



Centers for Disease Control and Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office

Positive Health Check Evaluation Trial

RFA-PS-15-001

Application Due Date: 03/16/2015

Positive Health Check Evaluation Trial

RFA-PS-15-001

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office (NCHHSTP ERPO)

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Funding Opportunity Announcement (FOA) Title

Positive Health Check Evaluation Trial

Activity Code

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Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-PS-15-001

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.941

Category of Funding Activity:

Health

FOA Purpose

HIV antiretroviral therapy (ART) can durably suppress the plasma HIV-1 viral load which improves individual survival and dramatically reduces further HIV transmission. Achieving HIV viral suppression is a primary goal when initiating ART. Unfortunately, there are gaps throughout the continuum of HIV care in the United States and research shows only 25% of all people living with HIV (PLWH) know they are infected, get regular medical care, take ART, and achieve HIV viral suppression. Recent studies show that computer-based interventions are effective in improving protective health behaviors including ART adherence and sexual risk reduction among PLWH. In response to the need for more comprehensive and feasible interventions, CDC has developed Positive Health Check, a brief, web-based video counseling intervention to improve clinical health outcomes for PLWH including ART initiation, ART adherence as measured by suppressed HIV-1 viral load, retention in care, and sexual risk reduction as measured by incident STDs. The intervention is to be used by English-speaking PLWH in HIV primary care to supplement existing clinical care services. The Positive Health Check Evaluation Trial will evaluate this intervention. The study will be conducted in three or four diverse HIV primary care clinics in the United States, and the trial will include a minimum of 2,320 eligible participants (1,160 per study arm). Electronic medical records, laboratory reporting data, medical charts, and appointment records will be used to determine patient eligibility for the study. PLWH eligible and enrolled in the trial will be randomized to either the intervention arm (i.e., Positive Health Check plus standard clinical care) or to the control arm (i.e., standard clinical care only). The Positive Health Check Evaluation Trial tests whether the intervention significantly improves persons' clinical outcomes, including ART initiation, ART adherence as measured by suppressed HIV-1 viral load, retention in care, and sexual risk reduction as measured by incident STDs. The trial will also document the cost and feasibility of implementing and integrating the Positive Health Check intervention in diverse HIV primary care clinic settings in the United States.

NOTE: A Summary of the Conference Call held on Tuesday, January 13, 2015 with Potential

Applicants for Funding Opportunity Announcement (FOA): PS15-001 “Positive Health Check Evaluation Trial” and Answers to Questions from Potential Applicants has been added as an amendment to the FOA in Section VIII. "Other Information" on pages 44-45.

Key Dates

Publication Date: To receive notification of any changes to RFA-PS-15-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 02/16/2015

Application Due Date: 03/16/2015

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 05/07/2015

Secondary Review: 06/12/2015

Estimated Start Date: 09/01/2015

Expiration Date: 03/17/2015

Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

Purpose: HIV antiretroviral therapy (ART) can durably suppress the plasma HIV-1 viral load which improves individual survival and dramatically reduces further HIV transmission. Achieving HIV viral suppression is a primary goal when initiating ART. Unfortunately, there are gaps throughout the continuum of HIV care in the United States and research shows only 25% of all people living with HIV (PLWH) know they are infected, get regular medical care, take ART, and achieve HIV viral suppression. Recent studies show that computer-based interventions are effective in improving protective health behaviors including ART adherence and sexual risk reduction among PLWH. In response to the need for more comprehensive and feasible interventions, CDC has developed Positive Health Check, a brief web-based video counseling intervention to improve clinical health outcomes for PLWH including ART initiation, ART adherence as measured by suppressed HIV-1 viral load, retention in care, and sexual risk reduction as measured by incident STDs. The intervention is to be used by English-speaking PLWH in HIV primary care to supplement existing clinical care services. The grantee will conduct the Positive Health Check Evaluation Trial and

evaluate the study intervention in eligible PLWH from three or four diverse HIV primary care clinics in the United States. The grantee will enroll a minimum of 2,320 eligible participants (1,160 per study arm) in the study trial, with a minimum of 580 to a maximum of 1,160 enrolled per clinic. Electronic medical records, laboratory reporting data, medical charts, and appointment records from participating clinics will be used to determine patient eligibility for the study. PLWH who are eligible and enrolled in the trial will be randomized to either the intervention arm (i.e., Positive Health Check plus standard clinical care) or to the control arm (i.e., standard clinical care only). The Positive Health Check Evaluation Trial tests whether the intervention significantly improves persons' clinical outcomes, including ART initiation, ART adherence (measured by suppressed HIV-1 viral load), retention in care, and sexual risk reduction (measured by incident STDs). The trial will also document the current standard of care for each collaborating clinic and the cost and feasibility of implementing and integrating the Positive Health Check intervention in diverse HIV primary care clinic settings in the United States.

- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** Estimated total funding available, to include direct and indirect costs for the entire project period, is \$2,900,000. The project period will be four years. There will be one award. The award issued under this FOA is contingent upon availability of funds, the total number of meritorious applications and cost of the applications received.
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first year (12-month budget period) will be \$300,000. The estimated total funding (direct and indirect) for the second year (12-month budget period) will be \$1,100,000, for the third year (12-month budget period) will be \$1,000,000, and for the fourth year (12-month budget period) will be \$500,000. The estimated total funding (direct and indirect) for the entire project period will be \$2,900,000. The project period will run from 09/01/2015 to 08/31/2019.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1. of this funding opportunity announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI for this project.
- **Number of Applications.** Each eligible applicant institution may submit only one application.
- **Application Type.** New
- **Special Date(s).** A potential applicant conference call will be held on Tuesday, January 13, 2015 from 10:00 am to 11:00 am Eastern Time. The bridgeline is: 1-866-662-8986; passcode: 8378091.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form C is to be used when downloading the application package.

http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Sections 301 and 318 of the Public Health Service Act (42 U.S.C. Sections 241 and 247(c), as amended).

1. Background and Purpose

CDC announces the availability of fiscal year (FY) 2015 funds for a cooperative agreement program called the Positive Health Check Evaluation Trial. The randomized trial will evaluate the efficacy of Positive Health Check, a brief web-based video counseling intervention, developed by CDC to improve clinical health outcomes among English-speaking persons living with HIV (PLWH) in care.

HIV antiretroviral therapy (ART) can durably suppress the plasma HIV viral load which improves individual survival and dramatically reduces further HIV transmission. Achieving HIV viral suppression is a primary goal when initiating ART. Unfortunately, there are gaps throughout the continuum of HIV care in the United States where a large proportion of PLWH are not able to fully maximize the health benefits of effective ART. It is estimated that over 1.1 million Americans were living with HIV in 2009, and decreasing proportions were diagnosed (82%), linked to care (66%), retained in care (37%) and prescribed ART (33%) (1). Only 25% of all people with HIV know they are infected, get regular medical care, take ART, and achieve HIV viral suppression (1).

There is a need to implement effective interventions that focus on enhancing prevention and care to improve the health of, and to reduce HIV transmission risk among, PLWH. Several studies have shown that brief computerized interventions can reduce self-reported sexual risk behaviors and ART adherence among PLWH (2, 3, 4, 5, 6). A recent study tested the efficacy of a computerized intervention supporting ART adherence and HIV transmission risk reduction and found that intervention participants, relative to controls, experienced greater suppressed HIV-1 viral load ($P=0.053$), reported greater ART adherence ($P=0.046$), and reported fewer sexual transmission risk behaviors ($P=0.040$) (7). Together, these studies suggest that computerized interventions are a promising approach to improve ART adherence and safer sex behaviors among PLWH (8). However, interventions should be developed with improved study design (e.g., large sample size) and relevant outcome measures (e.g., retention in HIV care, ART initiation, and ART adherence based on biologic measures of HIV-1 viral load suppression).

In response to this need, CDC developed Positive Health Check, a web-based video counseling intervention to improve clinical health outcomes among PLWH. Positive Health Check is a 15-20 minute English-language web-based video counseling intervention. The intervention is to be used by PLWH in HIV primary care settings to supplement existing clinical care services. The intervention aims to improve persons' ART initiation, ART adherence (measured by suppressed HIV-1 viral load), retention in care, and sexual risk reduction (measured by incident STDs). The intervention also aims to reduce mother-to-child transmission and risk of HIV transmission through injection drug use behavior.

The Positive Health Check Evaluation Trial will be a randomized trial to test whether the Positive Health Check intervention significantly improves the abovementioned clinical outcomes. The study will be conducted by one grantee through participation with three or four HIV primary care clinics in the United States that vary by location (i.e., located in different metropolitan statistical areas with high HIV prevalence (greater than 5000 diagnosed with HIV infection by year-end 2010) as indicated in Table 23 of CDC's 2011 HIV Surveillance Report (9) (see: http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf), type of clinic (e.g., Community Health Center,

Ryan White-funded, academic-affiliated, health maintenance organization, private, or Veterans Administration clinics) and meet the identified minimum criteria for selection. The grantee and its partner clinics will conduct the trial over a 24-month period of time and must enroll a minimum of 2,320 eligible participants (1,160 per study arm). The randomized trial will also document the cost and feasibility of implementing and integrating the Positive Health Check intervention in HIV primary care clinic settings.

Participants eligible for enrollment in this trial will have one or more of the following characteristics: not currently prescribed ART (including ART naïve or persons previously prescribed ART), new patient within the last year (including new patient to the clinic or newly diagnosed), has detectable viral load (≥ 200 copies/mL), previous laboratory test for viral load more than one year ago, missed at least one HIV primary care appointment within the last year, evidence of prior STD, or documented or self-reported indication of engaging in high risk sex or injection drug use. Positive Health Check contains modules to address each of these characteristics, and persons' navigation through the modules are guided by their personal prevention needs.

PLWH eligible and enrolled in the trial will be randomized to either the intervention arm (i.e., Positive Health Check plus standard clinical care) or to the control arm (i.e., standard clinical care only).

References:

1. United States Department of Health and Human Services, Centers for Disease Control and Prevention, "HIV in the United States: The Stages of Care." CDC Fact Sheet. July 2012. URL: http://www.cdc.gov/hiv/pdf/research_mmp_stagesofcare.pdf.
2. Gilbert, P., Ciccarone, D., Gansky, S. A., Bangsberg, D. R., Clanon, K., McPhee, S. J., *et al.* (2008). Interactive "Video Doctor" counseling reduces drug and sexual risk behaviors among HIV-positive persons in diverse outpatient settings. *PLoS ONE*, 3(4), 1-10.
3. Fisher, J. D., Amico, K. R., Fisher, W. A., Cornman, D. H., Shuper, P. A., Trayling, C., *et al.* (2011). Computer-Based Intervention in HIV Clinical Care Setting Improves Antiretroviral Adherence: The LifeWindows Project. *AIDS and Behavior*, 15(8), 1635-1646.
4. Noar, S. M., Black, H. G., Pierce, L. B. (2009). Efficacy of computer technology-based HIV prevention interventions: a meta-analysis. *AIDS*. 23(1), 107-15.
5. Hersch, R. K., Cook, R. F., Billings, D. W., Kaplan, S., Murray, D., Safren, S., *et al.* (2013). Test of a Web-Based Program to Improve Adherence to HIV Medications. *AIDS and Behavior*, 17, 2963-2976.
6. Bachmann, L. H., Grimley, D. M., Gao, H., Aban, I., Chen, H., Raper, J. L., *et al.* (2013). Impact of a computer-assisted, provider-delivered intervention on sexual risk behaviors in HIV-positive men who have sex with men (MSM) in a primary care setting. *AIDS Education and Prevention*, 25(2), 87-101.
7. Kurth, A. E., Spielberg, F., Cleland, C. M., Lambdin, B., Bangsberg, D. R., Frick, P. A., *et al.* (2014). Computerized Counseling Reduces HIV-1 Viral Load and Sexual Transmission Risk: Findings From a Randomized Controlled Trial. *Journal of Acquired Immune Deficiency Syndrome*, 65(5), 611-620.
8. Noar, S. M. (2011). Computer technology-based interventions in HIV prevention: State of the evidence and future directions for research. *AIDS Care*. 23(5), 525-33.
9. Centers for Disease Control and Prevention. *HIV Surveillance Report, 2011*; vol. 23. <http://www>

Healthy People 2020 and other National Strategic Priorities

The NCHHSTP of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This FOA addresses the "Healthy People 2020" priority area of HIV and is in alignment with: 1) performance goal HIV-10 (developmental) to increase the proportion of HIV-infected adolescents and adults who receive HIV care and treatment consistent with current standards by 2020; 2) performance goal HIV-11 to increase the proportion of persons surviving more than 3 years after a diagnosis with AIDS by 10% (from 84% to 92.4% by 2020; and 3) performance goal HIV-12 to reduce deaths from HIV infection by 10% (from 3.7 deaths due to HIV infection per 100,000 population to 3.3 deaths due to HIV infection per 100,000 population) by 2020. For more information, please see <http://www.healthypeople.gov/2020/topics-objectives/topic/hiv/objectives>

The National HIV/AIDS Strategy (NHAS) has also set goals and this proposed study supports goal #2 to increase access to care and improve health outcomes for people living with HIV. This proposed study also supports goal #3 to reduce HIV-related health disparities and the related anticipated results to increase the proportion of HIV-diagnosed gay and bisexual men, Blacks, and Latinos with undetectable viral load by 20%. For more information, please see <http://aids.gov/federal-resources/national-hiv-aids-strategy/overview/index.html>

Also related to NHAS, this study is in support of the White House's HIV Care Continuum Initiative which calls for coordinated action to increase the number of people living with HIV in the United States who have achieved the treatment goal of controlling the HIV virus. For more information, please see <http://aids.gov/federal-resources/policies/care-continuum/>

Public Health Impact

Although HIV antiretroviral therapy (ART) is a life-saving intervention that both improves quality of life and reduces further HIV transmission in the community, only an estimated 25% of people living with HIV know they are infected, get regular medical care, take ART and have the HIV virus under control and suppressed. The Positive Health Check Evaluation Trial will demonstrate the feasibility and efficacy of a brief online counseling intervention to improve health outcomes of PLWH. The ultimate goal is to demonstrate that the intervention is an efficacious public health program to improve HIV care and reduce HIV transmission in the United States.

Relevant Work

Positive Health Check: CDC's Prevention Research Branch has developed Positive Health Check a 15-20 minute English-language web-based video counseling intervention designed to improve clinical health outcomes for PLWH including ART initiation, ART adherence as measured by suppressed HIV-1 viral load, retention in care, and sexual risk reduction as measured by incident STDs. Positive Health Check also promotes protective behaviors for mother-to-child transmission and injection drug use. The intervention is to be used by English-speaking PLWH in HIV primary care to supplement existing clinical care services. A virtual doctor-actor of the patient's choice delivers tailored messages based on a patient's responses to screener questions and selected questions for their clinic doctor and tips to practice before their next clinic visit. Positive Health Check is housed within the CDC information technology server and internet domains and utilizes media streaming mechanisms to deliver the web-based intervention to target audiences.

The Positive Health Check (PHC) intervention is comprised of 8 modules (Opening, Treatment

Readiness, Adherence, Retention in Care, Sex Risk Reduction, Mother-to-Child Transmission, IDU and Closing) which are tailored to patients based on their responses to screener questions and personal selections. Development work has included the filming of all video clips with virtual medical staff, as well as programming the intervention to allow for an interactive, tailored delivery of the intervention. PHC (programming and video clips) is housed within the CDC domain and utilizes a streaming media mechanism to deliver the web-based intervention. Sample intervention video clips can be viewed here: <http://www.cdc.gov/hiv/policies/funding/positiveHealthVideos.html>.

CDC's 2011 HIV Surveillance Report: Centers for Disease Control and Prevention. *HIV Surveillance Report, 2011*; vol. 23. Published February 2013. Accessed July, 29, 2014.

<http://www.cdc.gov/hiv/topics/surveillance/resources/reports/>.

Prevention IS Care: The Prevention Is Care campaign encourages health care providers to counsel PLWH to reduce HIV-related risk behaviors and maintain low-risk behaviors. Prevention IS Care provides health care providers with tools that can be used on a daily basis with persons who are living with HIV. Informational posters and patient education brochures improve persons' knowledge about HIV, facilitate information exchange and strengthen persons' ability to make healthy choices. Tools and continuing education opportunities are available through <http://www.cdc.gov/actagainstaids/campaigns/pic/index.html>.

CDC's Winnable Battles: This FOA addresses one of CDC's Winnable Battle goals by:

- Intensifying HIV prevention efforts in communities where HIV is most heavily concentrated.
- Expanding targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches for persons living with HIV and those at high risk of infection.
- Maximizing the proportion of people with HIV who have suppressed viral load by improving diagnosis, linkage and retention in care, and antiretroviral provision and adherence.
- Improving data monitoring, dissemination, and feedback.
- Educating persons living in the US about the threat of HIV and how to prevent it.

Additional information about these key actions is available at: <http://www.cdc.gov/winnablebattles/targets/pdf/hiv-winnablebattles-progressreport.pdf>

CDC HIV Intervention and Dissemination Programs (examples): CDC's Capacity Building Branch (CBB) in the Division of HIV/AIDS Prevention (DHAP) develops a national dissemination and technical assistance plan and makes interventions available to any agency wishing to implement them in their communities. CBB is currently translating five HIV medication adherence strategies to improve health outcomes and reduce risk of HIV infections. In addition, CBB is preparing a training curriculum for patient navigators to actively engage people living with HIV in enhancing entry into HIV care, promote medication adherence, and facilitate retention in HIV care. Finally, CBB is disseminating the Anti-Retroviral Treatment and Access to Services (ARTAS) intervention, which is an individual-level, multi-session intervention with the goal of linking recently diagnosed persons with HIV to medical care soon after receiving their positive test result. Additional information about these activities is available at: <http://www.effectiveinterventions.org/en/HighImpactPrevention/BiomedicalInterventions/MedicationAdherence.aspx>.

CDC's Epidemiology Branch in DHAP is implementing and evaluating a multi-component HIV clinic-based intervention called APTCare to lower HIV-1 viral load among persons, and improve persons' adherence to ART, retention in care, and safer-sex practices. Persons who have a detectable viral load are encouraged to do a brief computer-based intervention (CBI) available at the clinic and work with a counselor or prevention case manager to provide additional support. The CBI, just one

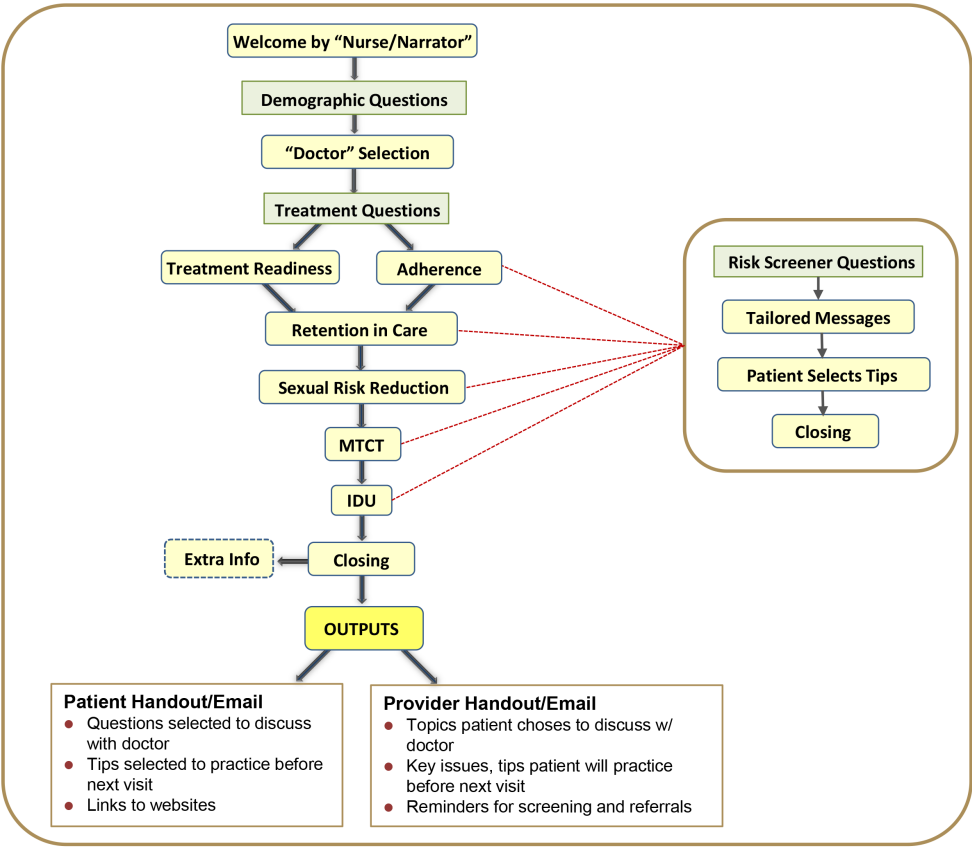
aspect of the program, engages the persons with questions and provides motivational messages, ideas, and tips for improving ART adherence, clinic attendance and sexual risk reduction as needed. For more information, see <http://clinicaltrials.gov/show/NCT02044484>.

2. Approach

CDC is proposing to conduct a randomized trial to determine if Positive Health Check, a brief online video counseling intervention improves clinical health outcomes among English-speaking PLWH in HIV primary care. Positive Health Check is a 15-20 minute English-language web-based video counseling intervention, developed and maintained by CDC, which is intended to be used by PLWH in HIV primary care to supplement existing clinical care services.

The intervention aims to increase viral load suppression and reduce risk of HIV transmission by targeting ART initiation, ART adherence as measured by suppressed HIV-1 viral load, retention in care, and sexual risk reduction as measured by incident STDs. The intervention also briefly addresses mother-to-child transmission and injection drug use behavior.

Figure 1. Positive Health Check Flow Diagram



The following describes a typical patient’s use of the Positive Health Check intervention. A schematic of the intervention flow is shown in **Figure 1** above (MTCT= Mother-to-Child HIV Transmission; IDU = Intravenous Drug Use).

Clinic persons log on to Positive Health Check using a laptop, desktop computer or tablet with WiFi or Internet access. After a virtual “nurse” welcomes the patient to the intervention, the patient completes a brief demographic survey. Next, the patient chooses a virtual “doctor” to work with

during the session. The virtual doctor delivers education and prevention messages tailored to the patient's risk behaviors, as determined by the patient's responses to screener questions on six topics: ART initiation, ART adherence, retention in care, sexual risk reduction, mother-to-child transmission, and injection drug use behavior. The patient then selects "tips," which are prevention strategies to practice before their next clinic visit. Examples of prevention "tips" for improving ART adherence include: (1) "When taking a trip, always keep your HIV meds with you, not in your suitcase; and bring extra doses in case of delays;" (2) "Set a reminder system like a note or set a daily alarm on your cell phone. You can also use an app or online reminder service;" and (3) "Keep an extra dose at work or with you in case of emergencies." Examples of prevention "tips" for improving retention in care include: (1) "If you have to miss an appointment, call the clinic ahead of time and reschedule it;" and (2) "Line up transportation to the clinic or arrange child care."

At the end of the session, the patient is invited to view "Extra Info" which includes videos and information materials on selected topics of interest. Finally, the patient is provided with a handout of the questions they selected to ask their provider during their clinic visit and tips they committed to practice before their next visit. The patient may choose to have the handout emailed to their private email address or shared with the provider. If unable to finish the intervention during the clinic visit, the patient may request to have a secure link to the intervention emailed to his/her private email address.

During the period of implementation of 24 months, persons will be expected to log on and complete the Positive Health Check intervention during each regularly scheduled clinic visit. It is anticipated that each patient enrolled in the trial will complete the intervention up to three times. Persons will also have the option of completing Positive Health Check on their personal devices while at home or at another location if they are unable to complete the intervention while in the clinic. The Positive Health Check intervention will be hosted on a secure server and maintained by CDC for the duration of the study.

After the award has been granted, CDC will work with the grantee to provide access to Positive Health Check materials and to train the grantee on intervention implementation. Following this orientation, CDC will collaborate with the grantee to develop a trial protocol. Although the trial details will be determined at that time, core activities and outcomes are discussed in this FOA.

To conduct the randomized trial, the applicant/prospective grantee will select and collaborate with three or four HIV primary care clinics in the United States to enable the recruitment of a minimum of 2,320 persons required for this study, with a minimum of 580 to a maximum of 1,160 enrolled from each clinic.

Participating HIV clinics will:

Vary by location and type:

- Each clinic will be located in different metropolitan statistical areas with high HIV prevalence (greater than 5000 diagnosed with HIV infection by year-end 2010) as indicated in Table 23 of CDC's 2011 HIV Surveillance Report (see: http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf).
- Clinics will be of different clinical service types (e.g., Community Health Centers, Ryan White-funded, academic-affiliated, health maintenance organization, private, or Veterans Administration clinics) and serve a patient population whose sociodemographics (e.g., race/ethnicity, gender, and socioeconomic status) are representative of people living with HIV in the applicant's local jurisdiction.
- The three or four clinics must be a combination of and represent at least two different clinical

service types (e.g., two Community Health Centers and one Ryan White or two Ryan White and one veterans Administration).

Meet the minimum criteria for eligibility as follows:

HIV Clinic Eligibility Criteria

HIV clinics working with the applicant will meet all of the following criteria in order to be determined eligible for participation in the randomized trial study.

- Serve a patient population whose sociodemographics (e.g., race/ethnicity, gender, and socioeconomic status) are representative of people living with HIV in the local jurisdiction;
- Be located in a United States Metropolitan Statistical Area of high HIV prevalence (greater than 5000 diagnosed with HIV infection by year-end 2010) as indicated in Table 23 of CDC's 2011 HIV Surveillance Report http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf
- Be representative of the types of HIV primary care clinics in the clinic's jurisdiction (e.g., Community Health Centers, Ryan White-funded, academic-affiliated, private, Veterans Administration);
- Use electronic medical records (EMRs) or other clinic databases to access patient clinical data, including laboratory-confirmed viral load (copies/mL), CD4 cell counts, STD screening and treatment history, ART prescriptions and refills, tests for pregnancy and provision of prescription for emergency contraception, and clinic attendance for HIV primary care;
- Perform routine STD screening as part of routine HIV care;
- Have access to sufficient numbers of clinic patients to warrant inclusion in the research study where approximately 580 to 1,160 persons are enrolled by each participating clinic. When combined, the 3 to 4 clinics must enroll a minimum of 2,320 persons.
- Provide a letter of support to conduct the Positive Health Check Evaluation Trial over a 24-month period of time;
- Identify and budget for a "champion" within the clinic (e.g., Medical Director) to endorse and promote trial activities over the 24-month period of participation in the trial (list as a key person in the application and include salary and percent effort in the detailed budget);
- Identify, and/or recruit, and budget for a full-time (12 calendar months) study coordinator and part-time (minimum 20% effort) data manager for the 24-month period of participation in the trial (list as key persons in the application and include salaries and percent effort in the detailed budget);
- Agree to share clinic data with the grantee and with CDC; and
- Perform only the Positive Health Check trial and no other coincident intervention or study using resources from this FOA.

The successful applicant will collect, from each eligible clinic, the clinic-specific information and clinical service data described below. The applicant will use these data in determining selection for participation. Included in the Appendix section of the application should be the names of the three or four collaborating clinics that were selected for participation, the associated clinic-specific information and clinical service data, a list of the qualifying clinics from which the participating clinics were selected, a description of how the participating clinics were selected, and a description of how these clinics meet the minimum criteria to participate in the randomized trial (e.g., provide HIV care to a minimum number of persons).

Required Clinic-Specific Information and Clinical Service Data

1. Number of HIV-positive persons served by the clinic over 12 months, including race/ethnicity,

- sex at birth, gender, sexual orientation, and HIV transmission category.
2. Estimated number of HIV-positive persons on ART, number of persons who are not virally suppressed, number of persons with inconsistent or irregular clinic attendance, and number of new persons referred to the clinical annually.
 3. Location of the clinic including state, city, and neighborhood(s).
 4. Length of time clinic has provided HIV and STD treatment and care services.
 5. Use of electronic medical records (EMRs) and other clinic databases to access patient clinical data including laboratory-confirmed viral load (copies/mL), CD4 cell counts, STD screening and treatment history, ART prescriptions and refills, pregnancy test results, request and provision of prescription for emergency contraception, and clinic attendance for HIV primary care.
 6. Conducts STD screening as part of routine HIV care.
 7. Nature of all HIV/STD prevention or other health promotion services provided at the clinic.
 8. Can identify a “champion” within the clinic (e.g., Medical Director) to endorse and promote the randomized trial.
 9. Agree to share data with grantee and CDC.
 10. Can identify a full time (12 months) project coordinator and part-time data-manager to oversee and manage the randomized trial (list as key persons in the application and include salaries and percent effort in the detailed budget);
 11. Statement of whether the proposed clinics have participated in any previous pilot test of the Positive Health Check intervention.
 12. Confirmation that the applicant proposes to evaluate the intervention Positive Health Check and no other intervention or study using resources funded from this FOA.

The applicants awarded through this FOA will ensure that appropriate security and confidentiality and data sharing agreements are in place between the grantee’s organization and the three or four collaborating HIV primary care clinics before work is initiated. Whereas multiple clinics will participate in this trial, the collaboration between each clinic and the grantee will be bilateral. Therefore, each clinic will share information with the grantee as part of this trial, but that information will not be shared with other clinics in the trial.

Implementation of the study will determine the efficacy of the Positive Health Check intervention for improving clinical health outcomes of English-speaking PLWH in primary care in the United States (Research Objective #1). Collaborating clinics will identify eligible persons for the trial including, but not limited to, persons with one or more of the following characteristics: not currently prescribed ART (including ART naïve or persons previously prescribed ART), new patient within the last year (including new patient to the clinic or newly diagnosed), has detectable viral load (≥ 200 copies/mL), previous laboratory test for viral load more than one year ago, missed at least one HIV primary care appointment within the last year, evidence of prior STD, or documented or self-reported indication of engaging in high risk sex or injection drug use.

Within each clinic, eligible persons will be identified by a full-time onsite study coordinator through examination of EMRs, medical charts, laboratory reporting data, and patient appointment records. Eligible persons will be randomized into the intervention arm (i.e., Positive Health Check plus standard clinical care) or the control arm (i.e., standard clinical care only). A computer program will be developed by the grantee to randomize persons. The computer program will also be used by the study coordinator to track patient exposure to the intervention during at least 3 regularly scheduled clinic visits. The grantee will provide sufficient computers, laptops or tablets to each participating clinic to make the Positive Health Check intervention available to eligible persons in the intervention

arm.

A quantitative assessment will include a comparison of outcomes among persons receiving the Positive Health Check intervention plus standard clinical care (intervention arm) with those persons receiving standard clinical care only (control arm). The study will seek to detect changes in:

- the number and proportion of persons with suppressed HIV-1 viral load;
- the number and proportion of persons prescribed ART;
- the number and proportion of persons attending scheduled HIV care appointments;
- the number and proportion of new cases of sexually transmitted diseases (STDs); and
- the number and proportion of persons with a documented unplanned pregnancy or request for emergency contraception.

The primary study question for this trial will be whether persons in the intervention arm are more likely to achieve viral suppression within 12 months after enrollment compared to persons in the control arm. The proportions of persons in the control and intervention arms who achieve HIV-1 viral load suppression will be compared using Fisher's Exact Test with a two-sided significance level of 5%. Assuming that the proportion of successes in the control and intervention arms are 70% and 77%, respectively, a relative difference of 10%, and allowing for an annual attrition rate of 25%, a minimum sample size of 2,320 persons (or 1,160 persons per study arm) will be required to have 80% power to reject the null hypothesis that the true proportion of successes is the same in both arms.

Major data elements to be collected by the grantee during the randomized trial will include routine clinical data including HIV-1 viral load laboratory results, ART prescription and refill receipt information, persons' attendance of scheduled clinic appointments, STD screening and treatment results, test for unplanned pregnancy, and provision of prescription for emergency contraception. Additional data elements will include, but are not limited to, information on basic patient demographics (e.g., month and year first tested HIV positive, age, biological sex, race, ethnicity, HIV risk exposure category, and primary insurance), clinic type, and trial classification (i.e., intervention vs. control).

In addition, the grantee will conduct in the three or four study clinics focus groups and in-depth structured interviews with key staff including, but not limited to, clinic directors/managers, case managers, nurses and physicians (Research Objective #2). The focus groups and interviews will be administered intermittently throughout the 24-month period of study implementation. These data will address how Positive Health Check fits into clinic flow and routine clinical practice; the feasibility of implementing the intervention in diverse clinic environments, including those with limited resources; how many persons are offered the intervention; number of exposures to the intervention; and how the intervention impacts patient-provider communication. CDC will provide the grantee with process data collected by the Positive Health Check intervention which will be programmed to automatically upload these process data to a database maintained by the CDC. The database will include several parameters including patient input in response to module-specific risk screener questions, length of time patient is logged on to the intervention, use of the email option, use of the handout option, number of persons that completed the intervention, and total number of individual patient exposures to the intervention. The intervention is considered complete when the patient has visited each intervention module. The grantee will use this information in statistical analyses.

The grantee will collect and document information on the cost of Positive Health Check intervention implementation (Research Objective #3). Cost factors to include but not limited to staff time,

computer equipment, and office supplies (fax/printer ink, etc.) will be identified. Additional considerations will be reviewed and identified after award.

Finally, the grantee will collect descriptive data on the standard of care for each HIV primary care clinic participating in the randomized trial including for example the use of risk reduction messages and appointment reminders (Objective #4.).

Consistent with the Consolidated Standards of Reporting Trials (CONSORT) statement (see: <http://www.consort-statement.org/>), the application must include a plan for an intention-to-treat analysis (i.e., an analysis of persons in study arms as originally assigned, analysis of persons regardless of the level of intervention exposure, and analysis using appropriate imputations to account for missing data due to attrition or other reasons), and individual-level randomization to study arms.

Objectives/Outcomes

Grantees awarded under this FOA will implement the Positive Health Check Trial in three or four HIV primary care clinics and must address each of the following research objectives:

Objective #1: Implement a randomized trial to test the efficacy of the Positive Health Check intervention for improving clinical health outcomes including:

- a. ART initiation;
- b. ART adherence (measured by suppressed HIV-1 viral load);
- c. Retention in care;
- d. Sexual risk reduction (measured by incident STDs);
- e. Other measures suggesting potential HIV transmission risk (e.g., unplanned pregnancy, request for emergency contraception).

Outcomes:

1. HIV-1 Viral Load Suppression: Calculate the number and proportion of HIV-infected persons who achieve viral load suppression (less than 200 copies/mL) within 12 months after randomization to either the intervention plus standard care study arm or the standard care only study arm.

a. All persons randomized to the intervention arm or control arm will be included in the denominator.

b. Outcomes will be dichotomized as either:

i. Achieved viral load suppression: suppressed viral load result (less than 200 copies/mL) within 12 months of the date of randomization.

ii. Did not achieve viral load suppression: either viral load results within 12 months of the date of randomization were not suppressed (greater than or equal to 200 copies/mL) or the patient had no viral load results.

c. HIV primary care clinic laboratory reporting data will be used to measure these outcomes.

2. Durable HIV-1 Viral Load Suppression: Calculate the number and proportion of HIV-infected individuals who achieved durable viral load suppression [two suppressed viral load results (less than 200 copies/mL) at least three months apart within 18 months] from the date of randomization to either less than the intervention plus standard care study arm or the standard care only study arm.

a. All persons randomized to the intervention arm or control arm will be included in the denominator.

- b. Outcomes will be dichotomized as either:
 - i. Achieved durable viral load suppression: two suppressed viral load results (less than 200 copies/mL) at least three months apart within 18 months of the date of randomization.
 - ii. Did not achieve durable viral load suppression: did not have two suppressed viral load results (less than 200 copies/mL) at least three months apart within 18 months of the date of randomization.
 - c. HIV primary care clinic laboratory reporting data will be used to measure these outcomes.
3. ART initiation: Calculate the number and proportion of HIV-infected persons naïve to ART (or treatment experienced but not currently prescribed ART) who receive a prescription for ART within 90 days from the date of randomization to either the intervention plus standard care study arm or the standard care only study arm.
- a. All persons randomized to either the intervention arm or control arm who were not currently prescribed ART therapy at randomization will be included in the denominator.
 - b. Outcomes will be dichotomized as either:
 - i. Prescribed ART within 90 days of the date of randomization.
 - ii. Was not prescribed ART within 90 days of the date of randomization.
 - c. HIV primary care clinic records will be used to measure these outcomes.
4. Retention in care: Calculate the number and proportion of HIV-infected persons who attend one clinic visit within 90 days from the date of randomization to either the intervention plus standard care study arm or standard care only study arm.
- a. All persons randomized to the intervention arm or control arm will be included in the denominator.
 - b. Outcomes will be dichotomized as either:
 - i. Retained in care: Attended one clinic visit within 90 days of the date of randomization.
 - ii. Not retained in care: Did not attend one clinic visit within 90 days of the date of randomization.
 - c. HIV primary care clinic patient appointment records will be used to measure these outcomes.
5. Engaged in care: Calculate the number and proportion of HIV-infected individuals who are engaged in care as measured by two clinic visits at least three months apart within 12 months from the date of randomization to either the intervention plus standard care study arm or the standard care only study arm.
- a. All persons randomized to either the intervention arm or control arms will be included in the denominator.
 - b. Outcomes will be dichotomized as either:
 - i. Engaged in care: Attended two clinic visits at least three months apart within 12 months of the date of randomization.
 - ii. Not engaged in care: Did not attend two clinic visits at least three months apart within 12 months of the date of randomization.
 - c. HIV primary care clinic patient appointment records will be used to measure these

outcomes.

6. Incident STD: Calculate the number and proportion of HIV-infected individuals who are diagnosed with an incident STD from the date of randomization to either the intervention plus standard care study arm or the standard care only study arm.

a. All persons randomized to either the intervention arm or control arm and screened for STDs at randomization will be included in the denominator.

b. Outcomes will be dichotomized as either:

i. Incident STD: received one or more laboratory-confirmed incident STD diagnosis during the study period.

ii. No incident STD: Did not receive incident STD diagnosis during the study period.

c. HIV primary care clinic laboratory data will be used to measure these outcomes.

d. All persons will be screened for STDs (including syphilis, gonorrhea, chlamydia and trichomoniasis [women only] consistent with CDC STD Treatment Guidelines) at the time of randomization.

7. Unplanned pregnancy or emergency contraception: Calculate the number and proportion of HIV-infected women randomized into the study who have an unplanned pregnancy or request and receive emergency contraception comparing the intervention plus standard care study arm and the standard care only study arm.

a. All women randomized to either the intervention arm or control arm will be included in the denominator.

b. Outcomes will be dichotomized as either:

i. Unplanned pregnancy or emergency contraception: Documented unplanned pregnancy or request and provision of prescription for emergency contraception during the study period.

ii. No unplanned pregnancy or emergency contraception: No documented unplanned pregnancy or request for emergency contraception during the study period.

c. HIV primary care clinic data (e.g., EMR or prescription records) will be used to measure these outcomes.

Objective #2: Conduct a qualitative feasibility assessment to determine strategies to facilitate implementation and integration of Positive Health Check into diverse HIV primary care clinics.

Outcomes:

1. Data will be collected and analyzed to determine feasibility and acceptability of integrating the Positive Health Check intervention into routine HIV clinical care. Specific information will be collected on:

a. How often and how many persons were offered the intervention.

b. How the intervention fits into routine clinic practice.

c. How the intervention impacts patient-provider communication.

2. Data will be downloaded from the intervention's IT database and provided to the grantee. These data include, but are not limited to:

a. Patient input in response to module-specific risk screener questions

- b. Length of time patient is logged on the intervention
- c. Use of the email option
- d. Use of Patient Handout (printed and delivered at clinic or printed from home)
- e. Use of Provider Handout (clinic data documenting protocol tasks completion)
- f. Number of persons who completed the intervention
- g. Total number of exposures to the intervention

Objective #3: Collect and document data on cost of Positive Health Check intervention implementation.

Outcome:

Documentation of cost data of Positive Health Check intervention implementation. Cost factors will be identified to include, but not be limited to, staff time, computer equipment and office supplies (fax/printer ink, etc.). Additional considerations will be reviewed and identified after award.

Objective #4: Collect and document descriptive data on the standard of care for each HIV primary care clinic participating in the randomized trial.

Outcome:

Compilation and presentation of descriptive data on the standard of care for each HIV primary care clinic.

Target Population

Persons living with HIV (PLWH) in metropolitan statistical areas with high HIV prevalence. CDC's 2011 HIV Surveillance Report; http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf

Collaboration/Partnerships

The successful applicant will collaborate with three or four clinics to achieve the randomized trial sample size of 2,320. The HIV primary care clinics involved in this FOA will be US clinics that vary by location (i.e., located in different metropolitan statistical areas with high HIV prevalence (greater than 5000 diagnosed with HIV infection by year-end 2010) as indicated in Table 23 of CDC's 2011 HIV Surveillance Report (see: http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf) and type of clinic (e.g., Community Health Centers, Ryan White-funded, academic-affiliated, health maintenance organization, private, or Veterans Administration clinics). These collaborating clinics should also serve a patient population whose sociodemographics (e.g., race/ethnicity, gender, and socioeconomic status) are representative of people living with HIV in their jurisdiction.

Evaluation/Performance Measurement

Applicants should develop a timeline to achieve designated milestones for this individual-level randomized trial and to develop metrics to monitor the trial's performance and progress. In each clinic, the study coordinator will track the number of persons identified as eligible for the trial, the number enrolled, and the number actually assigned to a study arm.

The primary study question for this trial will be whether persons in the intervention arm are more

likely to achieve HIV-1 viral load suppression within 12 months after randomization compared to persons in the control arm, within the 24-month implementation period. The proportions of persons in the control and intervention arms who achieve HIV-1 viral load suppression will be compared using Fisher's Exact Test with a two-sided significance level of 5%. Assuming that the proportion of successes in the control and intervention arms are 70% and 77%, respectively, a relative difference of 10%, and allowing for an annual attrition rate of 25%, a minimum sample size of 2,320 persons (or 1,160 persons per study arm) will be required to have 80% power to reject the null hypothesis that the true proportion of successes is the same in both arms.

The analysis plan includes comparing the following clinical outcomes by study arm: number and proportion of persons prescribed ART (measuring ART initiation); number and proportion of persons with suppressed viral load; number and proportion of persons retained in care; number and proportion of persons with incident STDs, and number and proportion of female persons who have unplanned pregnancy or request emergency contraception.

The grantee will collaborate with CDC to: (1) establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the applicant's project plan, and (2) develop and implement project performance measures that are based on specific programmatic objectives. The grantee will be required to provide descriptions of the development and implementation of project activities in annual performance measure data reports and other formats as required by CDC. The CDC will provide the template and guidance for these reports.

Translation Plan

This randomized trial evaluates the efficacy and feasibility of Positive Health Check, a brief web-based counseling intervention to improve the health of English-speaking PLWH who attend HIV primary care clinics. The ultimate goal is to reduce HIV-1 viral load and transmission risk by increasing ART initiation, improving adherence to ART, retaining PLWH in care, and reducing sexual risk behaviors. Moreover, this study aims to demonstrate that Positive Health Check is efficacious in improving health and clinic outcomes of persons in care. In addition, this study will demonstrate the feasibility of HIV primary care clinics in the United States to implement a brief web-based video counseling intervention, and cost of intervention implementation. The results of this study will be communicated through presentations at professional conferences, and through publications.

If Positive Health Check is demonstrated to be feasible and efficacious, the grantee in collaboration with the collaborating HIV primary care clinics and CDC will develop a plan to disseminate the trial's results to all of their relevant stakeholders. For example, the grantee will develop and present to CDC, at the conclusion of this trial, a plan to integrate this intervention into CDC's Prevention IS Care campaign (<http://www.cdc.gov/actagainstaids/campaigns/pic/index.html>) and CDC's effective interventions dissemination program (<http://www.effectiveinterventions.org>). The grantee will also develop a preliminary dissemination strategy by identifying relevant professional networks, partner organizations, key marketing venues, potential early adopters, and Positive Health Check champions in the field.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: \$2,900,000

Year 1: \$300,000

Year 2: \$1,100,000

Year 3: \$1,000,000

Year 4: \$500,000

Number of awards = 1

Estimated total funding available for the first year (12-month budget period) is \$300,000.

Estimated total funding available for entire project period is \$2,900,000 for 4 years, including direct and indirect costs.

The award issued under this FOA is contingent on the availability of funds and submission of a meritorious application.

Anticipated Number of Awards: 1

The ceiling and floor information below is for the first 12-month budget period only. Award amounts for successive years are indicated in the section above.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: \$300,000 Per Budget Period

Award Floor: \$275,000 Per Budget Period

Total Project Period Length: 4 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

- State governments
- County governments
- City or township governments
- Special district governments
- Independent school districts

Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=512ff78311f427c00454772dcf21523a&rgn=div8&view=text&node=48:1.0.1.6.34.0.1.18&idno=48>

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

N/A

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

The following **must** be included in the application to document successful capacity to achieve the study objectives and to be responsive to this FOA:

- a) A total cost for the *first 12 month budget period* equal to or greater than the budget floor amount of \$275,000 (total costs) but not more than the budget ceiling amount of \$300,000 (total costs).
- b) A total cost for the entire four year proposed project period of \$2,900,000 or less (total costs).
- c) The application will document in the Appendix section (preferred): 1) the names of the three or four collaborating clinics that were selected for participation; 2) the associated clinic-specific information and clinical service data listed in Section I.2 of this funding opportunity announcement under the heading ***"Required Clinic-Specific Information and Clinical Service Data"***; 3) a list of the qualifying clinics from which the participating clinics were selected; 4) a description of how the participating clinics were selected; and 5) a description of how these clinics meet the minimum criteria to participate in the randomized trial listed in Section I.2. of this funding opportunity announcement under the headings ***Participating HIV clinics will:*** and ***HIV Clinic Eligibility Criteria.***

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <https://www.sam.gov/portal/SAM/#1>.
- [Grants.gov](https://www.Grants.gov)
- [eRA Commons](https://www.eRA Commons)

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to

register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at <https://www.sam.gov/index.html>.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components.

3. Letter of Intent

Due Date for Letter of Intent: **02/16/2015**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

By the date listed above and in Part I. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Applicant

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity announcement

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

- 1. Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
- 2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
- 3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
- 4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY)
- 5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

- 6. Protection of Human Subjects**
- 7. Inclusion of Women and Minorities**
- 8. Targeted/Planned Enrollment Table** (for New Application ONLY)
- 9. Inclusion of Children**

Other Research Plan Sections

- 10. Vertebrate Animals**
- 11. Select Agent Research**
- 12. Multiple PD/PI Leadership Plan.**
- 13. Consortium/Contractual Arrangements**
- 14. Letters of Support**
- 15. Resource Sharing Plan(s)**
- 16. Appendix**

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin

such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide

(http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

The application will document in the Appendix section (preferred): 1) the names of the three or four collaborating clinics that were selected for participation; 2) the associated clinic-specific information and clinical service data listed in Section I.2 of this funding opportunity announcement under the heading ***"Required Clinic-Specific Information and Clinical Service Data"***; 3) a list of the qualifying clinics from which the participating clinics were selected; 4) a description of how the participating clinics were selected; and 5) a description of how these clinics meet the minimum criteria to participate in the randomized trial listed in Section I.2. of this funding opportunity announcement under the headings ***"Participating HIV clinics will:"*** and ***"HIV Clinic Eligibility Criteria"***.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons ([http:// grants.nih. gov/grants /guide/url _redirect .htm? id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; www.pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions:

If an application submission was unsuccessful, *the applicant* must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
 - b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **03/16/2015**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review ([http:// www. whitehouse.gov/ omb/ grants _spoc](http://www.whitehouse.gov/omb/grants_spoc)).

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

For more information on expanded authority and pre-award costs, go to: <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>.

Funds relating to the conduct of research involving human subjects will be restricted until appropriate assurances and Institutional Review Board approvals are in place.

Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, forms, plans. etc.) from 10 or more non-Federal individuals/entities are subject to PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance.

12. Other Submission Requirements and Information

Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a grant/cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

Under the PRA, a Federal agency sponsoring a standardized data collection or directly obtaining standardized or substantially similar information from ten or more persons in any 12-month period must obtain advance written approval from the OMB.

This document contains collection of information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard 424(R&R) and PHS 398 Forms have been approved by the Office of Management and Budget (OMB) under the control numbers 0925-0001, 0925-0002, and 4040-0001). It is also requested that a Standard Form (SF) 425 be completed. This form's approved OMB Control number is 0348-0061 and expires 2/28/2015.

Note: Notwithstanding any other provision of law, no person is required to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process,

visit Applying Electronically (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144).

Important reminders:

All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (<http://www.cdc.gov/about/organization/mission.htm>), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Are the proposed study activities likely to have a positive impact on HIV prevention?

Does the application explain why ART initiation, ART adherence, and retention in HIV care is a problem in their jurisdiction and whether it would be beneficial to implement a novel intervention for improving HIV-related health outcomes?

Does the application address the potential impact that a successful intervention could have within their jurisdiction both on patient outcomes (e.g., sexual risk reduction, retention in HIV medical care, ART initiation, and ART adherence) and clinical practice?

Does the application address the importance of improving patient and provider communication?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Do the investigator(s) have experience conducting research studies in HIV primary care clinics?

Have the investigators been involved in projects that use behavioral interventions to improve HIV clinical outcomes, including ART initiation, ART adherence, and retention in HIV care?

Have the investigator(s) been involved in projects that use electronic medical record (EMR) and other patient clinical databases to use laboratory data (HIV-1 viral load results) for improving HIV care?

Do the investigator(s) have the appropriate training and skills to conduct this trial?

Do the investigator(s) demonstrate epidemiologic, behavioral, clinical, administrative, and management experience needed to conduct the proposed study?

Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Do the investigator(s) have the ability to collect, manage, and analyze accurate data in a timely manner?

Does the application allocate a minimum of 20% effort (calendar year) for the Principal Investigator for the first 12-month budget period and a minimum of 10% effort (calendar year) for the remaining 12-month budget periods (years two, three and four) of the FOA?

Does each clinic have access to qualified personnel with realistic and sufficient percentage-time commitments relative to each phase of the study timeline?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Does the application propose an **individual-level** (required) randomized trial to test the efficacy of the Positive Health Check intervention in improving clinical health outcomes among persons living with HIV in clinical care?

Does the application provide an adequate timeline for conducting the research?

Does the application include a description of how each of the three or four collaborating clinics were selected based on the minimum eligibility criteria provided in this FOA and is a list of qualifying clinics from which the participating clinics were selected included in the Appendix as instructed?

Does the application indicate that each of the collaborating clinics met the minimum eligibility criteria for participation as listed in Section I.2. “**Participating HIV clinics will:**” and “**HIV Clinic Eligibility Criteria**” of this FOA?

Does the application include a letter of support from each of the participating clinics indicating commitment for the 24-month period of participation in the study?

For each participating clinic, does the application provide clinic-specific information and clinical service data as listed in Section I.2 “**Required Clinic-Specific Information and Clinical Service Data**” of this FOA?

Does the application demonstrate that policies and protocols are in place to assure that the collaborating three or four HIV primary care clinics will be able to share clinical data with the grantee?

Does the application explain how structural barriers (if any) to sharing data between the clinics, grantee and CDC will be overcome?

Does the application include a sampling plan to recruit and enroll 580 to 1,160 eligible persons from each of the three or four identified participating clinics to total 2,320 across the three or four clinics?

Does the application include a plan and describe procedures for collecting and analyzing process monitoring data during the conduct of the trial?

Does the application describe a practical mechanism to randomly assign individual persons within

clinics to either the control or the intervention arm?

Does the application sufficiently describe a process for sharing all data collected with CDC?

Does the applicaiton describe sufficient protection procedures in place to ensure data security?

Does the application present a viable and feasible plan that includes project goals and objectives that are specific, measurable, achievable, realistic and time-phased (SMART), and a comprehensive timeline for accomplishing project activities?

Is the proposed timeline sufficiently detailed, complete, and realistic for a four-year project period?

Does the application describe the process by which HIV-1 viral load test results will be used to quantify persons' clinical outcomes for each collaborating clinic?

Does the application describe how appointments are tracked at collaborating clinics and whether the information technology support at the collaborating clinics will be adequate to create lists of persons who are potentially eligible for the intervention? Characteristics of eligible persons include those not currently prescribed ART (including ART naïve or persons previously prescribed ART), new patients within the last year (including new patients to the clinic or newly diagnosed), those with a detectable viral load (≥ 200 copies/mL), those with a previous laboratory test for viral load more than one year ago, those who missed at least one HIV primary care appointment within the last year, and those with self-reported need for sexual and injection drug risk-reduction support.

Does the application describe the process for gathering data on patient's ART experience (i.e., prescription of ART and ART adherence)?

Does the application describe a process for systematically collecting descriptive data on standard-of-care for each collaborating clinic?

Does the application describe the process for gathering baseline and follow-up data on STD incidence in the collaborating clinics?

Does the application describe a plan to analyze data using the intention-to-treat approach?

Does the application describe the process for collecting data on cost factors for Positive Health Check intervention implementation?

Does the application describe the process for collecting and reporting data on the feasibility of integrating the Positive Health Check intervention into routine HIV care?

Does the application budget for adequate funds for clinics to implement the intervention during the study period?

Does the application provide a description of procedures for management of data security and participant confidentiality in order to achieve the research objectives?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Does the application describe how the applicant will work with three or four collaborating clinics to gain access to sufficient numbers of the selected target population to successfully conduct the proposed study?

Are each of the participating clinics located in a metropolitan statistical area with high HIV prevalence (greater than 5000 diagnosed with HIV infection by year-end 2010) as indicated in Table 23 of CDC's 2011 HIV Surveillance Report (http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf)?

Are the collaborating clinics representative of the types of HIV primary care clinics and sociodemographics (e.g., race/ethnicity, gender, and socioeconomic status) in the clinic's jurisdiction (e.g., Community Health Centers, Ryan White-funded, academic-affiliated, private, Veterans Administration)?

Will the planned location for the study provide access to adequate numbers of the proposed target population?

Does the application include letters of support indicating that participating clinics have not previously participated in a pilot test of the Positive Health Check intervention?

Does the application demonstrate that the collaborating clinics agree to and have the ability to: 1) extract study-related data from clinic databases (including ART status, HIV laboratory data, clinic appointment data, and ART prescriptions and refills); 2) share data with the applicant and CDC (via a previously agreed-upon approved, secure mechanism) at baseline and during designated intervals throughout the study period; and 3) follow IRB-approved implementation protocols for the proposed study period?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under [45 CFR Part 46](#), the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

(http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research

(http://www.cdc.gov/maso/Policy/Policy_women.pdf and

<http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1>) and the policy on the Inclusion of Persons Under 21 in Research (<http://www.cdc.gov/maso/Policy/policy496.pdf>).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25.

Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- The success of this Positive Health Check Evaluation Trial relies on the recruitment and participation of a target population that has not previously been exposed (i.e., is naïve) to this intervention tool. Applicants that submit proposals that utilize public health providers that have not been previously involved in a Positive Health Check study trial may be given preference.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement ([http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award ([http:// www.hhs.gov/ asfr/ogapa/ aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-3: Animal Subjects Requirements](#)

[AR-7: Executive Order 12372 Review](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2020](#)

[AR-12: Lobbying Restrictions](#)

[AR-14: Accounting System Requirements](#)

[AR-16: Security Clearance Requirement](#)

[AR-21: Small, Minority, And Women-owned Business](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

[AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009](#)

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Nonresearch](#)

[AR 32 –; FY 2012 Enacted General Provisions](#)

ARs applicable to HIV/AIDS Awards:

[AR-4: HIV/AIDS Confidentiality Provisions](#)

[AR-5: HIV Program Review Panel Requirements](#)

[AR-6: Patient Care](#)

Additional Policy Requirements

This document contains collection of information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard 424(R&R) and PHS 398 Forms have been approved by the Office of Management and Budget (OMB) under the control numbers 0925-0001, 0925-0002, and 4040-0001). It is also requested that a Standard Form (SF) 425 be completed. This form’s approved OMB Control number is 0348-0061 and expires 2/28/2015.

Note: Notwithstanding any other provision of law, no person is required to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:

[http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol _memo.html](http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html))

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov ([http:// www.usaspending. gov/](http://www.usaspending.gov/)). For the full text of the requirements, please review the following website: [https:// www.fsrc.gov/](https://www.fsrc.gov/).

Plain Writing Act

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: [http:// www.plainlanguage.gov/ plLaw/index.cfm](http://www.plainlanguage.gov/plLaw/index.cfm).

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the

recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
- <http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Collaborating with CDC to develop a protocol for the Positive Health Check Evaluation Trial and submitting the protocol for IRB approvals as required locally. Protocol development activities will include the development of algorithms to identify and verify that persons are out-of-care, methods to measure the study outcomes, and data management procedures.
- Identifying persons in HIV care and randomizing to either intervention or control arms.
- Enrolling an adequate number of HIV-infected individuals as determined by the study protocol and the program requirements.
- Following HIV-infected individuals as determined by the study protocols.
- Establishing procedures to maintain the rights and confidentiality of all HIV-infected individuals evaluated in this trial.
- Collecting and entering data into a suitable database and performing data analyses as determined in the study protocols.
- Collaborating with CDC to disseminate study results at national or international meetings and publishing research findings in peer-reviewed scientific literature.
- Participating in routine conference calls with CDC project officer(s) and research team.
- Hosting CDC project officer(s) for site visits.
- Attending initial and annual meetings with CDC to promote research dissemination.
- Developing and implementing research study protocol(s) and consent forms required for the project.

- Obtaining appropriate approvals from local Institutional Review Board(s) from all participating study sites, if required.
- Collaborating with CDC in conducting appropriate data analysis and interpretation, as needed.
- Collaborating with CDC to identify solutions and innovations needed for program effectiveness.
- Collaborating with CDC in all stages of the project, including study design, data analysis, and sharing data and results with CDC. This includes, but is not limited to, active participation in conference calls, webinars, and in-person meetings (i.e., grantee meetings and special project meetings).
- Ensuring all surveys, questionnaires, focus groups, interviews and other information collected from respondents includes a valid OMB Control Number, a burden statement, and government use of the information collected in each statement.
- Paperwork Reduction Act (PRA) eligibility will depend upon the evaluation and reporting methods to be used for each activity and if applicable, project managers will submit a PRA determination form for each of the activities and/or contact the NCHHSTP OMB Coordinator as soon as the data collection instruments and methods for evaluation have been developed.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program the abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish results and findings from this project without prior approval and clearance from CDC.
- PUBLICATIONS/PRESENTATIONS: The grantee will not seek to publish or present results or findings from this project without prior approval and clearance from CDC.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Providing technical assistance and support for the design, implementation, and evaluation of research and program activities.
- Providing access to and training on implementation of the Positive Health Check web-based counseling intervention.
- Facilitating and assisting in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. A CDC engagement determination will determine if the CDC IRB will also need to approve the protocol.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Reviewing and approving research and program protocols.
- Assisting, as needed, in designing a data management system.
- Facilitating storage of project data with participating grantee.
- Collaborating with grantee to disseminate study results at national or international meetings and publishing research findings in peer-reviewed scientific literature.
- Conducting site visits to ensure that collaborating clinics are properly selected, collaborations outlined in proposals are appropriate, the community is involved in the research activities, and

investigators are complying with the research protocol.

- Conducting initial and subsequent meetings of the study investigators to facilitate the exchange of research progress and to offer additional technical expertise for the conduct of research.
- Collaborating on data management, analysis, presentation, and publication of project findings, as warranted.
- Participating in the presentation of results and in preparation of manuscripts/reports for publication, if CDC contribution so merits.

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- Organizing agenda content for conference calls and planning meetings as needed.
- Attending investigator meetings and participating in conference calls for the purposes of assessing overall progress, problem solving, and for program evaluation purposes.
- Collaborating on presentation and publication of data.

Additionally, a Scientific Program Officer in the Extramural Research Program Office, NCHHSTP/OADS/OD will be responsible for the normal scientific and programmatic stewardship of the award as described below.

- Named in the NOA as the Program Official to provide overall scientific and programmatic stewardship of the award;
- Serves as the primary point of contact on official award-related activities including an annual review of the grantee's performance as part of the request for continuation application;
- Makes recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application;
- Carries out continuous review of all activities to ensure objectives are being met;
- Attends committee meetings and participates in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
- Monitors performance against approved project objectives.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, 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 Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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 recipients: **1) information on executive**

compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over \$25,000. It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000. See the HHS Grants Policy Statement ([http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) for additional information on this reporting requirement.

CDC is also requiring the submission of Non-Competing Continuation Progress Report Forms (PHS 2590). The use of these forms are covered by OMB Control numbers 0925-0001 and 0925-0002 (Expiration Date 08/31/2015).

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, [http:// www. cdc.gov/ od/pgo/ funding/ forms.htm](http://www.cdc.gov/od/pgo/funding/forms.htm) and at [http:// grants.nih.gov/grants/ funding/2590/ 2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm), **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, 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.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 ([http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm)) [http:// grants.nih.gov/grants/ funding/2590/2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm): Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
 - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings.

Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*

- How will the scientific findings be translated into public health practice or inform public health policy?
 - How will the project improve or effect the translation of research findings into public health practice or inform policy?
 - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
 - How will the findings advance or guide future research efforts or related activities?
- **Public Health Relevance and Impact (1 page maximum).** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include:*
- How will this project lead to improvements in public health?
 - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
 - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- **Current Budget Period Financial Progress:** Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- **New Budget Period Proposal:**
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
 - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- **New Budget Period Budget:** Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- **Publications/Presentations:** Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- **IRB Approval Certification:** Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include 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 in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends.** Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at [http:// grants.nih.gov/ grants/forms.htm](http://grants.nih.gov/grants/forms.htm). For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: <http://www.cdc.gov/od/pgo/funding/grants/eramain.shtm>.

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https:// commons. era.nih.gov/ commons/](https://commons.era.nih.gov/commons/)). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: <http://era.nih.gov/commons/>. Organizations not yet registered can go to [https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp](https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp) for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: [http:// era.nih.gov/ commons /index.cfm](http://era.nih.gov/commons/index.cfm).

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers,

practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- **Public Health Relevance and Impact:** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- **Publications; Presentations; Media Coverage:** Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

[eRA Commons Help Desk](#) (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)

Procurement and Grants Office

Telephone 770-488-2700

Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Program Official / Scientific Research Contact

Deborah Loveys, PhD

Extramural Research Program Office

Office of the Associate Director for Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8834

Fax: 404-718-8822

Email: hft6@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: gca5@cdc.gov

Financial/Grants Management Contact

Louvern Asante

Procurement and Grants Office

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2960 Brandywine Rd, MS-E15

Atlanta, GA 30341

Telephone: 770-488-2835

Fax: 770-488-2868

Email: lha5@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Sections 301 and 318 of the Public Health Service Act, 42 U.S.C. Sections 241 and 247(c), as amended.

Summary of the Conference Call held on Tuesday, January 13, 2015 with Potential Applicants for Funding Opportunity Announcement (FOA): PS15-001 “Positive Health Check Evaluation Trial” and Answers to Questions from Potential Applicants

A. Introductory Comments

Any scientific or technical questions should be addressed to Deborah Loveys (hft6@cdc.gov). Any questions on financial, grants management, or eligibility aspects should be addressed to Louvern Asante (lha5@cdc.gov). Questions regarding the Peer Review process should be addressed to Greg Anderson (gca5@cdc.gov). Their contact information can be found in the FOA, Part 2, Section VII. “Agency Contacts”. Information on application submission is listed in Section IV. “Application and Submission Information”.

B. Eligibility Information

Please see Part 2, Section III. “Eligibility Information” for questions regarding eligible applicants.

C. Required Registrations

Please see Part 2, Section III. 6. “Required Registrations” for information on required registrations.

D. Other Information

Please submit your application at least five days before the deadline to allow for error correction. No extensions will be granted due to applications that are rejected because of submission errors.

Potential applicants should pay close attention to Part 2, Section V. “Application Review Information, 1. Criteria”. The criteria must be addressed – these are the criteria that will be used by reviewers to score the application. Failure to provide required information could result in an unfavorable score. Please also pay close attention to Part 2, Section I. “Funding Opportunity Description, 2. Approach”. Applicants must respond to ALL objectives listed. All responses to Objectives should be written in “SMART” format, which means that they should be specific, measurable, appropriate, realistic, and time-based.”

Please remember that the Research Plan Narrative is limited to 25 pages. Also remember to submit a 4-year Research Plan and a budget for each year.

It is anticipated that there will be 1 award. The estimated total funding available for Year 1 is \$300,000. The estimated total funding for the entire project period is \$2,900,000. The floor amount for year 1 is \$275,000, including direct and indirect costs. The ceiling amount for year 1 is \$300,000, including direct and indirect costs. Awards issued under this FOA are contingent upon the availability of funds.

E. Questions and Answers:

1) Question: The FOA states that the project coordinators are to be considered key personnel. Typically, in a grant, key personnel would be required to have a biosketch. However, some of the indicated staff members may be “to be hired.” How should we address this?

Answer: If the project coordinators are to be determined at a later date, no biosketches for these positions need to be included in the application. However, please state in the application that these persons will be hired later. Biosketches will be required later for these positions, if an award is made.

2) Question: The FOA states that there are 508 compliance requirements. Can you confirm whether the requirements for 508 compliance apply to this work?

Answer: When designing, developing, fabricating or acquiring Electronic and Information Technology (EIT), the recipient of the grant or cooperative agreement must ensure that (1) Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by

Federal employees who are not individuals with disabilities; and (2) Members of the public with disabilities seeking information or services from the recipient have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities. Only if the application involves designing, developing, fabricating or acquiring Electronic and Information Technology (EIT) would this apply.

3) Question: How many site visits will CDC staff conduct over the cooperative agreement period? Visits to sites are mentioned, but not the number per year. Could you clarify how many in each year? We assume that CDC would pay for the travel of their own staff to these site visits - please confirm.

Answer: The CDC would be responsible for all costs associated with CDC staff travel to awardee institutions. The number and schedule for CDC site visits will be determined after award.

4) Question: On page 33 of the FOA, it states that the “Applicants that submit proposals that use public health providers that have not been previously involved in a Positive Health Check study trial may be given preference.” If we propose using an institution that was involved in a previous Positive Health Check study trial, but the clinic proposed for this FOA is different and can provide the required number of naïve patients and providers, would this be acceptable?

Answer: The FOA allows applicants to submit proposals that use public health providers that have been previously involved a Positive Health Check study. Applicants that submit proposals that utilize public health providers that have not been previously involved in a Positive Health Check study trial may be given preference.