

Centers for Disease Control and Prevention

NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STDS AND TB PREVENTION

Mass Mailing of HIV Self-Tests to Persons Disproportionately Affected by HIV in the U.S.

CDC-RFA-PS22-2210

07/11/2022

Table of Contents

A. Funding Opportunity Description 3
B. Award Information 18
C. Eligibility Information 20
D. Application and Submission Information 21
E. Review and Selection Process 33
F. Award Administration Information 36
G. Agency Contacts 44
H. Other Information 45
I. Glossary 46

Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-PS22-2210. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

Mass Mailing of HIV Self-Tests to Persons Disproportionately Affected by HIV in the U.S.

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS22-2210

E. Assistance Listings Number:

93.939

F. Dates:

1. Due Date for Letter of Intent (LOI):

The LOI date will generate once the Synopsis is published if Days or a Date are entered.

2. Due Date for Applications:

07/11/2022
11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call:
06/14/2022 at 2:00 pm Eastern Time
Zoom link

Join ZoomGov Meeting
https://cdc.zoomgov.com/j/1603385621?pwd=eTl4MmFIY1UyV29GdlVkcDNXRndSQT09

Meeting ID: 160 338 5621
Passcode: j3jD#S#.
One tap mobile
+16692545252,,1603385621#,,,,*49855396# US (San Jose)
+16468287666,,1603385621#,,,,*49855396# US (New York)

Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 669 216 1590 US (San Jose)
+1 551 285 1373 US
Meeting ID: 160 338 5621
Passcode: 49855396
Find your local number: https://cdc.zoomgov.com/u/abFMvdWlu2

Join by SIP
1603385621@sip.zoomgov.com

Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 338 5621
Passcode: 49855396

Join by Skype for Business
https://cdc.zoomgov.com/skype/1603385621

G. Executive Summary:

1. Summary Paragraph
The use of HIV self-tests (HIVSTs) is one mechanism to increase awareness of ones HIV status. This project will increase awareness of HIV infections in the U.S. among populations over-represented in the epidemic. The project supports the National HIV/AIDS Strategy (NHAS) and Ending the HIV Epidemic in the U.S. (EHE) initiative goal of increasing the proportion of people with HIV who have received a diagnosis. To achieve this, the project will distribute at least 875,000 HIVSTs over 5 years through direct-to-consumer digital marketing in both English and Spanish. The project has two strategies. 1) The adaptation of the recipient's own existing

HIVST distribution program which will include the optimization of a system of procurement, storage, processing orders and distribution of at least 175,000 HIVSTs per year directly to consumers in the U.S. and Puerto Rico. Adaptation will also require ensuring the pairing of their existing HIVST distribution program to match the look and feel of CDC's marketing campaigns for men who have sex with men (MSM), transgender women (TGW), and Black cis-gender women, in both English and Spanish. 2) Purchase and distribute HIVSTs and meet with CDC regularly (weekly) to monitor and discuss routinely collected program monitoring and evaluation data so that CDC can refine marketing strategies throughout the project.

a. Eligible Applicants:
Open Competition

b. Funding Instrument Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
1

d. Total Period of Performance Funding:
$41,500,000

e. Average One Year Award Amount:
$8,300,000

f. Total Period of Performance Length:
5

g. Estimated Award Date:
September 30, 2022

h. Cost Sharing and / or Matching Requirements:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview
In the United States as of 2019, an estimated 13% of persons with HIV were unaware of their HIV infection. This group accounts for a disproportionate number of new infections each year. Gay, bisexual, and other men who have sex with men (MSM) accounted for approximately 70% of new infections annually in the U.S.

Traditional healthcare venues and their access barriers often result in inadequate engagement with HIV testing, treatment, and prevention services. Socioeconomic factors, cultural norms, stigma, homophobia, and discrimination are associated with reduced access to HIV testing, prevention, and treatment. The long-standing and intersecting inequities in access to services both increase HIV infection rates and hinder access to testing services in traditional clinical or community settings. Black or African American (hereafter referred to as Black) and Hispanic/Latino (hereafter referred to as Hispanic) MSM are more severely affected by HIV than

other population groups. In 2019, Black and Hispanic MSM accounted for 37% and 32% of MSM diagnosed with HIV, respectively. Transgender women (TGW) are also disproportionately affected by HIV, and racial and ethnic disparities are also seen among TGW. National HIV Behavioral Surveillance data (2019-2020) reported that 62% of Black TGW and 35% of Hispanic TGW were living with HIV compared to 17% of White TGW. In 2019, 54% of infections among women were in Black women. A recently completed pilot project that distributed 100,000 HIV self-tests (HIVSTs) with focus on these population groups found success distributing tests to all groups by mail and that overall, 26% of those who ordered a test reported they have never previously tested for HIV. (CDC Contract# 75D30120C09658).

This project supports the first pillar of EHE by increasing the percentage of persons diagnosed with HIV. This program will provide HIVSTs to communities most affected by HIV. Effective HIV prevention services, including the opportunity to more frequently test for HIV, are needed to reach these populations. This program will provide free HIVSTs and resources for accessing HIV preventive services to people in communities most affected by HIV.

Most Americans are using the internet for a variety of purposes. Using tailored advertising materials and strategies developed by CDC, web-based information about HIV testing, prevention and treatment services will be provided. This online approach is effective in increasing awareness of HIV infection outside of traditional brick-and-mortar testing sites. This has been demonstrated by recent research on the distribution of HIVSTs to MSM (Contract #200-2011-41989), and the pilot national HIVST distribution program.

The direct-to-consumer distribution of HIVSTs represents a timely approach and complements existing local and national HIV testing efforts. Distributing HIVSTs can further leverage existing public health prevention efforts to reduce the number of persons with undiagnosed infection, and provide resources to help access treatment and prevention services. These efforts will contribute to the goals of reducing HIV transmission and preventing HIV disease progression.

The CDC Let's Stop HIV Together campaign (Together) is a comprehensive HIV prevention, testing, treatment and stigma reduction campaign. This program will be conducted with substantial involvement from CDC. Close collaboration with CDC will ensure that populations most in need of HIVSTs are reached through advertising, are able to order HIVSTs, and receive messages regarding HIV prevention and treatment.

b. Statutory Authorities
Public Health Service Act, Section 301(a) [42 USC 241(a)], as amended; 318(b)

c. Healthy People 2030
This program specifically addresses or contributes to multiple objectives included in Healthy People 2030 topic area of Sexually Transmitted Infections:

- Reduce the number of new HIV infections (HIV-01)
- Increase knowledge of HIV status (HIV-02)

For additional details on the Healthy People 2030 goals listed above, visit:
https://health.gov/healthypeople/search?query=hiv

d. Other National Public Health Priorities and Strategies

National HIV/AIDS Strategy (2022-2025): (https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025)

Ending the HIV Epidemic in the U.S. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

National Center for HIV, Viral Hepatitis, STD and TB Prevention Strategic Plan https://www.cdc.gov/nchhstp/strategicpriorities/default.htm

e. Relevant Work

This program builds on evidence from 3 previous programs:

1. CDC research contract 200-2011-41989 (2012) to evaluate the public health benefits of distributing rapid HIV self-tests to MSM in the United States
2. PS17-003 (2017) to evaluate strategies to reach Black and Hispanic MSM, and TGW
3. CDC contract 75D30120C09658 (2020) to distribute HIV self-tests through an online registration portal to persons who experience risk of HIV infection in the United States

This project supports the EHE goal of facilitating the diagnoses of people with HIV as early as possible, the first of the four EHE key strategies (Diagnose, Treat, Prevent, Respond). https://www.cdc.gov/endhiv/index.html

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-term Outcomes
Strategy 1. Refine recipient's existing HIVST distribution program for purchasing and distributing HIV self-tests to persons disproportionately affected by HIV in the U.S. and Puerto Rico	**1. Culturally appropriate imagery and information developed by CDC available on the self-test ordering portal.** **2. Fully functional comprehensive HIVST distribution program for procurement, storage, processing of orders and program monitoring.** **3. Increased access to HIV self-tests and prevention services including PrEP and STI testing among persons disproportionately affected by HIV.**	**1. Increased HIV testing among populations disproportionately affected by HIV.** 2. Increased awareness of HIV infection among populations disproportionately affected by HIV. 3. Increased awareness of PrEP among	1. Increased linkage to HIV medical care for persons diagnosed with HIV 2. Increased viral suppression among

Strategy 2. Implement HIVST distribution program and distribute HIV self-tests to persons disproportionately affected by HIV in the U.S.	**4. Increased understanding of strategies to successfully deliver HIV self-tests to populations disproportionately affected by HIV** **5. Increased understanding of user experience for HIV self-testing among populations disproportionately affected by HIV**	populations disproportionately affected by HIV 4. Increased initiation of PrEP among populations disproportionately affected by HIV	persons with HIV 3. Increased PrEP use. 4. Decreased HIV incidence

i. Purpose

This NOFO will optimize the recipient's existing web-based ordering portal and distribution program to provide at least 875,000 HIVSTs to U.S. populations disproportionately affected by HIV. The NOFO will maximize distribution of HIVSTs to MSM, TGW and Black cis-gender women via digital and traditional marketing strategies from CDC's *Together* campaigns, predominately in EHE jurisdictions. The use of the program's HIVSTs and referrals will increase awareness of HIV infection, prevent new infections, decrease HIV transmission, and improve overall health and well-being of participants.

ii. Outcomes

Short Term Outcomes

1. Culturally appropriate imagery and information developed by CDC available on the self-test ordering portal.

The recipient will work with the CDC Together campaign team to ensure a consistent look and feel between the HIVST distribution program and the CDC produced advertising materials and strategies. The HIVST distribution program will be available in English and Spanish and designed to be culturally appropriate for the priority populations, e.g., MSM, (particularly Black and Hispanic MSM), TGW and Black cis-gender women.

2. Fully functional comprehensive HIVST distribution program for procurement, storage, processing of orders and program monitoring.

HIV HIVST distribution program that will be capable of delivering approximately 175,000 HIVSTs within the first year, and at least 875,000 HIVSTs during the 5-year period of performance.

3. Increased access to HIVSTs and prevention services including PrEP and STI testing among populations disproportionately affected by HIV.

The HIVST distribution program will include online resources for participants to obtain contact information for local HIV and STI testing and prevention service providers.

4. Increased understanding of strategies to successfully deliver HIVSTs to populations disproportionately affected by HIV.

Through continual (weekly and quarterly) review of program monitoring and evaluation data, there will be a better understanding on the content of materials and strategies required to effectively reach populations disproportionately affected by HIV with HIVSTs and HIV prevention information, especially those living in EHE jurisdictions.

5. Increased understanding of user HIV self-testing experience among populations disproportionately affected by HIV.

Through continual (weekly and quarterly) review of program monitoring and evaluation data, there will be a better understanding of the user experience, including how the user heard about the program, how and when they used the HIVSTs, the user's overall satisfaction with the systems, and the effectiveness of the program in identifying undiagnosed HIV infection.

Intermediate Outcomes:
1. Increased HIV testing among populations disproportionately affected by HIV.

iii. Strategies and Activities

Strategy 1.

Refine recipient's own existing HIVST distribution program for purchasing and distributing HIV self-tests to persons disproportionately affected by HIV in the U.S. and Puerto Rico.

The recipient will modify their own existing HIVST distribution program that is currently able to fulfill at least 175,000 orders in a calendar year to persons in the U.S. and Puerto Rico. The recipient will collaborate with CDC on updating their HIVST distribution program. The collaboration will produce a consistent look and feel between the HIVST distribution program web portal and the CDC *Together* campaigns. The HIVST distribution program should have the capacity to ship HIVSTs to registered participants within 2 business days and ensure that most orders are delivered within 7 days.

Activity 1.

Work collaboratively with CDC to refine recipients existing HIVST distribution program, including procurement, storage, processing of orders, and program monitoring.
The recipient collaborates with CDC in the refinement of their existing HIVST distribution program. Refinements to existing HIVST distribution program should be conducted in consultation with CDC throughout the duration of the project to ensure the program is able to demonstrate the required HIVST distribution over the 5-year period of performance. The refinements should ensure that tools (e.g., UTM codes and unique web-links linked to website traffic information in Google analytics) are able to capture information needed to conduct routine monitoring described in Strategy 2, Activity 3.

Activity 2.

Refine HIVST distribution program's registration and fulfillment web-portal to match the look and feel of CDC's Together marketing campaigns, in English and Spanish.

The recipient will collaborate with CDC in the refinement of the registration and fulfillment web-portal of the HIV distribution program to ensure that it is consistent with the look and feel of CDC's Together marketing campaigns. The portal will be available in both English and Spanish.

Strategy 2.
Implement HIVST distribution program and distribute HIVSTs to persons disproportionately affected by HIV in the U.S.
The HIVST distribution program will register program participants and distribute HIVST. The registration system will be able to limit the number of HIVSTs that can be requested by registered participants over a specified period of time.

Activity 1.
Procure and store HIVSTs for distribution.
The recipient will purchase HIVSTs and effectively distribute free HIVSTs to populations disproportionately affected by HIV in the U.S.

Activity 2.
Send HIVSTs to program participants using an approved shipping service.
The recipient will have the capacity to ship a limited number of HIVSTs (e.g., 1 to 4) to registered program participants in all 50 U.S. states and Puerto Rico. The shipping service must be capable of fulfilling orders for HIVSTs in 2 business days and ensure that >95% of orders are delivered within 7 days. The registration system of the HIVST distribution program must be able to limit repeated requests for HIVSTs by a single user to predetermined timeframes (e.g., every 90 days). HIVSTs are not recommended to be used by persons taking HIV pre-exposure prophylaxis (PrEP) or who have been diagnosed with HIV and are taking anti-retroviral therapy (ART). Therefore, the system should identify individuals taking PrEP or ART and provide messaging recommending that these persons only order tests to share with their peers.

Activity 3
Routinely monitor the program's reach to disproportionately affected populations, user's satisfaction, experience, test result interpretation, and linkage to other services, such as HIV and STI testing, HIV Pre-Exposure Prophylaxis (PrEP) and HIV treatment.
The recipient will conduct routine monitoring of their HIVST distribution program in collaboration with CDC. Program monitoring must be able to determine geographic and demographic characteristics of persons being screened for eligibility prior to ordering HIVSTs online. The system should be able to use cross-sectional evaluations conducted with program users to determine the use of the HIVSTs, access to other HIV services after using the self-tests, user satisfaction with the program and barriers experienced by program users for ongoing program improvement through regular consultation with CDC.

Activity 4
Regularly review monitoring data with CDC to allow for refinement of the CDC marketing campaign. The recipient will monitor web-traffic using CDC-provided UTM codes and google analytics and provide and review data on web-traffic and order data with CDC on a regular (weekly) basis. The recipient will provide deidentified web-traffic and monitoring and evaluation

data to CDC. These data will be used to ensure that CDC advertising materials and strategies remain effective in encouraging populations disproportionately affected by HIV in the U.S to use the system to order HIVSTs.

1. Collaborations

a. With other CDC projects and CDC-funded organizations:

Where it would be beneficial to the overall HIV self-test distribution program performance, or it's monitoring and evaluation the recipient has the option to establish and maintain working partnerships with other CDC recipients (e.g., city and county health departments; directly funded CBOs; and the state health department), as needed. If a partner will be responsible for implementing program activities or any aspect of the monitoring and evaluation of the program, the applicant must file the MOU or MOA, as appropriate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov.

b. With organizations not funded by CDC:

The recipient should establish, build, and maintain collaborative relationships with organizations not funded by CDC that will support implementation of the proposed program. Strategic partnerships might include the following types of organizations: non-CDC-funded CBOs and other agencies providing health services including federally qualified health centers (FQHCs), Ryan White HIV/AIDS Program treatment clinics, Veterans' Administration facilities, LGBT health centers, STD and sexual health clinics, hospitals, and specialty clinics; substance use and mental health treatment centers; other relevant federal agencies; community advocates; community members; and other stakeholders that may have a vested interest in promoting health through HIV prevention, care, and treatment. If the organization is responsible for implementing program activities or providing information or data for the monitoring and evaluation of the program, the applicant must file an MOU or MOA, as appropriate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov .

"A list of CDC-directly funded Community-based organizations is available here Funded Organizations | PS21-2102 | Announcements | Funding | HIV/AIDS | CDC"

2. Target Populations

It is expected that in the first year of the program CDC marketing will focus on MSM, especially Black and Hispanic MSM, transgender persons, especially transgender women, and Black cis-gender women. However, the populations in focus may change over the life of the program and the look and feel of the HIVST distribution program and marketing campaign will be updated accordingly.

a. Health Disparities

The program supports efforts to improve the health of populations disproportionately affected by HIV, Viral Hepatitis, sexually transmitted diseases (STDs) and TB by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity.

A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in HIV, Viral Hepatitis, STDs, and TB are inextricably linked to a complex blend of social determinants that influence which populations are most

disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (https://www.cdc.gov/socialdeterminants/index.htm). These include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic challenges. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after health disparities are eliminated.

The CDC has used data, including social determinants data, to identify communities within jurisdictions that are disproportionately affected by HIV, Viral Hepatitis, STDs and TB and related diseases and conditions, and develop marketing for this program designed to bring persons from jurisdictions and population groups disproportionately affected by HIV to the HIVST ordering portal to help eliminate health disparities. In collaboration with CDC and other partners and appropriate sectors of the community, this program will consider social determinants of health in the development, implementation, and evaluation of program specific materials and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

This HIVST distribution program will support HIV testing among populations disproportionately affected by HIV in the U.S. and Puerto Rico. Distribution of HIV self-tests will overcome barriers related to transportation and stigma associated with accessing HIV testing services at community-based organizations and healthcare settings. Overcoming these barriers helps to address social determinants that underlay the disparities in HIV diagnoses among these populations by making HIVSTs readily available and removing barriers to accessing existing services.

iv. Funding Strategy

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Since this NOFO does not involve the generation or collection of public health data, a Data Management Plan is not required for this NOFO.

For each of the NOFOs program strategies, a partial list of outcomes and indicators is presented below. While the specific process and outcome measures will be finalized in collaboration with the recipient, proposed measures include:

Strategy 1 Refine recipient's own existing HIVST distribution program for purchasing and distributing HIV self-tests to persons disproportionately affected by HIV in the U.S. and Puerto

Rico.
Process measures may include:

- Meetings with CDC to discuss options for the look and feel of the self-test ordering portal
- Integration of a Google Analytics web-based tracking system into recipient's HIV self-test ordering portal
- Framework for regular (weekly) data updates to CDC linking google analytics to order data and participant geographic, demographic and HIV risk information
- Provision of data dictionary or sample data provided to CDC within 3 months of award
- Adaptation of existing user experience, and test use information collection to allow for periodic monitoring of program performance

Strategy 2 Implement HIVST distribution program and distribute HIV self-tests to persons disproportionately affected by HIV in the U.S.
Process measures may include:

- Number of marketing campaign impressions resulting in users landing on the HIVST distribution program webpage.
- Number of persons requesting HIVSTs each week, and the number of kits ordered per person.
- Number of HIVSTs delivered each week.
- Cumulative number and percent of people who report a positive HIVST result.
- Demographic and geographic data for program participants who ordered HIVSTs including race, ethnicity, gender identity, and prior HIV testing history.
- Number of people who report access to ART and PrEP after using the HIVST among registered participants.

Short Term Outcomes and measures will include:

- Culturally appropriate imagery and information developed by CDC available on the self-test ordering portal.

  Measures may include: Integration of look and feel of CDC Together campaign materials into the HIVST distribution program web portal
- Fully functional comprehensive HIVST distribution program for procurement, storage, processing of orders and program monitoring.

  Measure may include: Completion of at least one test order within the first 6 months of award
- Increased access to HIVSTs and prevention services including PrEP and STI testing among populations disproportionately affected by HIV. Documentation of this should be

accomplished through the recipient's existing monitoring system, e.g., through follow-up surveys with registered program participants.

Measures may include:

- Number and proportion of program participants who have never previously tested for HIV, or whose last test was more than 1 year prior to their order.
- Number and proportion of program participants reporting that they accessed PrEP services after placing an order.
- Number and proportion of program participants reporting that they accessed STI testing after placing an order.
- Number and proportion of program participants reporting that they access additional HIV testing or other prevention services after placing an order.

The above metrics should be summarized by demographic and geographic factors included in the data collected through follow-up surveys with registered program participants.

- Increased understanding of strategies to successfully deliver HIVSTs to populations disproportionately affected by HIV Through continual (weekly and quarterly) review of program monitoring and evaluation data, there will be a better understanding on the content of materials and strategies required to effectively reach populations disproportionately affected by HIV with HIVSTs and HIV prevention information, especially those living in EHE jurisdictions.
- Increased understanding of user HIV self-testing experience among populations disproportionately affected by HIV.

Through continual (weekly and quarterly) review of program monitoring and evaluation data, there will be a better understanding of the user experience, including how the user heard about the
program, how and when they used the HIVSTs, the user's overall satisfaction with the systems, and the effectiveness of the program in identifying undiagnosed HIV infection.

Intermediate Outcome:

- Increased HIV testing among populations disproportionately affected by HIV. Through existing program monitoring and evaluation systems the recipient will document increased access to HIV Self-tests.
- Measures may include:
    - The proportion of all orders placed by individuals never previously tested for HIV
    - The proportion of all orders placed by individuals who have not tested for HIV in the past year

The above metrics should be able to be summarized by demographic and geographic factors included in the data collected routinely from those who order self-tests.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additional-requirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

Program evaluation and performance measurement will be conducted by the recipient in collaboration with CDC. The draft program monitoring and evaluation plan submitted with the application will be finalized during the first six months after the award is made with input from CDC. A draft plan submitted with the application must address all CDC-specified program strategies, activities, and outcomes described in this NOFO. Applicants may not alter the CDC-specified strategies, activities, or long-term outcomes; however, they may include additional activities, short- or intermediate-term outcomes, or outcome measures that are currently used by their program managers to monitor and improve their existing program.

The NOFO logic model captures all required strategies, activities, and outcomes; therefore, applicants need not submit a logic model. However, if they intend to add activities, short- or intermediate- term outcomes, they should add these to the NOFO logic model and include the revised logic model with their draft local monitoring and evaluation plan.

Evaluation and performance measurement should use multiple methods, such as collection, analysis, and interpretation of existing data sources on program implementation and performance. New data collection systems should not be required.

Depending on the data source, monitoring and evaluation findings should be reviewed by recipients and CDC weekly, monthly or quarterly, as determined by the recipient and CDC within 30 days of the award. The review of these data should be used to monitor, evaluate, and continuously improve program processes and performance. The data should be used to determine corrective actions needed to ensure the success of the program in reaching the populations identified in the NOFO, and ensure that HIVSTs are distributed in expected quantities (at least 175,000 in year one and 875,000 over the course of the performance period).

The draft program monitoring and evaluation plan submitted with the application should include at least the following elements:

• Description of type of evaluation currently conducted, both process and outcome for program monitoring and evaluation.
• Description of key questions addressed by current evaluations.
• Description of sources of data currently obtained for program monitoring and evaluation.

As part of the program evaluation and performance measurement plan, the recipient may elect to conduct in-depth, detailed evaluation of selected program activities. These special evaluation activities might compare the effectiveness of different approaches or strategies the recipient uses to accomplish activities and may allow the recipient and CDC to identify the most effective methods for accomplishing project goals.

Recipient may use funds to support the collection of monitoring and evaluation data (including demographics, geography, and HIV risk characteristics) using systems the recipient currently implements to ensure program reach and effectiveness. Applicants should plan for sufficient staffing and resources to accomplish all activities related to these evaluation measures, including planning, data collection, data entry, data management, reporting data to CDC, data analysis and interpretation, use of data for program improvement, development and dissemination of reports, and attendance at monitoring and evaluation meetings. Recipients must describe how funds will be allocated to support evaluation activities.

c. Organizational Capacity of Recipients to Implement the Approach
Applicants should describe their organizational capacity to implement the strategies and activities in the NOFO, including:

- Capacity of existing HIVST distribution program for advertising, procurement and storage of HIVST, participant registration and distribution of materials to populations disproportionately affected by HIV in the US, including Black MSM, Hispanic MSM, transgender persons and Black cis-gender women;
- Capacity of the existing HIVST distribution program to accommodate the distribution of at least 175,000 HIVSTs during the first year, and at least 875,000 HIVSTs during the period of performance;

- Capacity to update their existing HIVST distribution program through which participant eligibility can be ascertained, as well as obtaining information necessary to fulfill test kit orders and ensure shipping within 2 business days and delivery of materials to program participants within 7 days;
- Capacity to maintain and continuously update a secure HIV distribution program.
- Capacity for program planning, implementation, monitoring and evaluation(including staffing) to ensure program goals are being achieved), financial reporting, budget management and administration, and personnel management;
- Relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes; experience and capacity to implement the evaluation plan; a staffing plan that clearly defines staff roles, and project management structure sufficient to achieve the project outcomes;
- A financial management system that will allow proper funds management and segregation of funds by program, and meet the requirements as stated in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards: "45 CFR Part 75.302." The financial system should permit the preparation of reports required by general and program-specific terms and conditions; and the tracing of funds to a level of expenditure adequate to establish that such funds have been used according to the federal statutes, regulations, and terms and conditions of the federal award; this should include descriptions of the applicants existing self-test distribution system and the ability to monitor inventory, limit the number of orders made by individuals (e.g., per shipping address or email address), and the ability to detect and prevent fraud within the ordering system.
- Ability to manage the required procurement efforts, including the ability to write, award, and manage contracts in accordance with applicable grants regulations;
- Applicant should provide CVs for key staff and note whether key positions need to be filled. CVs of key staff should be named "CVs" and uploaded as one pdf file at www.grants.gov.

d. Work Plan

Work plans will allow CDC project officers and recipients to monitor (1) implementation of project strategies and activities (i.e., process monitoring) and (2) progress toward achieving period-of-performance outcomes, both for outcomes with CDC-specified targets and those without specified targets (i.e., outcome monitoring).

Applicants should provide a detailed draft work plan for the first year of the project and a high-level work plan for subsequent years. Draft work plans will be expanded and finalized during the first six months of the project and will be updated annually in conjunction with the Annual Performance Report.

Process Monitoring

For process monitoring in Year 1, work plans should (a) describe the tasks or steps to be done in implementing project strategies and activities, and, for each task (b) designate a responsible

party, (c) describe how progress toward completing the task will be measured, and (d) provide process objectives, including a date by which the task is expected to be completed.

For subsequent years, work plans should provide a high-level description of process monitoring. Work plans should clearly show how tasks align with the strategies, activities, and outcomes depicted in the project logic model and described in narrative sections of the NOFO. The tasks described in the work plan can be relatively high-level, summary tasks, or can include more detailed tasks. The level of detail of the tasks included in the plans will be determined by recipients; however, the primary purpose of the work plans submitted to CDC is to allow project officers to ensure that strategies and activities are being implemented on time, and as planned, which should not require a high level of detail. The following are some examples of tasks that might be included in a work plan:

- Establish a project management team
- Update written policies, protocols, and procedures to guide project activities
- Finalize contracts to procure and distribute HIVSTs
- Hire and train project staff
- Revise existing advertisement campaigns and look and feel of the ordering portal
- Update monitoring and evaluation systems and procedures

Outcome Monitoring
For outcome monitoring, work plans should also provide specific, annual outcome objectives for the period-of-performance outcomes. These objectives indicate the progress recipients expect to make each year toward achieving expected outcome targets.

An example of a work plan format is presented below that demonstrates alignment of the work plan with the logic model and narrative. In this format, the table would be completed for each period of performance outcome. If a particular activity leads to multiple outcomes, it should be described under each outcome measure.

Period of Performance Outcome: *[from Outcomes section and/or logic model]*		**Outcome Measure:** *[from Evaluation and Performance Measurement section]*	
Strategies and Activities	**Process Measure** *[from Evaluation and Performance Measurement section]*	**Responsible Position/Party**	**Completion Date**
1.			
2.			
3.			

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

- Planning and leading the project kick-off meeting, routine project management calls, virtual or in-person recipient meetings, and site visits
- Monitoring progress in achieving the goals of the project and providing feedback on performance during routine weekly project management calls
- Recipient feedback – CDC will hold weekly conference calls to review progress and, when necessary, will provide written feedback within 3 business days, by email.

f. CDC Program Support to Recipients

In this cooperative agreement, recipient will collaborate with CDC on overall program design and implementation. CDC will support the recipient by:

- Collaborating with the recipient to determine the appropriate FDA-approved HIVSTs to be distributed in the program.
- Obtaining all required regulatory approvals including Paperwork Reduction Act (PRA) review and a CDC IRB non-research determination as necessary
- Collaborating on the development of a monitoring and evaluation approach for the project to ensure successful implementation of the advertising campaign to register participants and provide at least 175,000 HIVSTs to populations disproportionately affected by HIV in the U.S. during year 1, and at least 875,000 HIVSTs during the 5 year

period of performance. This will include ensuring that the following measures and feedback approach are included:

Priority measures – Inclusion of CDC's marketing materials into recipients ordering and distribution system. Demonstration of successful ordering and delivery of HIVSTs through the recipients online system. Number of marketing campaign impressions resulting in users landing on the HIVST distribution program webpage. Number of persons requesting HIVSTs each week, and the number of kits ordered per person. Number of HIVSTs delivered each week. Cumulative number and percent of people who report a positive HIVST result. Demographic and geographic data on distribution of HIVST program participants, including race, ethnicity, gender identity, and prior HIV testing history. Number of people who access ART and PrEP following the use of the HIVST.
Feedback – Data will be submitted weekly or quarterly based on monitoring requirements in final data management plan. Data will be obtained from: advertising conducted by CDC in collaboration with the recipient, and mechanisms to track web-traffic to the ordering portal (e.g., google analytics), digital sites used to advertise program, registrations and orders completed; and data from their monitoring and evaluation systems that are collected as part of registration, ordering and follow-up with participants.

- Adapting the recipients existing HIVST distribution program to ensure that the program is consistent with the look and feel of CDC marketing throughout the duration of this project. This will require the recipient to share data from their monitoring and evaluations of program performance with CDC each week, once the program is distributing HIVSTs.
- Collaborating with the recipient to determine online outreach strategies for the proposed populations. This will ensure that the content on the HIVST distribution program is culturally appropriate and representative of the priority populations it aims to serve.
- Conducting the marketing campaign, including the development of the marketing strategies and materials for the campaign, utilizing resources developed by the Let's Stop HIV Together communications program, and will work collaboratively with the recipient to track the effectiveness of marketing, and adapt it throughout the life of the project.
- Collaborating with the recipient to review monitoring and evaluation data to ensure successful implementation and use of HIVSTs by program participants.
- Collaborating with the recipient to prepare presentations for national conferences and meetings, and publications for peer-reviewed journals

B. Award Information

1. Funding Instrument Type:
CA (Cooperative Agreement)
CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism:
U62 Prevention/Surveillance Activities/Studies of AIDS
Cooperative Agreements

Prevention/Surveillance Activities/Studies of AIDS

3. Fiscal Year:
2022
4. Approximate Total Fiscal Year Funding:
$8,300,000

5. Total Period of Performance Funding:
$41,500,000
This amount is subject to the availability of funds.

Estimated Total Funding:
$41,500,000
6. Total Period of Performance Length:
5
year(s)
7. Expected Number of Awards:
1
8. Approximate Average Award:

$8,300,000
Per Budget Period
9. Award Ceiling:
$0
Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor:
$0
Per Budget Period
11. Estimated Award Date:
September 30, 2022

12. Budget Period Length:
12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and

the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is not available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

State controlled institutions of higher education

American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

Non-government Organizations

American Indian or Alaska native tribally designated organizations

Other

Ministries of Health

2. Additional Information on Eligibility

N/A

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number by registering in SAM.gov prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned to the registering organization.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their UEI numbers before accepting any funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

c. Grants.gov:

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	System for Award Management (SAM)	1. Go to SAM.gov and designate an E-Biz POC (You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an individual account in Grants.gov using organization's new UEI number to become an Authorized	It takes one day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM) which will allow	Register early! Applicants can

		Organization Representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	you to register with Grants.gov and apply for federal funding.	register within minutes.

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed)

Due Date for Letter Of Intent 06/27/2022

06/27/2022

b. Application Deadline

Due Date for Applications 07/11/2022

07/11/2022

11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

Due Date for Information Conference Call

06/14/2022 at 2:00 pm Eastern Time
Zoom link

Join ZoomGov Meeting
https://cdc.zoomgov.com/j/1603385621?pwd=eTl4MmFIY1UyV29GdlVkcDNXRndSQT09

Meeting ID: 160 338 5621
Passcode: j3jD#S#.
One tap mobile
+16692545252,,1603385621#,,,,*49855396# US (San Jose)

+16468287666,,1603385621#,,,,*49855396# US (New York)

Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 669 216 1590 US (San Jose)
+1 551 285 1373 US
Meeting ID: 160 338 5621
Passcode: 49855396
Find your local number: https://cdc.zoomgov.com/u/abFMvdWlu2

Join by SIP
1603385621@sip.zoomgov.com

Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 338 5621
Passcode: 49855396

Join by Skype for Business
https://cdc.zoomgov.com/skype/1603385621

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit

a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

A Letter of Intent (LOI) is requested but not required. The LOI will allow CDC program staff to estimate the number of and plan for the review of submitted applications.

Please provide the name and the url for the website of the existing distribution program that will serve as the foundation for the proposed project in your letter of intent. The letter of intent should be sent by email to:
Kevin P. Delaney
CDC,
National Center for HIV, Viral Hepatitis, STD and TB prevention
Division of HIV Prevention

Email address: HRBNOFO@cdc.gov

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the “Table of Contents” for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include **all** of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see http://www.hhs.gov/ ocio/policy/collection/.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub

accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

15. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS

identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

16. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

Recipient may not use funds for the development of new public health data systems.

17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:
https://www.cdc.gov/grants/additional-requirements/ar-25.html.

18. Other Submission Requirements

a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t= Get_Started%2FGet_Started. htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry

2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

   If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements

i. Approach **Maximum Points:** 35

- The extent to which the applicant describes a process for revising their own existing HIV self-test distribution program, including the integration of CDC's advertising materials and strategies into their web-portal. (10 points)
- The extent to which the applicant describes the process by which data from ongoing program monitoring will be used to inform revisions of the CDC advertisement and recruitment strategy to ensure communications materials and strategies do not become stale and ineffective. (10 points)
- The extent to which the applicant describes the online screening and registration process to ensure that appropriate participants are enrolled into the program, prevent fraudulent enrollment, and manage participant information securely. (5 points)
- The extent to which the applicant describes the process for procuring and storing HIVSTs and the fulfillment process to ensure shipping within 2 business days and delivery of materials to program participants within 7 days. (5 points)

- The extent to which the applicant describes the work plan for Year 1 of the project. (5 points)

ii. Evaluation and Performance Measurement **Maximum Points:** 30

- The extent to which the applicant describes their current ability to use existing data systems and partnerships that ensures advertising materials and strategies are effective in reaching priority populations and creates demand for orders of HIV self-tests in their existing system. (5 points)
- The extent to which the applicant describes the anticipated revisions to existing monitoring and evaluation processes that will be needed to ensure all priority populations are effectively reached. (5 points)
- The extent to which the applicant describes the current processes to conduct scheduled cross-sectional program evaluation to monitor user satisfaction and determine how the HIVSTs were used (e.g., by the user or given to someone else), access to other HIV services after using the self-tests (including follow-up testing for HIV or other STIs and access to PrEP, user satisfaction and barriers experienced by program users. This description should include the methods for administrating the follow-up surveys (e.g., at the time the order is received, monthly, etc. and response rates for existing cross-sectional surveys). (10 points)
- The extent to which the applicant describes the current evaluation questions for the existing program and how they are addressed by the data collected. (5 points)
- The extent to which the applicant describes anticipated modifications to the existing program evaluation procedures that may be needed to evaluate the success of the proposed project. (5 points)

iii. Applicant's Organizational Capacity to Implement the Approach **Maximum Points:** 35

- The extent to which the applicant describes an existing HIVST distribution program that includes procurement of HIVSTs, storage of HIVST, registration and distribution of materials to populations disproportionately affected by HIV in the US. The existing HIVST distribution program must be able to accommodate the distribution of at least 175,000 HIVSTs during the first year, and at least 875,000 HIVSTs during the period of performance. (10 points)
- The extent to which the applicant describes their prior experience with programs that advertise to the priority populations described in the announcement. (e.g., Black and Hispanic MSM, Transgender persons and Black cis-gender women) (5 points)
- The extent to which the applicant describes their capacity to maintain and continuously update a secure HIV distribution program (5 points)
- The extent to which the applicant describes their capacity to ensure delivery of materials to program participants within 7 days. (5 points)

- The extent to which the applicant describes their capacity, including staffing, to conduct ongoing program monitoring and evaluation to ensure program goals are being achieved, including descriptions of existing data systems that can be utilized for this purpose(10 points)

Budget **Maximum Points:** 0

Is the budget reasonable and consistent with the projected goals of the 5-year project such that recipient will purchase and distribute at least 875,000 HIVSTs?

c. Phase III Review

Applications will be funded in order by score and rank determined by the review panel

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

Announcement: May 26, 2022

Informational call: June 14, 2022 @ 2:00pm
LOI Due: June 27, 2022
Applications Due: July 11, 2022
Notice of Award: by 9/30/2022

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at https://www.cdc.gov/grants/additional-requirements/index.html.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

- *AR-10: Smoke-Free Workplace Requirements*

- *AR-11: Healthy People 2030*
- *AR-12: Lobbying Restrictions*
- *AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities*
- *AR-14: Accounting System Requirements*
- *AR-21: Small, Minority, And Women-owned Business*
- *AR-32: Enacted General Provisions*
- *AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020*
- *AR-15: Proof of Non-profit Status*
- *AR-23: Compliance with 45 CFR Part 87*

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

• Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

• For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

• HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

• For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as summary of annual activities and a yearly continuation application.	Yes
Data on Performance Measures	Data will be from two sources: 1) weekly reports for order data from routine automated data collections systems used to allow for modifications to marketing in a timely manner, and 2) quarterly reports for monitoring and evaluation of routinely collected registered participant follow-up survey data to evaluate the use of HIV STs and impact of the programs in increasing access to services and allow for modifications if needed. To reduce burden on recipient, CDC staff will conduct analyses of these data.	Yes
Federal Financial	90 days after the end of the budget period	Yes

Reporting Forms		
Final Performance and Financial Report	90 days after end of period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)
With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

• Performance measures and targets
• The frequency that performance data are to be collected.
• How performance data will be reported.
• How quality of performance data will be assured.
• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
• Dissemination channels and audiences.
• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).
• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publicly available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)
The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
    - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
    - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
    - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.
- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs.

- Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

This report is due no later than 120 days before the end of the budget period and serves as the continuation application each year. CDC staff may also review specific deadline dates identified
in Fiscal Year Planning Memo. This report must not exceed 45 pages excluding administrative reporting. Attachments are not permitted when submitting this report.

The deadline date for submitting the Annual Performance Report is no later than 120 days before the
end of the budget period. This report should include the information specified in the solicitation from the GMS/GMO via https://www.grantsolutions.gov.. The contact information for the GMS is listed in the "Agency Contacts" section of the NOFO.

The recipients must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

Performance measures captured at the time a program participant places an order for HIVSTs should be submitted and reviewed with CDC weekly while the system is receiving orders. More frequent reporting (daily monitoring) may be required at the initiation of new advertising materials or strategies. Reports will include information on links (using CDC provided UTM codes) to specific advertisement placements and marketing that led participants to the ordering portal, number of visits to portal, number of persons who completed an order, by demographic characteristics and geographic locations.

Program evaluation data from the cross-sectional surveys will be submitted within 30-days of the end of each quarter. These data should include demographic characteristics of program users, barriers experienced, satisfaction with program, use of HIVSTs, result of HIVSTs and uptake of other HIV and STI prevention services after receiving the self-test, including PrEP and ART. Reports format(s) will be finalized before the ordering portal goes live for order placement may take the form of summary reports, frequencies tables, and deidentified line lists of program users information collected at the time of order and during follow-up surveys in excel format.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the

information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

Recipients must provide a deidentified comprehensive dataset on registered participants who completed an order and a separate deidentified dataset on program evaluation participants in excel format. Data collected at the time an order is placed should be provided weekly once the system is open for ordering. Program evaluation (follow-up) data should be provided within 30 days of data collection or summarized every 6 months (whichever is more feasible based on the cycle of follow-up survey administration currently used by the recipient's system). Final data for orders and follow-up will also be shared with CDC at the completion of the project.

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:
"Commodity" means any material, article, supplies, goods, or equipment;
"Foreign government" includes any foreign government entity;
"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;
b. contact name with phone, fax, and e-mail;
c. agreement number(s) if reporting by agreement(s);
d. reporting period;
e. amount of foreign taxes assessed by each foreign government;
f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

First Name:
Kevin

Last Name:
Delaney
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

Address:
National Center for HIV, Viral Hepatitis, STD and TB prevention
Division of HIV Prevention
Address: 1600 Clifton Rd MS US8-4

Telephone:

Email:
HRBNOFO@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance,** contact:

First Name:
Edna

Last Name:
Green
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:
2939 Flowers Road, MS-TV2

Telephone:
770-488-2858

Email:
EGreen@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:
Resumes / CVs

Position descriptions

Letters of Support

Organization Charts

Non-profit organization IRS status forms, if applicable

Indirect Cost Rate, if applicable

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see .https://www.cdc.gov/grants/additional-requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings: A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. https://www.cdc.gov/grants/additional-requirements/index.html.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing

or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance –formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

UEI: The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is free. If an organization does not know its UEI number or needs to register for one, visit www.sam.gov.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

NOFO-specific Glossary and Acronyms

HIVST – HIV self-test