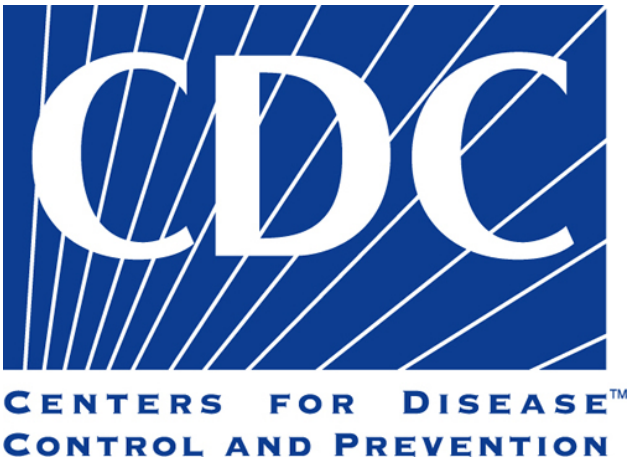

Centers for Disease Control and Prevention

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

Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic

CDC-RFA-PS22-2209

02/25/2022

Table of Contents

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-PS22-2209. 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:

Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic

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)).

New – Type 1

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS22-2209

E. Assistance Listings Number:

93.944

F. Dates:

1. Due Date for Letter of Intent (LOI):
01/31/2022

2. Due Date for Applications:
02/25/2022
11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call:
To obtain a schedule of the pre-application and additional information related to this notice of funding opportunity, please visit (https://www.cdc.gov/hiv/funding/announcements/ps22-2209/index.html).

G. Executive Summary:

1. Summary Paragraph
Transgender (TG) persons, especially transgender women (TGW), have a high lifetime risk of acquiring HIV. Black/African American (Black) and Hispanic/Latino (Hispanic) TGW have the highest prevalence of HIV among TG persons. Many TG persons experience poverty, homelessness, stigma, discrimination, and abuse; have mental health and substance use disorders; and need essential support services. In this demonstration project, organizations will be funded to work in transgender health care organizations (TG clinics) in collaboration with transgender-serving community-based organizations (TG CBOs) to develop models for community-to-clinic, status-neutral HIV prevention and care services. Recipients will provide comprehensive, co-located health services including HIV testing, preexposure prophylaxis (PrEP), gender-affirming hormone therapy, primary health care, and navigation. Navigation will be used to link TG persons as needed to services for mental health and substance use disorders and essential support services. Recipients will work with TG CBOs to engage TG persons in HIV testing and education and navigate them to TG clinics. Key outcomes in the project include an increased number of TG persons who initiate, adhere to, and persist with PrEP; increased rates of viral suppression among TG persons with diagnosed HIV; and an increased number of TG persons with unmet needs who receive services for mental health and substance use disorders and other essential support services.

a. Eligible Applicants:
Open Competition

b. Funding Instrument Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
4
The number of awards and average award amount will be subject to availability of funds.

d. Total Period of Performance Funding:
$8,000,000

e. Average One Year Award Amount:
$500,000

f. Total Period of Performance Length:
4

g. Estimated Award Date:
May 13, 2022

h. Cost Sharing and / or Matching Requirements:

No
No cost sharing or matching funds are 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 because level annual funding is anticipated.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

TG persons, especially transgender women (TGW), have a high prevalence of HIV and lifetime risk of acquiring HIV. In 2019, 625 TGW and 45 transgender men (TGM) were diagnosed with HIV in the United States and 6 dependent areas.[1] About half (51%) of these diagnoses were in persons aged 20-29 years. In the 2019-2020 National HIV Behavioral Surveillance Trans cycle, 42% of TGW tested positive for HIV.[2] Racial/ethnic disparities in positivity were also found, with positivity rates of 62% among Black TGW and 35% among Hispanic TGW compared to 17% among White TGW.

Despite the disproportionate burden of HIV among TGW, receipt of HIV prevention and care services have been suboptimal. Among TG persons, 92% reported that they were aware of PrEP but only 32% that they have used it.[2] In 2019, viral suppression among persons with diagnosed HIV was 67% among TGW.[3] Large proportions of TG persons were living at or below the poverty level, experienced homelessness, or exchanged sex for money or drugs.[2] Large proportions of TGW also reported verbal or physical abuse, including by a sexual partner, and suicidal ideation and behavior.[2] Substance use is prevalent in TG populations.[4] All of these factors impact access to and utilization of HIV prevention and care services by TG persons. In addition, some clinical staff might lack TG cultural awareness, and this can be a barrier to TG persons remaining engaged in health care.

Feminizing or masculinizing gender-affirming hormone therapy was reported by 72% of TGW, with an additional 20% wanting to take hormones.[2] Many TG persons seek hormone therapy at TG clinics that serve as centers of excellence for TG health and well-being. These encounters provide opportunities for HIV education and counseling, HIV testing and risk assessment, status-neutral HIV services, sexually transmitted infection (STI) testing, and other health care services. HIV testing identifies HIV-negative persons who should be assessed for PrEP and nonoccupational postexposure prophylaxis (nPEP) indications,[5,6] and if indicated, offered and prescribed PrEP or nPEP. Patients who seek care in TG clinics for gender-affirming services such as hormone therapy can be assessed for PrEP indications and offered PrEP. HIV testing can also identify persons with HIV for rapid antiretroviral therapy (ART) initiation.

TG CBOs might be better poised than TG clinics to reach TG persons who are not already engaged in HIV prevention or care services for HIV education and counseling, HIV testing, and referral to TG clinics for PrEP, nPEP, ART, gender-affirming services, and other health care services.

In the demonstration project, organizations will be funded to work in TG clinics in collaboration with TG CBOs to develop holistic community-to-clinic service models to provide health care

and wellbeing services for TG men and women that include co-located HIV prevention and care; gender-affirming services including hormone therapy and other procedures; STI testing and treatment; hepatitis testing, treatment, and vaccination; preventive health care; and chronic disease care. Navigation will be provided to support use of any needed mental health and substance use disorder services and essential support services. All services will be culturally and linguistically responsive for TG persons to ensure that they feel welcomed, heard, and cared for.

The recipients will also participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons.

b. Statutory Authorities
This program is authorized under Sections 301 and 318(b) of the Public Health Service Act; 42 USC Sections 241 and 247c(a), as amended.

c. Healthy People 2030
This program specifically addresses or contributes to multiple objectives included in Healthy People 2030:

- Reduce the number of new HIV infections (HIV-01)
- Increase knowledge of HIV status (HIV-02)
- Reduce the number of new HIV diagnoses (HIV-03)
- Increase linkage to HIV medical care (HIV-04)
- Increase viral suppression (HIV-05).

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
This program specifically addresses or contributes to the following:

HIV National Strategic Plan (2021-2025) https://www.hiv.gov/federal-response/hiv-national-strategic-plan/hiv-plan-2021-2025

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's (NCHHSTP) Strategic Plan https://www.cdc.gov/nchhstp/strategicpriorities/default.htm

e. Relevant Work
CDC-RFA-PS15-1509 "Targeted Highly-Effective Interventions to Reverse the HIV Epidemic (THRIVE)"

CDC-RFA-PS16-003 " Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons who have Sex with Men"

CDC-RFA-PS17-1704 "Comprehensive HIV Prevention Projects for Young Men of Color Who Have Sex with Men and Young Transgender Persons of Color"

CDC-RFA-PS18-1802 “Integrated HIV Surveillance and Prevention Programs for Health Departments” CDC-RFA-PS21-2102 “Comprehensive High-Impact HIV Prevention Programs for Community-Based Organizations”

CDC-RFA-PS19-1904 “Capacity Building Assistance (CBA) for High Impact HIV Prevention Program Integration”

CDC-RFA-PS20-2010 “Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the U.S.”

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Provide integrated HIV testing, status-neutral HIV prevention and care services, & comprehensive TG health services to TG persons through TG CBO and clinic collaboratives Develop collaborations between TG clinics, TG CBOs, and HIV clinics Implement HIV testing and status-neutral HIV prevention and care services in TG clinics Support use of mental health and substance use disorder services & other essential support services by TG persons Identify needs and support linkage to services Provide services that are culturally and linguistically responsive for TG persons, especially for Black and Hispanic persons Participate in a national learning collaborative to share best practices and lessons learned for community-to-care, status-neutral, comprehensive HIV & other services for TG persons	Increased availability of HIV testing for TG persons Increased awareness of HIV status among TG persons Increased access to STI testing and treatment for TG persons **Increased capacity of TG clinics to provide or link to HIV prevention and care services as well as provide comprehensive TG health services** **Increased PrEP initiation by PrEP-eligible TG persons** **Increased nPEP initiation by nPEP-eligible TG persons** **Increased rapid ART initiation by TG persons with diagnosed HIV** **Increased linkage to HIV care among TG persons with diagnosed HIV**	**Increased adherence to PrEP by TG persons** **Increased persistence with PrEP by TG persons** **Increased retention in HIV care among TG persons with diagnosed HIV** **Increased viral suppression among TG persons with diagnosed HIV** Increased receipt of mental health, substance use disorder, and other essential support services by TG persons	Decreased HIV transmission among populations of TG persons Decreased HIV incidence among TG persons Decreased HIV-related morbidity and mortality among TG persons

i. Purpose
This NOFO will fund organizations to work in TG clinics and partner with TG CBOs to develop community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services. These models will increase use of HIV prevention and treatment by TG persons to decrease HIV transmission and improve overall health and wellbeing.

ii. Outcomes
As depicted in the logic model (bolded outcomes), the recipient will be expected to demonstrate progress in the following:

Short Term Outcomes

- Increased capacity of TG clinics to provide or link to HIV prevention and careservices as well as provide comprehensive TG health services
- Increased PrEP initiation by PrEP-eligible TG persons
- Increased nPEP initiation by nPEP-eligible TG persons
- Increased rapid ART initiation by TG persons with diagnosed HIV
- Increased linkage to HIV care among TG persons with diagnosed HIV
- Increased linkage to mental health, substance use disorder, and other essential support services among TG persons with need for services

Intermediate Outcomes

- Increased adherence to PrEP by TG persons
- Increased persistence with PrEP by TG persons
- Increased retention in HIV care among TG persons with diagnosed HIV
- Increased viral suppression among TG persons with diagnosed HIV

iii. Strategies and Activities
CDC will work in partnership with recipients to develop community-to-clinic integrated and holistic models to provide co-located services for TG persons. Status-neutral services include HIV testing, gender-affirming services including hormone therapy and other procedures, STI testing and treatment, hepatitis testing and treatment, preventive health care, chronic disease care, mental health and substance use disorder services need assessments and linkage to services, and social service need assessment and linkage to services. Co-located health services have been associated with persons remaining engaged in health care and better health outcomes. These services will be developed with cultural and linguistic responsiveness for TG persons.

This project has four strategies: (1) To provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives; (2) To support use of mental health and substance use disorder services and other essential support services by TG persons with needs for these services; (3) To provide services that are culturally sensitive for TG persons, especially for Black and Hispanic

persons; and (4) To support development of and participation in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide community-to-clinic, status-neutral, comprehensive services for TG persons

Note that all activities need to be implemented according to CDC-approved protocols and procedures.

<u>Strategy 1.</u> Provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives

- Recipients will identify TG CBOs and other entities that serve the needs of TG populations and will
    - Lead development of collaborations between TG clinics, TG CBOs, and HIV clinics to engage TG persons in the community in HIV prevention and TG health services
    - Consult with health departments for optimal collaboration and efficient use of available resources such as HIV, STI, and hepatitis testing; local PrEP Medication Assistance Programs (MAPs) and other PrEP programs; PrEP navigation; mental health and substance use disorder services; and other essential support services
- Recipients will
    - Conduct HIV testing in both TG CBOs and TG clinics
        - Conduct Ag/Ab HIV testing
        - Conduct STI testing and treatment
        - Conduct hepatitis testing, treatment, and vaccination
    - Provide status-neutral HIV services
        - If tested negative for HIV:
            - Assess for PrEP or nPEP indications
            - If PrEP or nPEP indicated, initiate PrEP or nPEP
            - If tested in TG CBO, navigate to TG clinics for PrEP and nPEP services
            - Train providers in TG clinics to provide PrEP and nPEP care
            - Provide PrEP and nPEP care
            - Use CDC-developed algorithms to identify TG persons in clinical care who might need frequent HIV testing and PrEP
            - Support PrEP and nPEP adherence through patient navigation, adherence counseling, or other strategy
            - Support PrEP persistence through patient navigation, adherence counseling, or other strategy
        - If diagnosed with HIV:
            - Train providers in TG clinics to provide rapid initiation of first line ART and HIV care
            - Provide rapid ART initiation

- Provide HIV care in the TG clinic or link to an HIV clinic
- Identify practice models for HIV care integrated in TG clinics, which may include:
    - Hiring an infectious disease clinician in TG clinics
    - Assessing cost and revenue generation associated with hiring a full-time or part-time HIV care provider in the TG clinic
    - Training or telementoring TG clinicians to provide HIV care
- Develop protocols for nursing support and telemedicine
- Support ART adherence through patient navigation, adherence counseling, or other strategy

- Provide comprehensive health and well-being services
    - Feminizing and masculinizing gender-affirming services including hormone therapy
    - Education, counseling, and linkage to other gender-affirming procedures
    - STI testing and treatment
    - Hepatitis testing, treatment, and vaccination
    - Primary health care
    - Preventive care (e.g., vaccinations)
    - Chronic care (e.g., diabetes care)
    - Referrals to specialty care as needed
- Increase financial access of TG persons to health care services
    - Expand enrollment in health insurance if eligible, including Medicaid
    - Develop protocols for the use of MAPs and local PrEP programs
        - Include protocols for starter packs for PrEP, nPEP, and ART while awaiting MAP approval
    - Develop and implement strategies to remove barriers to accessing mental health and substance use service

- Other collaborative activities recipients may engage in to improve access of TG persons to HIV prevention and TG health services include
    - Provide training/telemedicine support for clinicians in HIV clinics who want to provide gender-affirming hormone therapy to TG persons
    - Provide training/telemedicine support for clinicians who practice in geographic areas remote from a TG clinic to provide gender-affirming hormone therapy, PrEP care, and ART and HIV care

- Recipients may fund collaborating TG CBOs with up to 20% of its funds to
    - Implement evidence-based models in CBOs for community outreach to engage TG persons for HIV testing and prevention, such as conducting community

outreach events and implementing snowballing incentive programs for referral of peers for HIV testing and status-neutral HIV services
    - Support TG CBOs to provide HIV and PrEP education, counseling, HIV testing, and HIV self-test kits
    - If HIV testing is occurring in TG CBOs, implement evidence-based models in TG CBOs for navigation of TG persons to TG clinics for PrEP; to TG clinics or HIV clinics for ART; and to mental health and substance use disorder services, and other essential support services

Strategy 2. Support use of mental health and substance use disorder services and other essential support services by TG persons to address social determinants of health

- Recipients will collaborate to support receipt of mental health and substance use disorder services and other essential support services by TG persons
    - Identify service providers in the TG clinics or community
    - Identify client need for mental health or substance use disorder services
        - Support linkage to needed mental health or substance use disorder services
    - Identify client need for essential support services (e.g., health insurance, housing, food assistance, child care, transportation, legal services, job training, employment assistance) to address social determinants of health
        - Support linkage to needed essential support services

Strategy 3. Provide services that are culturally sensitive for TG persons and for Black and Hispanic persons

- Provide TG cultural awareness training for all CBO staff, PrEP and ART clinical providers, navigators, and all other staff
    - Include training for all clinical providers on gender-affirming hormone therapy, surgery and procedures, and sexual health care
- Recruit project staff with experience and cultural awareness in providing care for TG persons
- In TG and HIV clinics, develop/ensure electronic health record (EHR) capability to identify persons by their affirmed gender and appropriate name

Strategy 4. Participate in a national learning collaborative for recipients to share lessons learned and best practices for community-to-care, status-neutral, comprehensive TG service models

- Recipients will participate in a new national learning collaborative to share lessons learned and best practices with other TG CBOs and TG clinics in the United States
- Recipients will support other TG CBOs and TG clinics to provide HIV status-neutral, community-to-clinic comprehensive services for TG persons

1. Collaborations

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

Recipients are required to collaborate with local TG CBOs to provide outreach to TG populations to engage them in HIV testing; HIV and PrEP education and counseling; and linkage to TG clinics. Recipients are required to collaborate with state or local health departments in their jurisdiction for optimal and efficient use of available resources such as HIV, STI, and hepatitis testing, treatment, and vaccination; state and local PrEP Medication Assistance Programs (MAPs) and other PrEP programs; navigation services; mental health and substance use disorder services and other essential support services; and training for PrEP and ART clinical service provision; and training for navigation. Recipients may provide up to 20% of their award to the collaborating TG CBO(s) to provide outreach to TG populations to engage them in HIV testing; HIV and PrEP education and counseling; linkage to TG clinics; and data collection for evaluation. TG CBOs may receive funding if they are not funded for similar activities through other CDC programs, or if funded but require additional resources for evaluation activities.

Applicants are required to obtain MOUs/MOAs from CBOs and health departments as evidence for the collaboration, must file the MOU/MOA, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov. The MOA/MOU should be reflective of the services most requested by the priority population. Recipients are encouraged to establish additional collaborations supported by MOAs/MOUs over the course of the period of performance.

When establishing prevention and essential support services MOAs/MOUs, the applicant should consider the following:
· Proximity of the provider to the applicant's service area.
· The provider's capacity and history to serve the priority population(s).
· Payment requirements for services rendered (e.g., Ryan White provider, type of health insurance accepted).
· Types of services accessible for persons with HIV and HIV-negative persons at increased risk of acquiring HIV.
· Availability and accessibility of telehealth by the provider if option is requested by the applicant.

Additionally, the MOAs/MOUs must include, but is not limited to, the following:
· Name and address of the provider(s).
· Name, title, and contact information (i.e., primary work address, email, and phone number) for the primary point of contact for the provider.
· Detailed description of the agreed-upon referral processes for prevention and essential support services between the applicant and the prevention and essential support service provider.
· Process for confirming that the individual accessed the service, in accordance with federal, state, and local policies.
· Signatures from the Business Official for the applicant and the prevention and essential support services provider.

b. With organizations not funded by CDC:
Recipients are required to collaborate with local TG CBOs for TG outreach. Recipients may provide up to 20% of their award to the TG CBO to provide outreach to TG populations to engage them in HIV testing; HIV and PrEP education and counseling; linkage to TG clinics; and data collection for evaluation.

Applicants are required to obtain MOUs/MOAs from CBOs as evidence for the collaboration, must file the MOU/MOA, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov. The MOA/MOU should be reflective of the services most requested by the priority population. Recipients are encouraged to establish additional collaborations supported by MOAs/MOUs over the course of the period of performance.

When establishing prevention and essential support services MOAs/MOUs, the applicant should consider the following:
· Proximity of the provider to the applicant's service area.
· The provider's capacity and history to serve the priority population(s).
· Payment requirements for services rendered (e.g., Ryan White provider, type of health insurance accepted).
· Types of services accessible for persons with HIV and HIV-negative persons at increased risk of acquiring HIV.
· Availability and accessibility of telehealth by the provider if option is requested by the applicant.

Additionally, the MOAs/MOUs must include, but is not limited to, the following:
· Name and address of the provider(s).
· Name, title, and contact information (i.e., primary work address, email, and phone number) for the primary point of contact for the provider.
· Detailed description of the agreed-upon referral processes for prevention and essential support services between the applicant and the prevention and essential support service provider.
· Process for confirming that the individual accessed the service, in accordance with federal, state, and local policies.
· Signatures from the Business Official for the applicant and the prevention and essential support services provider.

2. Target Populations
The recipients will focus their activities on transgender women, especially Black and Hispanic TGW, to achieve the greatest impact on HIV prevention and care and health equity for TG populations.

Clinical organizations that serve TG persons in the 50 jurisdictions included in Phase 1 of the Ending the HIV Epidemic in the U.S. (EHE) initiative, listed in the table below, are encouraged to apply (https://ahead.hiv.gov). More than half of U.S. HIV diagnoses in 2016-2017 were in these 50 jurisdictions, so resources allocated to these disproportionately affected communities can most effectively support ending the HIV epidemic.

U.S. counties and jurisdictions included in Phase 1 of the Ending the HIV Epidemic in the U.S. initiative

Arizona		**Illinois**		**North Carolina**
Maricopa County		Cook County		Mecklenburg County
California		**Indiana**		**Ohio**
Alameda County		Marion County		Cuyahoga County

Los Angeles County		**Louisiana**		Franklin County
Orange County		East Baton Rouge Parish		Hamilton County
Riverside County		Orleans Parish		**Pennsylvania**
Sacramento County		**Maryland**		Philadelphia County
San Bernadino County		Baltimore City		**Tennessee**
San Diego County		Montgomery County		Shelby County
San Francisco County		Prince George's County		**Texas**
Florida		**Massachusetts**		Bexar County
Broward County		Suffolk County		Dallas County
Duval County		**Michigan**		Harris County
Hillsborough County		Wayne County		Tarrant County
Miami-Dade County		**Nevada**		Travis County
Orange County		Clark County		**Washington**
Palm Beach County		**New Jersey**		King County
Pinellas County		Essex County		**Washington D.C.**
Georgia		Hudson County		**Puerto Rico**
Cobb County		**New York**		San Juan Municipio
Dekalb County		Bronx County		
Fulton County		Kings County		
Gwinnett County		New York County		
		Queens County		

a. Health Disparities

This project supports efforts to improve the health of populations disproportionately affected by HIV, viral hepatitis, sexually transmitted diseases (STDs), and tuberculosis (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 occurs 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 living and working conditions that influence health, and

- Continuous efforts to maintain a desired state of equity after health disparities are eliminated.

Recipients should use data, including social determinants data, to identify communities within their jurisdictions that are disproportionately affected by HIV, viral hepatitis, STDs, and TB and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, recipients should consider social determinants of health in the development, implementation, and evaluation of program-specific efforts and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

iv. Funding Strategy

The number of awards and amount of each award will be subject to the availability of funds. Funding will be made available for organizations to work in TG clinics in collaboration with TG CBOs. Recipients may fund their collaborating TG CBOs with up to 20% of their award. TG CBOs may receive funding if they are not already funded for similar activities through another CDC program, or if funded but require additional resources for evaluation activities.

Applicants that are not TG clinics are required to identify the TG clinic where the work will occur and must submit a letter from the director (or another official) at the clinic indicating their support of the application and plans to implement proposed activities.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC will collaborate with recipients to develop evaluation and performance measurement plans to ensure appropriate and successful implementation of the strategies and activities; progress in achieving outcomes; and understanding the barriers to progress during the period of performance. CDC will collaborate with recipients to develop a plan to use performance measurement and evaluation data to improve processes to achieve intended outcomes.

Recipients may also be expected to participate in special evaluations as needed throughout the period of performance using existing or newly collected data. Special evaluation studies, such as formative surveys, interviews, or focus groups with TG persons or providers in TG CBOs and TG clinics may be conducted for information to optimize service models to meet the needs of TG persons. Key evaluation questions and data sources for such evaluations will be determined throughout the period of performance to appropriately meet the specific evaluation requirements in the project.

A data management plan is required and should include:

- A description of the data to be collected or generated in the proposed project
- The standards to be used for the collected or generated data
- Mechanisms for, or limitations to, providing access to the data, including a description for the provisions for the protection of privacy, confidentiality, security, and intellectual property, or other rights
- Statement of the use of data standards that ensure all documentation that describes the method of collection, what the data represent

- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified
- Other additional requirements based on the program

CDC will request de-identified person-level longitudinal data at baseline and every 6 months from recipients, collected and stored through EHRs and then deidentified and transmitted to CDC. These data will allow CDC to calculate process and outcome measures in order to evaluate recipient performance and progress toward intended outcomes. These data will be used to develop dashboards with calculated outcome measures that serve as feedback to programs to guide ongoing quality improvement activities. The dashboards will help ensure success by providing program effectiveness information that can be helpful to manage the project and ensure progress towards achieving intended outcomes. The information is also helpful to determine applicability of evidence-based approaches for different populations, settings, and contexts as a component of ongoing quality improvement. Extraction of data from EHR allows data collection to be efficient and timely. Data collection and transmission to CDC every 6 months has been found in a previous demonstration project (CDC-RFA-PS15-1509) to be an effective approach to support ongoing quality improvement and to facilitate program success. It also supported recipients to monitor the quality of activities provided by their contractors, facilitating any necessary changes to ensure achieving intended outcomes. The data will be de-identified and comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.

For client demographic and behavioral information, the date of data collection should be included. For services provided by the TG clinic, TG CBO, or other entity or organization, the date of service should be included. Person-level longitudinal data will include demographic characteristics and self-reported sexual and injection drug use behaviors of clients and information about their encounters at TG clinics, TG CBOs, HIV clinics, and other clinics or organizations to understand TG persons enrolled in the project and linkage and receipt of services. These data will be linked at the person-level with health care data extracted from EHR in TG clinics and HIV clinics. All data linkages will be conducted by the TG clinic and de-identified data will be transmitted to CDC at least every 6 months to inform quality improvement activities.

CDC will request the following information at baseline and every 6 months from recipients as process measures for the proposed strategies and activities. For aggregate numbers requested, recipients will extract data from their EHR and deidentify and transmit data to CDC for CDC to calculate measures:

- Strategy: Provide integrated HIV testing, status-neutral HIV prevention and care services, and comprehensive TG health services to TG persons through TG CBO and clinic collaboratives
    - Process measures: Report on status of collaborations and linkage processes between TG clinics, TG CBOs, and HIV clinics

        - Data for CDC to calculate numbers of HIV tests by site and numbers of referrals of TG persons to HIV prevention and care services by TG clinics and CBO

- Strategy: Support use of mental health and substance use disorder services and other essential support services by TG persons:
    - Process measures: Report on status of identification of mental health, substance use, and other essential support service needs and linkage processes
        - Data for CDC to calculate numbers of TG persons with mental health disorders, substance use disorders, and other essential support service needs and referral and linkage to appropriate services by TG clinics and CBOs

- Strategy: Provide services that are culturally and linguistically responsive for TG persons, especially for Black and Hispanic persons
    - Process measures: Report on trainings of staff to improve cultural and linguistic responsiveness for TG persons by TG clinics and CBOs

- Strategy: Participate in a national learning collaborative to share best practices and lessons learned for community-to-car, status-neutral, comprehensive HIV and other services for TG persons
    - Process measures: Report on attendance and participation in national learning collaborative among participating TG clinics and TG CBOs

CDC will request de-identified person-level longitudinal data, collected and stored through EHRs, at baseline and every 6 months from recipients for CDC to calculate outcome measures for the intended outcomes:

- Outcome: Increased capacity of TG clinics to provide or link to HIV prevention services and HIV care as well as provide comprehensive TG health services
    - Measures:
        - Data for CDC to calculate number of TG persons encountered by TG CBO and TG clinic
        - Data for CDC to calculate number of TG persons in TG clinic who received gender-affirming hormone therapy, other gender-affirming procedures
        - Data for CDC to calculate number of TG persons who received primary care services by type of service including vaccinations by type of vaccine, STI testing, positive STI tests by STI and anatomical site, treatment for STIs, and testing for other infections (HBV, HCV)
        - Data for CDC to calculate number of TG persons encountered who were tested for HIV by site and HIV test result
        - Data for CDC to calculate number of TG persons tested for HIV who were linked to a TG clinic or HIV clinic by site and HIV test result
        - Data for CDC to calculate number of TG persons provided navigation to a clinic and accepted or declined navigation

        - Data for CDC to calculate number of TG persons linked to a TG clinic or HIV clinic using navigation by site and HIV test result
        - Data for CDC to calculate number of TG persons initiating PrEP, nPEP, and ART at the TG clinic

- Outcome: Increased PrEP initiation by PrEP-eligible TG persons
    - Measures:
        - Data for CDC to calculate number of TG persons prescribed same-day PrEP
        - Data for CDC to calculate number of TG persons prescribed PrEP at a later date

- Outcome: Increased adherence to PrEP by TG persons
    - Measure:
        - Data for CDC to calculate number of TG persons adhered to PrEP

- Outcome: Increased persistence with PrEP by TG persons
    - Measure:
        - Data for CDC to calculate number of TG persons persisted with PrEP

- Outcomes: Increased nPEP initiation by nPEP-eligible TG persons
    - Measures:
        - Data for CDC to calculate number of TG persons assessed for nPEP
        - Data for CDC to calculate number of TG persons provided nPEP if eligible

- Outcomes: Increased rapid ART initiation by TG persons with diagnosed HIV
    - Measures:
        - Data for CDC to calculate number of TG persons tested for HIV with a positive test by site of testing
        - Data for CDC to calculate number of TG persons provided rapid ART initiation
        - Data for CDC to calculate number of TG persons received an ART prescription

- Outcomes: Increased linkage to HIV care among TG persons with diagnosed HIV
    - Measures:
        - Data for CDC to calculate number of TG persons linked to a TG clinic or HIV clinic (if tested in a TG CBO)
        - Data for CDC to calculate number of TG persons provided navigation to TG clinic or HIV clinic and accepted or declined navigation

- Outcomes: Increased retention in HIV care among TG persons with diagnosed HIV
    - Measure:
        - Data for CDC to calculate number of TG persons retained in HIV care

- Outcomes: Increased viral suppression among TG persons with diagnosed HIV
    - Measure:

        - Data for CDC to calculate time to viral suppression among TG persons who received ART

- Outcomes: Increased linkage to mental health services by TG persons with needs for services
    - Measures:
        - Data for CDC to calculate the number of TG persons with unmet mental health service needs
        - Data for CDC to calculate number of TG persons provided navigation to link to mental health services, and accepted or declined navigation
        - Data for CDC to calculate number of TG persons linked to mental health services

- Outcomes: Increased linkage to substance use disorder services by TG persons with needs for services
    - Measures:
        - Data for CDC to calculate number of TG persons with unmet substance use service needs
        - Data for CDC to calculate number of TG persons provided navigation to link to substance use disorder services, and accepted or declined navigation
        - Data for CDC to calculate number of TG persons linked to substance use disorder services

- Outcomes: Increased linkage to other essential support services by TG persons with needs for services
    - Measure:
        - Data for CDC to calculate number of TG persons with unmet essential support service needs
        - Data for CDC to calculate number of TG persons provided navigation to link to essential support services, and accepted or declined navigation
        - Data for CDC to calculate number of TG persons linked to other essential support services

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.

All recipients are expected to comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs (2011). All standards included in the NCHHSTP Data Security and Confidentiality Guidelines should be implemented by recipients, unless otherwise justified. A Certification of Compliance statement signed by an overall responsible party or parties (ORP) will be submitted annually to the CDC Project Officer at the same time the Annual Performance Report (APR) is submitted. For information on the data security and confidentiality guidelines and example certification statement, please refer to
http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf

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 for program planning, program evaluation, performance monitoring, financial reporting, budget management and administration, and personnel management. Capacity for program evaluation and monitoring should include demonstration of ability to collect person-level longitudinal clinical data and other information using EHR and data collection systems.
- Relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes for the priority population; experience and capacity to implement the evaluation plan; and a staffing plan and project management structure sufficient to achieve the project outcomes and that clearly defines staff roles. Relevant experience should include demonstration of experience and

credibility in providing clinical services to TG persons consistently for at least the last 24 months, with demonstration of the scope of their current work and experience in providing gender-affirming hormone therapy and other healthcare services for TG persons, especially Black and Hispanic TGW Applicants should demonstrate that they provided clinical services for at least 100 TGW in 2019 and served a population comprised of at least 50% Black or Hispanic TG persons in the application narrative. For applicants that are not TG clinics, a letter from the partnering TG clinic indicating their support of the application and plans to implement proposed activities is required. Applicants should name this letter "Support from partner transgender clinic" and upload as a pdf at www.grants.gov.

- 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
- Ability to manage the required procurement efforts, including the ability to write, award, and manage contracts in accordance with applicable grants regulations

Applicants should provide CVs for key staff and note whether hiring new staff will be required as well as organizational charts. For CVs, applicants must name this file "CVs/Resumes" or "Organizational Charts" and upload it at www.grants.gov.

d. Work Plan

Applicants must provide a detailed work plan for the first year of this award and a high level work plan for the subsequent years of the award. The detailed work plan must describe the applicant's approach to conduct the required strategies and activities and accomplish each process measure. The work plan must also include a timeline and the person responsible for completing each activity. The budget submitted must be consistent with the work plan and include resources needed to conduct these activities.

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.			
4.			
5.			
6.			

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.

Recipients performing at a less than sufficient level to achieve program objectives within stated timeframes will be placed on a time-phased Improvement Plan (IP) developed by the CDC Project Officer in collaboration with the recipient. The IP is a comprehensive tool used to assist recipients to improve program performance through identifying factors contributing to less than sufficient performance and developing specific action steps to address areas in need of improvement.

In addition to those listed, other activities deemed necessary to monitor the award may be applied.

f. CDC Program Support to Recipients

In a cooperative agreement, CDC and recipients share responsibility for successfully implementing the award and meeting identified outcomes. CDC will support recipients by providing:

- Technical assistance with project management; expertise in HIV testing and status-neutral HIV services; training and capacity building support; evaluation and performance measure support; database creation and management; data analyses; drafting of manuscripts
- Development of a learning collaborative for information sharing among recipients through presentation of interim performance measure data, lessons learned, best practices, and challenges. This information will be shared through conferences, committees, meetings, guidance, and material development.
- Planning and leading the project kick-off meeting and virtual or in-person recipient meetings
- Monitoring progress in achieving the goals of the project and providing feedback on performance during routine project management calls
- Disseminating findings by presentations at national conferences and meetings and by publications in peer-reviewed journals
- Obtaining all required regulatory approvals including a Paperwork Reduction Act (PRA) review and a CDC IRB non-research determination

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

3. Fiscal Year:
2022

4. Approximate Total Fiscal Year Funding:
$2,000,000

5. Total Period of Performance Funding:
$8,000,000
This amount is subject to the availability of funds.

Estimated Total Funding:
$8,000,000

6. Total Period of Performance Length:
4

year(s)

7. Expected Number of Awards:
4
The number of awards and average award amount will be subject to availability of funds.

8. Approximate Average Award:

$500,000
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:
May 13, 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:
99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

2. Additional Information on Eligibility

The applicant must have a history of providing clinical services to transgender persons, including gender affirming hormone therapy, or must have a history of working with an organization that provides clinical services to transgender persons, including gender affirming hormone therapy.

- For applicants that are TG clinics, a history of providing clinical services to TG persons, including gender affirming hormone therapy, should be described in the application narrative.
- For applicants that are not TG clinics, a letter from the partnering TG clinic indicating their support of the application, description of current TG-specific clinic services offered, and plans to implement proposed activities is required

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No
No cost sharing or matching funds are 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 because level annual funding is anticipated.

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.

In preparation for the federal government's April 4, 2022 transition to the Unique Entity Identifier (UEI) from the Data Universal Numbering System (DUNS), **applicants must include a UEI in applications (SF-424, field 8c) due on or after January 25, 2022**. 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. Entities registering in SAM.gov prior to April 4, 2022 must still obtain a DUNS number before registering in SAM.gov registration. Additional information is available at: https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-systems-information-kit/unique-entity-identifier-update, SAM.gov, https://www.grants.gov/forms/sf-424-family.html and https://grantsgovprod.wordpress.com/2021/09/14/how-to-find-an-applicants-uei-within-grants-gov/.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number to register in SAM.gov prior to April 4, 2022. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B).

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number

will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS 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	Data Universal Number System (DUNS) (Required until April 4, 2022)	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM)	1. Retrieve organizations DUNS number (required until April 4, 2022)	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/

		2. 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.		home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized 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	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

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 or postmarked by)

Due Date for Letter Of Intent 01/31/2022

01/31/2022

b. Application Deadline

Number Of Days from Publication 60

02/25/2022

11:59 pm U.S. Eastern Standard 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

To obtain a schedule of the pre-application and additional information related to this notice of funding opportunity, please visit (https://www.cdc.gov/hiv/funding/announcements/ps22-2209/index.html).

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 DUNS.

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 is recommended but not required. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

LOIs may be sent via email to:

Anne Kimball, Lead Project Officer for PS22-2209, HRBNOFO@cdc.gov; 404-718-3642

Please include:

- Number and title of this NOFO
- Descriptive title of proposed project
- Name, address, telephone number, and email address of the Principal Investigator or Project Director, or both
- Name, address, telephone number, and e-mail address of the primary contact for writing and submitting this application

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.

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 (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

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:** 25

The extent to which the applicant:

- Describes an overall strategy and activities consistent with the CDC Project Description and logic model for the priority population of TGW, especially Black or Hispanic TGW (10)
- Describes strategies and activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable) (5)
- Presents outcomes that are consistent with the period of performance outcomes described in the CDC Project Description and logic model (5)
- Shows that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the period of performance outcomes, presents a plan for allocating up to 20% of funds to collaborating TG CBOs if applicable, and presents a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC (5)

ii. Evaluation and Performance Measurement **Maximum Points:** 25

The extent to which the applicant:

- Demonstrates the ability to collect data on the outcome performance measures specified by CDC in the project description and presented by the applicant in their approach (10)
    - Describes a plan for collection of client enrollment and TG CBO, TG clinic, and HIV clinic encounter data
    - Describes a plan for collection of EHR data in TG clinics and HIV clinics
    - Describes a plan for linkage and de-identification of enrollment and encounter data with EHR data, and transmission to CDC
    - Includes a preliminary Data Management Plan (DMP)
- Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities (5)

- Describes how performance measurement and evaluation findings will be reported and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement (5)
- Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base and describe an evaluation plan in detail (5)

iii. Applicant's Organizational Capacity to Implement the Approach **Maximum Points:** 50

The extent to which the applicant:

- Demonstrates relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes for the priority population of TG persons (5)
- Provides a staffing plan, MOUs/MOAs from CBOs, and project management structure that will be sufficient to achieve project outcomes and to implement the evaluation plan, which clearly defines staff roles, shows evidence of collaboration and provides an organizational chart (5)
- Demonstrates that it provided clinical services for at least 100 TGW in 2019, that it served a population comprised of at least 50% Black or Hispanic TG persons, and that it operates in one of the 50 jurisdictions included in Phase 1 of Ending the HIV epicemic (15)
- Demonstrates that it provided clinical services for gender-affirming hormone therapy and other health care services for TG persons (15)
- Demonstrates that it uses EHR for patient care (10)

Budget **Maximum Points:** 0

The extent to which the budget is reasonable, clearly itemized and justified, consistent with the intended use of funds, aligned with the work plan, and supports project activities

c. Phase III Review

Final funding determinations will be based on application scores from the Objective Review and CDC's funding preferences.

The following factors also may affect the funding decision:

- Preference for the balance of funded applicants based on (1) burden of HIV within jurisdictions, (2) disproportionately affected geographic areas, as measured by CDC, and (3) geographical diversity.
- Preference for applicants who have the experience and capacity to provide clinical services for TG persons, including gender-affirming hormone therapy, and to collect clinical data on TG persons through use of an EHR for program evaluation.
- Preference to ensure equitable balance in terms of priority racial or ethnic minority groups and/or population (The number of funded applicants serving each priority group may be adjusted based on the burden of HIV disease in that group as measured by HIV reporting.)

- Preference to avoid unnecessary duplication of services, especially for organizations currently receiving funding, from all funders, to provide similar services.

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

Successful applicants will be notified by email no later than May 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 the DUNS, 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 or by U.S. mail.

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 http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.

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

Recipients must comply with the administrative requirements outlined in 45 C.F.R. Part 74 or Part 92, as appropriate. Brief descriptions of relevant provisions are available at http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

The following Administrative Requirements (AR) apply to this project:

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-9: Paperwork Reduction Act
- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2030
- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010

- AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)

ARs applicable to awards associated with HIV/AIDS issues:

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel
- AR-6: Patient Care

Organization-specific ARs:

- AR-8: Public Health System Reporting (community-based, nongovernment organizations)

For more information on the C.F.R., visit the National Archives and Records Administration at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.

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) including EHR data on performance measures	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures*	6 months into award and every 6 months during period of performance for CDC and recipients to monitor progress for ongoing program evaluation and improvement	Yes
Federal Financial Reporting Forms	90 days after the end of the budget period	Yes
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

CDC will require each recipient to submit de-identified person-level longitudinal clinical data extracted from participants' EHRs every 6 months. Extraction of data from EHR allows data collection to be efficient and timely. Data collected from the first 6 months of the award will be baseline data on the performance measures. Subsequent data will be collected every 6 months, with one of the submissions per year occurring with the APRs, if feasible, to streamline submission of data and other information to CDC. The performance measures collected every 6

months will be complementary to and align with the APRs. The information requested in the APRs will be limited to the few process measures that cannot be calculated using EHR data.

CDC will use these performance data to develop dashboards with calculated outcome measures that serve as feedback to programs to guide ongoing quality improvement activities. The dashboards will help ensure success by providing program effectiveness information that can be helpful to manage the project and ensure progress towards achieving intended outcomes. CDC will calculate outcome measures and update the dashboards with every data submission and will disseminate with each recipient within one month. Information from the dashboards can be used by recipients to demonstrate progress in their APRs. The performance data that is requested is also helpful to determine applicability of evidence-based approaches for different populations, settings, and contexts as a component of ongoing quality improvement. Data collection and transmission to CDC every 6 months has been found in a previous demonstration project (CDC-RFA-PS15-1509) to be an effective approach to support ongoing quality improvement and to facilitate program success. It also supported recipients to monitor the quality of activities provided by their contractors, facilitating any necessary changes to ensure achieving intended outcomes..

*Dependent on OMB/PRA approval

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 publically 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.

For year 2 and beyond of the award, recipients may request that as much as 75% of their estimated
unobligated funds be carried over into the next budget period.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances); and
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

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.

CDC provided guidance above describing CDC's request for deidentified person-level longitudinal data at baseline and every 6 months, which will be collected through the TG clinic's EMR and transmitted securely to CDC as de-identified data so that CDC can calculate outcome measures. CDC will work with recipients on developing data management and submission processes that will include required person-level data structure, variables, and formats for submission every six months. CDC will support recipients in data management and submission. Reporting of performance measures every 6 months will be dependent on OMB/PRA approval.

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).

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:
Anne

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

Address:
1600 Clifton Road NE, MS US8-4
Atlanta, GA 30329

Telephone:
404-718-3642

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:
2920 Brandywine Rd MS TV-2
Atlanta, GA 30341

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:
Organization Charts

Position descriptions

Resumes / CVs

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Indirect Cost Rate, if applicable

Letters of Support

References

1. Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas, 2019. https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed July 23, 2021.
2. Centers for Disease Control and Prevention. HIV infection, risk, prevention, and testing behaviors among transgender women. https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published April 2021. Accessed July 23, 2021.
3. Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021. https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed July 23, 2021.
4. Connolly D, Gilchrist G. Prevalence and correlates of substance use among transgender adults: A systematic review. Addict Behav 2020;111:106544.
5. Centers for Disease Control and Prevention. Preexposure prophylaxis for the prevention of HIV infection in the United States—2017. at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. Accessed July 23, 2021.
6. Centers for Disease Control and Prevention. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf. Accessed July 23, 2021.

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 compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

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.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

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.

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