratory work, or provider visits into one visit
- Other improvements and modifications to existing clinic infrastructure and logistics to consolidate and facilitate early entry into care (e.g., accelerated intake, paperwork/insurance/benefits support, lab tests, ART supplies, drafting or revising policies and procedures, system enhancements, etc.)

#### Identification, Rapid Linkage, and Retention in HIV Care

Describe how people with HIV who are out of care will be identified and referred to your organization for HIV primary medical care services. Describe your organization’s collaborations, partnerships, or affiliation with sites that provide HIV testing and case finding, and how these and any other relationships will be a source of both newly identified people with HIV and existing people with HIV who are out of care.

Describe the proposed referral and linkage networks to your organization, including referral activities from community stakeholders or collaborations. Include



information about how you will assist people with HIV who are newly diagnosed and out of care with all proposed rapid ART initiation service components, including engagement/re-engagement into care to help them achieve and sustain viral suppression.

Describe your proposed retention strategies to optimize adherence to medication, including use of case management staff and peer navigators to proactively address barriers to increase retention, utilizing clinic resources, and providing workforce training to support long-term retention in care following a rapid start intervention. Retention in care for people with HIV consists of the strategies, services, and efforts used to provide HIV primary medical care and maintain treatment adherence and follow-up HIV primary care services.

#### Collaboration with the ETAP

As mentioned in the Purpose section above, funded implementation sites (recipients) will be required to collaborate with the ETAP (to be funded separately under announcement number HRSA-20-113), which will lead a multi-site evaluation to measure the effectiveness of the implementation of rapid start interventions and provide and facilitate TA to the funded sites.

#### Multi-Site Evaluation

Implementation sites will be expected to collect and report relevant quantitative and qualitative outcomes, and process and cost measures data for their rapid start interventions as part of the national multi-site evaluation. As such, the implementation sites must be able to report these indicators, either as a direct clinical provider or through the execution of partnership and data user agreements with a medical clinic for HIV health care services.

Describe your commitment and plan to participate in all aspects of the national multi-site evaluation led by the ETAP. Your plan should include the process for timely collection and submission of relevant quantitative, cost, and qualitative data related to the performance measures and implementation of the rapid start intervention. HRSA encourages you to read the requirements for the ETAP (funded under announcement number HRSA-20-113) to understand the requirements of the national, multi-site evaluation that the ETAP will coordinate.

#### Technical Assistance

The ETAP will provide technical assistance (TA) to the implementation sites during regular teleconferences; through its website and webinars; during site visits; and at national annual meetings, led by the ETAP in collaboration with the implementation sites and HRSA program staff. Implementation sites are expected to host one site visit per year that the ETAP and relevant partners will conduct.

#### Learning Collaborative

The ETAP will also facilitate TA through learning collaboratives including peer-to-peer exchange. As part of this, the ETAP will seek experienced organizations that have successfully implemented rapid start programs to promote peer-to-peer learning with implementation sites funded through this initiative. This will provide opportunities for engagement with subject matter experts to guide the development and implementation of rapid start interventions. When possible, the

ETAP will pair funded implementation sites with subject matter experts at other organizations that have successfully implemented rapid ART interventions that are similar in geographic location, size of the clinical setting, or available resources. This will facilitate learning and exchange of information to further capacity development activities, advance the knowledge of existing providers, and expand the provider base of personnel skilled in administering rapid start interventions.

State your commitment to participate in an ETAP-facilitated learning collaborative. Describe your plan to ensure participation from key personnel in the scheduled learning sessions, including a presentation on your rapid start intervention to share current methods and promising practices.

### Implementation Protocols

Post-award and prior to launch and implementation, HRSA will require funded implementation sites to create and finalize an implementation protocol for their proposed rapid start intervention. The ETAP will provide additional TA to develop site-specific protocols as needed.

Describe your plan to develop and finalize a written implementation protocol that details the manner in which your clinical setting will carry out rapid start intervention. This should include a step-by-step guide on all aspects of rapid start service delivery, from receipt and intake of new clients, through eligibility and processing, clinical provider visits, follow-up, and any additional services provided by support staff.

HRSA encourages award recipients to collaborate with their regional AIDS Education and Training Center (AETC) programs and AETC local performance sites for training support needed to successfully implement their protocols. Specifically, implementation start awardees may use the AETC-developed guide titled *“Immediate ART Initiation: Guide for Clinicians”*<sup>7</sup> to facilitate the development of their implementation protocols.

### Dissemination

The ETAP will lead the dissemination of successful findings and best practices for purposes of replication at the national level. Funded implementation sites must participate in the development of toolkits, strategies, publications, and dissemination of program findings and lessons learned to support replication in collaboration with the ETAP and HRSA program staff.

Describe your commitment to fully participate in the publication, dissemination and replication efforts for the initiative’s findings and lessons learned, as coordinated by the ETAP and SPNS Program. Describe your plan to participate in the development of an intervention manual, which will document the methodology, implementation, and outcomes of your intervention project, in order to guide potential replication in the future.

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<sup>7</sup> AETC National Coordinating Resource Center. *Immediate ART Initiation: Guide for Clinicians*. Available at: <https://aidsetc.org/blog/immediate-art>

Recipients are also strongly encouraged to collaborate with their regional AETCs and local performance sites for expert support to disseminate key findings, implementation challenges, and lessons learned to replicate promising practices of rapid start models. AETC contact information is available at <https://aidsetc.org/aetc-program/regional-offices>.

Describe your commitment and plan to collaborate with the ETAP and SPNS program in the publication, dissemination, and replication efforts for the initiative's findings and lessons learned. Describe your plan to develop an intervention manual, which will document the methodology, implementation and outcomes of your rapid start model, in order to guide potential replication in the future. Implementation sites must have personnel with the necessary skills to communicate project findings and lessons learned to local communities, state and national conference attendees, and policymakers, as well as write and publish findings in peer-reviewed journals and presentations at conferences.

#### Sustainability and Program Integration

HRSA expects recipients to sustain key elements of their interventions, e.g., strategies or services, which have been effective in improving practices and those that have led to improved outcomes for the target population. The funded implementation sites will be required to demonstrate the capacity to sustain a rapid start intervention during the period of performance and after the funding for the project ends.

Thus, you must also propose a plan for project sustainability after the period of federal funding ends. Describe a detailed plan for the sustainability of the proposed rapid start intervention, including the incorporation of your rapid start service delivery into your standard of care beyond the 3-year funded period of performance.

#### Collaborations

Describe the proposed collaborations with needed partners to successfully implement the proposed rapid start activities. Clearly describe each proposed partner and explain how their services and/or resources can augment and support the implementation activities you propose. Identify the tasks that each partner proposes to perform. Include letters of agreement from each partner and/or collaborating entity as **Attachment 4**.

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

A work plan is a concise easy-to-read overview of your goals, strategies, objectives, activities, and timeline, and includes those responsible for making the program successful.

Describe the activities or steps that you will use to achieve each of the objectives proposed to implement rapid start services during the entire period of performance. Use a timeline that includes each activity, targeted date for completion, and identifies responsible staff. As relevant, identify the measures you will use to evaluate success. As appropriate, identify meaningful support and

collaboration with key partners in planning, designing, and implementing all activities.

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; (2) objectives that are specific, time-framed, and measurable; (3) action steps; (4) staff responsible for each action step, and; (5) anticipated dates of completion. Key activities to address in the timeline include, but are not limited to, start-up activities, assessments, implementation of clinic or system components, training activities, and documentation of the comprehensive rapid start strategy.

Submit the work plan as **Attachment 1**. You must submit the detailed work plan for each 12-month period of the three-year period of performance of September 1, 2020 through August 31, 2023. The first 12-month budget period will address activities from September 1, 2020 to August 31, 2021, with ensuing work plans covering years two and three.

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

Discuss challenges you are likely to encounter in the planning and implementation of your proposed rapid start project. Describe the specific activities or strategies you will use to mitigate or resolve such challenges.

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

Implementation sites must work with the ETAP to participate in and submit data as part of a national multi-site evaluation. HRSA requires implementation sites to collect and report relevant quantitative and qualitative outcomes, process, and cost measures data for their rapid start interventions. To show the impact of the implementation of a rapid start intervention as it relates to linkage to care and ART provision, as well as long term effectiveness on retention in care and sustained viral suppression, this initiative will collect and utilize RSR data<sup>8</sup> and client-level outcomes, among other sources.

Describe your plan to participate and cooperate in all aspects of a national, multi-site evaluation led by the ETAP, who will provide evaluation-related TA to the sites in order to collect data and measure the impact of the implementation of effective models for rapid start. Your plan should include the process for obtaining patient consent if needed, and the timely collection and submission of relevant qualitative and quantitative client-level data related to the following performance measures: the timeliness of linkage to care, retention in HIV care, and viral suppression of people with HIV. In addition, implementation sites may opt to conduct a separate

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<sup>8</sup> Health Resources and Services Administration, Ryan White HIV/AIDS Program Services Report (RSR). Available at: <https://hab.hrsa.gov/program-grants-management/ryan-white-hiv-aids-program-services-report-rsr>

local evaluation with outcome and/or other measures that demonstrate achievement of individual sites' rapid start program goals and objectives.

Since implementation sites will report relevant quantitative and qualitative outcome, process, and cost measures data to the ETAP, proposed staffing plans must include an evaluator to oversee the multi-site evaluation and a data coordinator to assist in data management, collection and reporting (**Attachment 2**). The data coordinator should have experience in data collection and reporting.

Describe your current ability to collect the above data. Describe your plan to collect and manage data for this project, including using any electronic medical record (EMR), electronic health record (EHR), or data management software that allows for accurate and timely reporting of performance and implementation outcomes. Include information about how you will collect and share data with the ETAP, including participation in a cost analysis study that will collect labor, training, structural, and other relevant costs you may incur for the administration of your rapid start intervention.

Include a description of your plan to develop policies and procedures that ensure the privacy and confidentiality of clients participating in the proposed rapid start intervention. This description must indicate what types of data sharing agreements must be in place in order to submit data to the ETAP. Include a description of procedures for the electronic and physical protection of study participant information and data, in accordance with HIPAA and Common Rule (45 CFR 46) regulations. Describe your plan to obtain and submit documentation for any required local IRB review and approval on all evaluation activities and data collection instruments for both the local (optional) and multisite evaluation (required).

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

Succinctly describe your organization's current mission, structure, and scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Include an organizational chart. Describe your experience in providing comprehensive HIV outpatient primary health care and support services and your capacity to respond to the needs of subpopulations experiencing poor health outcomes. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings. Describe how you will routinely assess and improve the unique needs of target populations of the communities served.

Note: You must have the ability to provide HIV services, either directly or through an agreement with an organization that will provide such services (**Attachment 4**).

Describe specific organizational capabilities that will contribute to successfully implementing the proposed activity. Describe the organizational skills, capabilities,

and resources, including staff who will contribute to your organization’s ability to carry out the proposed activity. Highlight key staff with relevant expertise and experience with similar work. This information should align with the staffing plan you provide in **Attachment 2** and the biographical sketches of key personnel you provide in **Attachment 3**. In addition, describe your experience with the fiscal management of grants and contracts. Include information on your organization’s experience managing multiple federal grants.

Provide an overview of the structure of your organization and its current and future capacity to successfully implement a rapid start intervention and provide direct HIV care and treatment services within your proposed service area.

Provide a description of the strength of the organization’s fiscal and management information systems, and the capacity to meet program requirements. Describe your organization’s program experience as it relates to planning, developing, and implementing rapid start services to the target populations and subpopulations in your proposed service area.

Describe the current capacity and infrastructure of your organization, including staffing, workflow, and any specialized funding or resources that will help provide rapid start services to people with HIV who are newly diagnosed or out of care. Describe the ability of your organization to track and collect related clinical outcomes for the multi-site evaluation.

<b>NARRATIVE GUIDANCE</b>	
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.	
<b><u>Narrative Section</u></b>	<b><u>Review Criteria</u></b>
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

### **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.

Awarded funds may be used to support the design, planning, implementation, and evaluation of rapid start intervention models. This includes linkage, referral services, patient navigation, medications, and clinic-level coordination and reform in the support of rapid start implementation.

In addition, the *Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program* requires the following:

- Because of the data requirements of the project, including collection and reporting of the relevant quantitative and qualitative outcome, process, and cost measures to the ETAP, proposed staffing plans and budget must include a proportion of an evaluator to oversee the implementation of multi-site evaluation activities and a data coordinator's time and effort to assist in data collection and reporting.
- In addition, HRSA requires implementation sites to attend an annual grant recipient meeting during each year of the period of performance, as coordinated by the ETAP. While the ETAP will coordinate the overall logistics, each implementation site must cover their travel, lodging, per diem and other incidental expenses for two (2) key personnel for these meetings. Award recipient meetings will be held in the Washington, D.C. Metropolitan area.
- Finally, please include travel to the biennial National Ryan White Conference on HIV Care and Treatment, to be held in the Washington, D.C. 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 Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS 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 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 clearly 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](#). If you will make subawards 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. In the event that a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

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

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents



that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are signed and dated.

*Attachment 5: Project Organizational Chart*

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.

*Attachments 7-10: 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 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 *Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program – Implementation Sites* is 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 \$205,000 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 Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program – Implementation Sites* Program has six review criteria. See the review criteria outlined below with specific detail and scoring points.

*Criterion 1: NEED (15 points) – Corresponds to Section IV’s Introduction and Needs Assessment*

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

- The strength and clarity of the applicant’s description of the proposed project, the organization’s need for capacity development to initiate rapid start activities, and how additional funding for rapid start will help improve the timeliness of access, linkage, and retention to quality HIV primary care services for people with HIV, especially racial and ethnic minorities.
- The strength and clarity of the applicant’s description of the incidence and/or prevalence rates of HIV infection in their service area.
- The strength and clarity of the applicant’s description of the existing HIV medical care and support services currently available in their service area, including any relevant gaps or barriers in engaging, linking and retaining people with HIV into care.
- The strength and extent of the applicant’s understanding of issues regarding the need for improvement of timeliness in linkage, retention, and viral suppression among people with HIV, including information specific to the implementation of rapid start that the project hopes to overcome.
- The strength and extent of the applicant’s description of the client population who could benefit from a rapid start intervention, i.e., people with HIV who are newly diagnosed, people with HIV who are engaged in care but were never provided ART, or people with HIV who were lost to care, including racial and ethnic minorities, in their service area.
- The strength and extent of the applicant’s description of their organization’s capacity and specific need for project funding in order to successfully implement a rapid start intervention, including how the proposed project will build upon the current standard of care activities.

*Criterion 2: RESPONSE (40 points) – Corresponds to Section IV’s Introduction, Methodology, Work Plan, and Resolution of Challenges.*

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

- Introduction(5 points)
  - The extent to which the applicant organization clearly describes the proposed intervention and rationale for the proposed rapid start intervention.
  - The strength and extent to which the applicant describes how their proposed activities will address unmet HIV care and treatment needs in the proposed service area.

- *Methodology (20 points)*
  - The strength, extent, and clarity of the applicant organization's description of their proposed rapid start intervention, including its rationale.
  - The strength, extent, and clarity of the applicant's inclusion of core rapid start components, i.e., how their organization will identify newly diagnosed persons with HIV, expedite linkage to care, and initiate rapid ART start (within the same day, next day or within a week), and other rapid start activities proposed as part of their intervention.
  - The strength and clarity of the applicant's description of how people with HIV who are out of care and newly diagnosed will be identified and referred to their organization, including any collaborations, partnerships, or referral networks.
  - The strength and clarity of the applicant's description of proposed retention strategies to optimize adherence to medication and ultimately sustained viral suppression.
  - The extent and clarity to which the applicant organization states their commitment to participate in all aspects of the national multi-site evaluation, including their plan to include timely submission of relevant quantitative, cost, and qualitative data to the ETAP.
  - The extent and clarity to which the applicant organization states their commitment to participate in a learning collaborative facilitated by the ETAP, and their plan to ensure participation and presentations from key personnel in the scheduled learning sessions.
  - The extent and clarity of the applicant organization's plan to develop and finalize a written implementation protocol post-award that details the manner in which their rapid start intervention will be carried out in their clinical setting.
  - The extent and clarity of the applicant organization's commitment to fully participate in the publication, dissemination, and replication efforts for the initiative's findings and lessons learned, including the development of an intervention manual to guide potential replication in the future.
  
- *Work Plan (10 points)*
  - The extent and strength of the applicant's commitment and plan to actively participate in a peer-to-peer learning collaborative facilitated by the ETAP, including frequency of participation and attendance at virtual meetings.
  - The strength and clarity of the applicant's plan to develop and finalize an implementation protocol that details the manner in which rapid start services will be carried out in their clinical setting.
  - The clarity and strength of the roles for identified partners and collaborators in the proposed project, and the tasks for each partner as described in the letters of support/commitment, if applicable.
  - The strength of the proposed work plan as evidenced by measurable and appropriate objectives.
  
- *Resolution of Challenges (5 points)*
  - The extent to which the applicant identified potential challenges to be encountered in designing, implementing, and measuring rapid start intervention.

- The strength, clarity, and feasibility of the proposed resolution of challenges.

*Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV’s Evaluation and Technical Support*

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.

- The extent to which the applicant’s narrative demonstrates the ability to analyze and evaluate its performance measure data for health outcome disparities and to take action to eliminate them.
- The strength and clarity of the applicant’s narrative which demonstrates the capacity to manage, collect, and report client-level data and to comply with all program reporting requirements.
- The strength, extent, and clarity of the applicant’s plan to participate and cooperate in all aspects of a national, multi-site evaluation led by the ETAP, including reporting relevant quantitative and qualitative, outcome, process, and cost measures and obtaining patient consent if needed.
- The strength and extent of the applicant’s description of their current ability and plan to collect and manage data for this project, including a specific description of the experience of the proposed evaluator and data coordinator in assisting in data collection and reporting, and how they will collect and share data with the ETAP.
- The clarity and strength of the applicant’s plan to ensure the privacy and confidentiality of clients participating in the rapid start intervention, including data sharing agreements, description of the electronic and physical protection of study participant information and data, and plan for IRB review and approval.

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

The extent to which the proposed project has a public health impact and the project will be effective if funded. This may include: the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

- The strength, extent, and clarity of the applicant organization’s plan for sustainability, including the incorporation of their rapid start service delivery into the standard of care after the period of federal funding ends.
- The strength of the proposed work plan as evidenced by measurable and appropriate objectives that reflect the provision of rapid start for people with HIV who are newly diagnosed or out of care.
- The strength of the applicant’s description of organizational, procedural, operational, workflow, or any other activities required for rapid start implementation.

- The strength of the proposed work plan that documents rapid start activities in the applicant's service area.
- Strength of the proposed plan to develop an intervention manual for replication.

*Criterion 5: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity*

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.

- The strength and clarity of the applicant organization's capacity and infrastructure to provide direct HIV care, treatment, and support services for the provision of a rapid start intervention. Note: if the applicant is not a direct provider of HIV services, the strength and clarity of their written agreement with a partner organization to provide such services (**Attachment 4**).
- The strength of the applicant organization's experience as it relates to the target populations and subpopulations in the proposed service area.
- The clarity and completeness of the applicant's description of project personnel who are qualified by training and/or experience to provide rapid start services as a component of the recipient's overall HIV primary care services.
- The strength of the applicant's description of current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature provided in the staffing plan **Attachment 2**. This includes personnel with the necessary skills to communicate project findings and lessons learned to local communities, state and national conferences, and policymakers, as well as write and publish findings in peer-reviewed journals and making presentations at conferences.
- The extent to which the applicant describes the organization's current mission and structure, the scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. The clarity of the applicant's project organizational chart provided in **Attachment 5**.
- The extent to which the applicant organization has fiscal and management controls, information systems, and the capacity to meet program requirements.
- The strength of the applicant's description of its participation, or intent to participate, in the evaluation and technical assistance activities conducted by other project-funded staff and entities.

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

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

- The appropriateness of the applicant's budget in that it aligns with the scope of work stated in the narrative and the objectives stated in the work plan.

- 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.
- The applicant's program-specific line-item budgets, budget justification narrative, and SF-424A are aligned.

## 2. Review and Selection Process

The objective review process provides an objective evaluation of 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 subrecipients 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 subrecipient 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 [FAPIS](#), 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 10NWH04  
Rockville, MD 20857  
Telephone: (301) 443-7065  
Email: [BSmith@hrsa.gov](mailto: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: Building Capacity to Implement Rapid Antiretroviral Therapy (ART) Start to Improve Care Engagement in the Ryan White HIV/AIDS Program – Implementation Sites (HRSA-20-114)*  
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](mailto:ACajina@hrsa.gov) or [SPNS@hrsa.gov](mailto: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](mailto:support@grants.gov)  
Self-Service Knowledge Base: <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center  
Telephone: (877) 464-4772  
TTY: (877) 897-9910  
Web: <http://www.hrsa.gov/about/contact/ehbhelp.aspx>

## **VIII. Other Information**

### **Technical Assistance**

HRSA has scheduled following technical assistance:

#### *Webinar*

Day and Date: Wednesday, April 29, 2020

Time: 1 p.m. – 2:30 p.m. ET

Call-In Number: 1-888-391-7047

Participant Code: 5501604

Weblink: <https://hrsa.connectsolutions.com/hrsa-20-114>

Playback Number: 1-888-566-0406

Passcode: 2156

### **Additional Resource**

Implementation site applicants may adapt and build upon evidence-informed rapid start models from the literature and/or suggestions from the AETC guide titled "*Immediate ART Initiation: Guide for Clinicians*"<sup>9</sup> to develop their proposed rapid start intervention.

### **Tips for Writing a Strong Application**

See Section 4.7 of HRSA's [SF-424 Application Guide](#).

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