Centers for Disease Control and Prevention

Center for Global Health

Improving Isoniazid Preventive Therapy Penetration through Intensification of Case Findings at the Community Level in Rural South Africa under PEPFAR

CDC-RFA-GH15-1625

Application Due Date: 04/15/2015

Signature

Date

Improving Isoniazid Preventive Therapy Penetration through Intensification of Case Findings at the Community Level in Rural South Africa under PEPFAR

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Part I. Overview Information

A. Federal Agency Name:

Centers for Disease Control and Prevention

B. Funding Opportunity Title:

Improving Isoniazid Preventive Therapy Penetration through Intensification of Case Findings at the Community Level in Rural South Africa under PEPFAR

C. Announcement Type:

This announcement is only for non-research international activities supported by CDC. If research is proposed, the application will not be considered. Research for this purpose is defined at:

http://www.cdc.gov /od /science /integrity /docs /cdc -policy -distinguishing -public -health -research -nonresearch.pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-GH15-1625

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.067

F. Dates:

1. Due Date for Letter of Intent: **N/A**

2. Due Date for Applications: **04/15/2015**

3. Date for Informational Conference Call: **03/06/2015**

G. Executive Summary:

1. Summary Paragraph:

The purpose of this single eligibility funding opportunity announcement (FOA) is to conduct data quality assurance, data analysis, and dissemination of findings for an evaluation entitled "Improving Isoniazid Preventive Therapy (IPT) Penetration through Intensification of Case Finding at the Community Level in Rural South Africa under PEPFAR, South Africa."

a. Eligible Applicants: Single Eligibility Award

b. FOA Type: Cooperative Agreement

c. Approximate Number of Awards: 1

d. Total Project Period Funding: $317,588

e. Average One Year Award Amount: $317,588

f. Number of Years of Award: 1

g. Approximate Date When Award will be Announced: February, 2015

h. Cost Sharing and /or Matching Requirement: None required

(As funding is available)

Part II. Full Text

A. Funding Opportunity Description

1. Background

To date, although all HIV positive individuals in South Africa are recommended to receive IPT to reduce risk of developing TB disease, South Africa's IPT initiative has been largely based in its antiretroviral (ARV) clinics. Thus it has focused on clinic-based populations already receiving or newly initiating antiretroviral therapy (ART). This project focuses on HIV positive individuals, who are not yet linked to HIV care and treatment to whom IPT would not normally be offered.

The project is nested into a larger community based HIV and TB intensive case finding (ICF) program in a rural, resource limited setting with among the highest rates of TB and HIV in the world. IPT is one of the three World Health Organization (WHO) recommended pillars of TB control in areas having high prevalence of TB and HIV. The uptake of IPT at the time this protocol was developed was poor and both adherence and treatment completion among those initiating IPT has been disappointing. Strategies enhancing IPT uptake, adherence and completion, with careful program evaluation, are critically needed. This protocol aimed to broaden access to a community based population eligible for but not receiving IPT and also aimed to achieve high levels of IPT adherence and completion success.

Alignment with PEPFAR/Host Country National Government Priorities:

Isoniazid preventive therapy (IPT) is included in the PEPFAR Blueprint as a priority intervention to reduce morbidity due to TB in persons living with HIV in order to achieve an AIDS Free Generation. IPT is also a priority TB/HIV collaborative activity of the South Africa National Department of Health and this builds upon their previous work in IPT implementation and scale-up.

a. Statutory Authorities

This program is authorized under Public Law 108-25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, et seq.] and Public Law 110-293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), and Public Law 113-56 (PEPFAR Stewardship and Oversight Act of 2013).

The President's Emergency Plan for AIDS Relief (PEPFAR) has called for immediate, comprehensive and evidence based action to turn the tide of global HIV/AIDS. The overarching purpose of this FOA is to fund activities to prevent or control disease or injury and improve health, or to improve a public health program or service. Recipients may not use funds for research. Certain activities that may require human subjects review due to institutional requirements but that are generally considered not to constitute research (e.g., formative assessments, surveys, disease surveillance, program monitoring and evaluation, field evaluation of diagnostic tests, etc.) may be funded through this mechanism

b. Healthy People 2020

The Global Health Initiative is essentially an attempt to coordinate US Government programs and resources dedicated to improving health globally. For example, programs dedicated to HIV, such as PEPFAR, invest in activities that also can be leveraged to improve general maternal health. Healthy People 2020 is the US Government's health goals and activities to address domestic US health through 2020. These domestic plans have typically been released for each decade, with the last one being Healthy People 2010. For the first time, Health People 2020 has included the vital role that improving international health plays in protecting domestic health. Thus, the Healthy People 2020 includes the international goal: "Improve public health and strengthen U.S. national security through global disease detection, response, prevention, and control strategies".

c. Other National Public Health Priorities and Strategies

Alignment with PEPFAR/Host Country National Government Priorities:

Isoniazid preventive therapy (IPT) is included in the PEPFAR Blueprint as a priority intervention to reduce morbidity due to TB in persons living with HIV in order to achieve an AIDS Free Generation. IPT is also a priority TB/HIV collaborative activity of the South Africa National Department of Health and this builds upon their previous work in IPT implementation and scale-up.

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (HHS/CDC) works with host countries and other key partners to assess the needs of each country and design a customized program of assistance that fits within the host nation's strategic plan and partnership framework.

HHS/CDC focuses primarily on two or three major program areas in each country. Goals and priorities include the following:

- Achieving primary prevention of HIV infection through activities such as expanding confidential counseling and testing programs linked with evidence based behavioral change and building programs to reduce mother-to-child transmission;
- Improving the care and treatment of HIV/AIDS, sexually transmitted infections (STIs) and related opportunistic infections by improving STI management; enhancing laboratory diagnostic capacity and the care and treatment of opportunistic infections; interventions for intercurrent diseases impacting HIV infected patients including tuberculosis (TB); and initiating programs to provide anti-retroviral therapy (ART);
- Strengthening the capacity of countries to collect and use surveillance data and manage national HIV/AIDS programs by expanding HIV/STI/TB surveillance programs and strengthening laboratory support for surveillance, diagnosis, treatment, disease monitoring and HIV screening for blood safety; and
- Developing, validating and/or evaluating public health programs to inform, improve and target appropriate interventions, as related to the prevention, care and treatment of HIV/AIDS, TB and opportunistic infections.

In an effort to ensure maximum cost efficiencies and program effectiveness, HHS/CDC also supports coordination with and among partners and integration of activities that promote Global Health Initiative principles. As such, grantees may be requested to participate in programmatic activities that include the following activities:

- Implement a woman and girl centered approach;
- Increase impact through strategic coordination and integration;
- Strengthen and leverage key multilateral organizations, global health partnerships and private sector engagement;
- Encourage country ownership and invest in country-led plans;
- Build sustainability through investments in health systems;
- Improve metrics, monitoring and evaluation; and
- Promote research, development and innovation (research is not supported by this FOA).

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address:
http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

d. Relevant Work

This FOA builds upon previous work by CDC and partners in developing guidelines for IPT and intensified TB case finding. Importantly, this FOA builds upon initial patient enrollment and data collection activities that were initiated in a previous award to Philanjalo. This FOA will allow the awardee to complete required data cleaning, data analysis and dissemination activities to ensure that the findings of this evaluation are made available to the South Africa Department of Health, CDC and international stakeholders.

2. CDC Project Description

N/A

A.2.a. Approach

1. CDC Project Description			
a. Approach:			
Activities	**Outcomes**		
	Short Term Outcomes (1-2 Years)	**Intermediate Outcomes (3-4 Years)**	**Long Term Outcomes (5+ Years)**
Data cleaning and data analysis	Data is prepared for analysis and quality is ensured	Data can be used as baseline for monitoring progress	Improved scale-up of IPT and linkage from community to facility based programs
Dissemination of data	Data is shared and discussed with South Africa Department of Health, national and international stakeholders	National approaches are modified to improve IPT scale-up and access	Improved scale-up of IPT and linkage from community to facility based programs

i. Problem Statement

Isoniazid preventive therapy (IPT) reduces morbidity due to tuberculosis (TB) in persons living with HIV. To date, although all HIV positive individuals in South Africa are recommended to receive IPT, South Africa's IPT initiative has been largely based in its antiretroviral (ARV) clinics. Thus it has focused on populations already receiving or newly initiating antiretroviral therapy (ART). This project focuses on HIV positive individuals, who are not yet linked to care and, although eligible, to whom IPT would not normally be offered.

This FOA is expected to build upon previous efforts by Philanjalo to implement activities of the approved protocol entitled "Improving Isoniazid Preventive Therapy Penetration through Intensification of Case Finding at the Community Level in Rural South Africa under PEPFAR" and to complete data analysis and dissemination activities.

ii. Purpose

The purpose of this FOA is to conduct data analysis and dissemination activities in order to complete an evaluation of a community based IPT intervention in South Africa. The findings from this evaluation may contribute to a strategy to increase the initiation of HIV positive persons onto IPT care using a community based approach.

iii. Outcomes

By the end of the project period, as a result of this program:

- The findings of the evaluation will have been analyzed and disseminated to facilitate the South Africa Department of Health approach to delivery of IPT.
- Cost-effectiveness data will be available to allow other countries and subnational level units to facilitate resource allocations for this set of interventions.
- Ideally as a result of this evaluation and analysis IPT will be scaled-up to add additional persons with linkage from the community.

iv. Funding Strategy

See above

v. Strategies and Activities

- The grantee will conduct data quality assurance, and cleaning of data from an evaluation supported by a previous FOA in order to prepare for analysis and ensure accuracy of data.
- Grantee will analyze data from the evaluation to respond to stated protocol objectives and hypotheses.
- Findings from the evaluation will be disseminated to the South Africa Department of Health and external stakeholders.

1. Collaborations

With CDC funded programs:

The awardee will be required to collaborate with representatives from CDC South Africa and CDC Headquarters on activities including required reporting and conduct of site visits.

With organizations external to CDC:

Awardee will be required to collaborate with the South Africa Department of Health and apprise the DOH on progress of activities and findings.

2. Target Populations

The target population was formally identified in Phase I of implementation. Data collection of these individuals was served by an intensified TB case finding intervention in a rural region of KwaZulu-Natal with a high HIV prevalence and elevated risk of TB.

(This is a follow-on to continue the analysis of data collected during a research FOA that is now expiring. The study population was identified on the original award so this cohort is what they will observe under this SEJ.)

d

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC will work with the awardee to determine the effectiveness of their activities through structured monthly progress reports, site visits and data quality audits. In addition CDC will collaborate on data analysis and dissemination efforts in order to measure effectiveness of the intervention and meet stated goals as outlined in the IRB approved protocol.

The awardee and relevant stakeholders will be engaged in the evaluation and performance measurement planning processes through regular calls and communication with CDC.

- Key evaluation measures are outlined in the IRB approved protocol
- Performance measures must be reported on a monthly basis
- Dissemination channels will include meetings with country stakeholders, development of abstracts for conferences as well as submission of manuscripts.

ii. Applicant Evaluation and Performance Measurement Plan

.See above

c. Organizational Capacity of Awardees to Execute the Approach

Applicant must be able to manage program performance, evaluation, performance monitoring, financial reporting, and must have capacity to manage the required funds in accordance with the HHS Grants Policy Statement, which can be found at: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf

d. Work Plan

Applicant must include a work plan that demonstrates how the outcomes, strategies, activities, timelines, and staffing will take place over the course of the award. Applicants must submit a detailed work plan for the first year of the project and a high level plan for the subsequent years.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). HHS grants policy specifies the following HHS expectations for post-award monitoring for grants and cooperative agreements:

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

Monitoring may also include the following activities:

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

Other activities deemed necessary to monitor the award, if applicable.

These may include monitoring and reporting activities as outlined in HHS grants policy that assists grants

management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

See above

f. CDC Program Support to Awardees

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program are as follows:

1. Organize an orientation meeting with the grantee for a briefing on applicable U.S. Government, HHS/CDC, and President's Emergency Plan for AIDS Relief (PEPFAR) expectations, regulations and key management requirements, as well as report formats and contents. The orientation could include meetings with staff from HHS agencies and the Office of the U.S. Global AIDS Coordinator (OGAC).

2. Review and make recommendations as necessary to the process used by the grantee to select key personnel and/or post-award subcontractors and/or subgrantees to be involved in the activities performed under this agreement, as part of the President's Emergency Plan for Relief (PEPFAR) Country Operational Plan (COP) review and approval process, managed by the OGAC.

3. Review and approve grantee's annual work plan and detailed budget, as part of the Emergency Plan for AIDS Relief Country Operational Plan review-and-approval process, managed by the Office of the U.S. Global AIDS Coordinator.

4. Review and approve the grantee's Evaluation and Performance Measurement Plan, and ensure alignment with strategic information guidance established by the OGAC and other HHS/CDC requirements, e.g. Data for Partner Monitoring Program (DFPM).

5. Meet on a regular basis with the grantee to assess expenditures in relation to approved work plan and modify plans as necessary.

6. Meet on a quarterly basis with the grantee to assess quarterly technical and financial progress reports and modify plans as necessary.

7. Meet on an annual basis with the grantee to review annual progress report for each U.S. Government Fiscal Year, and to review annual work plans and budgets for the subsequent year, as part of the PEPFAR review and approval process for COPs, managed by OGAC.

8. Provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This could include expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, and confidential counseling and testing.

9. Provide in-country administrative support to help the grantee meet U.S. Government financial and reporting requirements approved by the Office of Management and Budget (OMB) under 0920-0428 (Public Health Service Form 5161).

10. Collaborate with the grantee on designing and implementing the activities listed above, including, but not limited to: the provision of technical assistance to develop program activities, data management and analysis, quality assurance, the presentation and possibly publication of program results and findings, and the management and tracking of finances.

11. Provide technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the awardee. All such data collections-- where CDC staff will be or are approving, directing, conducting, managing, or owning data-- must undergo OMB project determinations by CDC and may require

OMB PRA clearance prior to the start of the project.

12. Provide consultation and scientific and technical assistance based on appropriate HHS/CDC and OGAC documents to promote the use of best practices known at the time.

13. Assist the grantee in developing and implementing routine data quality-assurance criteria and procedures.

14. Facilitate in-country planning and review meetings for technical assistance activities.

15. Provide technical oversight for all activities under this award.

16. Conduct service delivery site visits through the Site Monitoring System (SMS) to monitor and evaluate site capacity to provide high-quality HIV/AIDS services in all program areas by assessing and scoring key program area elements of site performance and work with the grantee on identified gaps and continuous quality improvement.

17. Provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters. Evaluations can be processor outcome or both.

- Process Evaluation: measures how and whether the intervention was delivered as planned, what worked/did not, differences between the intended population and the population served, and access to the intervention.
- Outcome Evaluation: determines effects of intervention in target population(s) or organization (e.g., change in knowledge, attitudes, behavior, capacity, etc.).

18. Supply the awardee with protocols for related evaluations.

B. Award Information

1. Funding Instrument Type:	Cooperative Agreement
	CDC's substantial involvement in this program appears in the CDC Program Support to Awardees Section.
2. Funding Activity Category:	HL
3. Fiscal Year:	2015
Estimated Total Funding:	$317,588
4. Approximate Total Fiscal Year Funding:	$317,588
5. Approximate Project Period Funding:	$317,588
6. Total Project Period Length:	1 year(s)
7. Expected Number of Awards:	1

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the “Notice of Award.” This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

Note: Applicant must only apply for the first budget period funding, taking into consideration the floor of the individual award range and the ceiling of the individual award range. The proposed budget for the first budget period must not exceed the ceiling of the individual award range. If a funding amount greater than the ceiling of the individual award range is requested, the application will be considered non-responsive and will not be entered into the review process.

8. Approximate Average Award: $317,588 Per Project Period
9. Award Ceiling: $317,588 Per Project Period
10. Award Floor: $317,588 Per Project Period
11. Estimated Award Date: 05/01/2015
12. Budget Period Length: 12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Funds Tracking

Applicant is required to track fund by P-accounts/sub accounts for each project/cooperative agreement awarded.

14. Direct Assistance

Direct assistance is not available through this FOA.

15. Indirect Costs

Indirect Costs are an allowable cost through this FOA.

C. Eligibility Information

1. Eligible Applicants

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

2. Special Eligibility Requirements

Philanjalo

3. Justification for Less than Maximum Competition

Philanjalo is the only organization that is approved under the governing institutional review boards (IRBs) to perform the proposed activity of data analysis for the evaluation " Improving Isoniazid Preventive Therapy Penetration through the Intensification of Case Finding at the Community Level in South Africa." Philanjalo staff (and staff on their sub-award) have completed required training and are on record with the approving IRB.

Please note the following two regulations that support the requirement to use Philanjalo staff to conduct data analysis using the IRB approved protocol:

1. Good Clinical Practice Section 4 Investigator Requirements and Agreements; ICH GCP E6 Section 4 Common Rule 45
2. 45 CFR Part 46 - Federal Policy for Protection of Human Subjects

Philanjalo previously received an award from CDC entitled "Improving Isoniazid Preventive Therapy Penetration through Intensification of Case Finding at the Community Level in Rural South Africa" with a Project Period of 8/1/12-7/31/15. This activity is evaluating if a program at the community level in South Africa can successfully link people living with HIV with a program to provide isoniazid preventive therapy

in order to reduce sickness and death from tuberculosis in people living with HIV.

This new project is Phase II of a two part activity. This second phase will conduct data analysis, data cleaning and dissemination of data. Phase I of the award had consisted of protocol development and data collection.

4. Other

N/A

5. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

No matching is needed with this Cooperative Agreement

6. Maintenance of Effort

No Maintenance of Effort needed

D. Application and Submission Information

1. Required Registrations

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

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/webform/ displayHomePage.do. The DUNS number will be provided at no charge.

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

b. System for Award Management (SAM):

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

c. Grants.gov:

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

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

possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http:// fedgov.dnb.com/webform 2. Select Begin DUNS search/request process 3. Select your country or territory and folllow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CRR)	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will not not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact www.fsd.gov/US Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

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

3. Application Package

Applicants must download the SF-424 application package associated with this funding opportunity from www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

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

If Grants.gov cannot receive applications due to an emergency or other unanticipated event (and circumstances preclude advance notification of an extension), then applications must be submitted by the first business day on which government operations resume.

Due Date for Applications: **04/15/2015**

Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

Date for Informational Conference Call: 03/06/2015

5. CDC Assurances and Certifications

All applicants are required to sign and submit CDC Assurances and Certifications documents that can be found on the CDC Web site: http://www.cdc.gov/grants/interestedinapplying/applicationprocess.html

Applicants may follow either of the following processes:

- Applicants must name this file "Assurances and Certifications" and upload as a PDF on www.grants.gov.
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http:// www.cdc.gov/od/pgo/ funding/grants/ foamain.shtm

Assurances and certifications submitted directly to CDC will be kept on file for 1 year and will apply to all applications submitted to CDC within one year of the submission date.

6. Contents and Form of Applications Submission

Applicants are required to submit all of the documents outlined below as their application package on www.grants.gov.

7. Letter of Intent (LOI)

N/A

8. Table of Contents

(No page limit, not included in project narrative page limit). Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum of 1 page, single spaced, 12 point font, 1-inch margins). A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Maximum of 18 pages single spaced, Calibri 12 point, 1-inch margins, number all pages, content beyond 18 pages will not be reviewed). The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section.

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov.

a. Background

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

b. Approach

i. Problem Statement

Applicants must describe the core information relative to the problem for the jurisdictions or populations they serve. The core information should help reviewers understand how the applicant's response to the FOA will address the public health problem and support public health priorities. (See CDC Project Description).

ii. Purpose

Applicants must describe specifically how their application will address the problem as described in the CDC Project Description.

iii. Outcomes

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

- The findings of the evaluation will have been analyzed and disseminated to facilitate the South Africa Department of Health approach to delivery of IPT.
- Cost-effectiveness data will be available to allow other countries and subnational level units to facilitate resource allocations for this set of interventions.
- Ideally as a result of this evaluation and analysis IPT will be scaled-up to additional persons with linkage from the community

iv. Strategy and Activities

The applicant must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Whenever possible, applicants should use evidence-based program strategies as identified by the Community Guide (or similar reviews) and reference it explicitly as a source. Applicants may propose additional strategies and activities to achieve the outcomes. Applicants should select

existing evidence-based strategies that meet their needs, or describe the rationale for developing and evaluating new strategies or practice-based innovations. (See CDC Project description: Strategies and Activities section).

- The grantee will conduct data quality assurance, and data cleaning of data from an evaluation supported by a previous FOA in order to prepare for analysis and ensure accuracy of data.
- Grantee will analyze data from the evaluation to respond to stated protocol objectives and hypotheses.
- Findings from the evaluation will be disseminated to the South Africa Department of Health and external stakeholders.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement.

The plan must:

- Describe how key program partners will be engaged in the evaluation and performance measurement planning processes.
- Describe the type of evaluations to be conducted (i.e. process and/or outcome).
- Describe key evaluation questions to be answered.
- Describe other information, as determined by the CDC program (e.g., performance measures to be developed by the applicant) that should be included.
- Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
- Describe how evaluation findings will be used for continuous program and quality improvement.
- Describe how evaluation and performance measurement will contribute to development of that evidence base, where program strategies are being employed that lack a strong evidence base of effectiveness.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

CDC will work with the awardee to determine the effectiveness of their activities through structured monthly progress reports, site visits and data quality audits. In addition CDC will collaborate on data analysis and dissemination efforts in order to measure effectiveness of the intervention and meet stated goals as outlined in the IRB approved protocol.

The awardee and relevant stakeholders will be engaged in the evaluation and performance measurement planning processes through regular calls and communication with CDC.

- Key evaluation measures are outlined in the IRB approved protocol
- Performance measures must be reported on a monthly basis
- Dissemination channels will include meetings with country stakeholders, development of abstracts for conferences as well as submission of manuscripts.

Applicants must provide an overall jurisdiction or community-specific evaluation and performance measurement plan that is consistent with the CDC strategy. At a minimum, the plan must:

- Describe how key program partners will participate in the evaluation and performance measurement planning processes.
- Describe the type of evaluations (i.e., process, outcome, or both) to be conducted.
- Describe key evaluation questions. Describe other information (e.g., performance measures to be developed by the applicant), as determined by the CDC program, that must be included.
- Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
- Describe how evaluation findings will be used for continuous program quality improvement.
- Describe how evaluation and performance measurement will contribute to developing an evidence base for programs that employ strategies lacking a strong effectiveness evidence base.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first six months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach
Applicant must address the organizational capacity requirements as described in the CDC Project Description.

Applicant must be able to manage program performance, evaluation, performance monitoring, financial reporting, and must have capacity to manage the required funds in accordance with the HHS Grants Policy Statement, which can be found at: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf

11. Work Plan

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

Applicants must name this file "Work Plan" and upload it as a PDF file at www.grants.gov.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

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

For guidance on completing a detailed budget, see Budget Preparation Guidelines at:
http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

Applicants should name this file "Budget Narrative" and upload it as a PDF file to www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement must have been made less than 12 months earlier. Applicants

must name this file "Indirect Cost Rate" and upload it to www.grants.gov.

The detailed budget should identify costs associated with potential data collection activities from persons, personal records, or for laboratory specimen collection and testing that may result in a public report. For each of the potential data collection activities, also state the costs for any preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation).

All budget justification pages must be numbered.

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

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 recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care,or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http://www.gsa.gov/ graphics/pbs/Guidelines_for__Federal__Concessions_and_Vending__ _Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

   http://www.cdc.gov/ nccdphp/dnpao/hwi/ toolkits/ tobacco/index.htm
   http://www. thecommunityguide.org/ tobacco/index.html
   http://www.cdc.gov/ chronicdisease/resources/ guidelines/food-service-guidelines.htm

14. Intergovernmental Review

Executive Order 12372 does not apply to this program.

15. Funding Restrictions

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

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care except as allowed by law.
- Awardees may only use funds for reasonable program purposes, including personnel, travel, supplies, and services (such as contractual).
- Generally, awardees may not use HHS/CDC/ATSDR funding for the purchase of furniture or equipment. Any such proposed spending must be clearly identified in the budget in accordance with CDC's budget guidelines.
- Reimbursement of pre-award costs is not allowed.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - Publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - The salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
    - See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC awardees.

The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

- The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required.)

- All plans for data collection from persons or personal records and for laboratory specimen collection and testing that are expected to result in public reports will require protocols for technical review and review of institutional human subjects protection considerations by CDC. Funds for implementing these activities will be restricted until all necessary institutional protocol approvals have been obtained. Funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) may be provided prior to protocol approval. To facilitate the early availability of funding, the budget and narrative should clarify which activities are preparatory.

- Human subjects data collection funding restrictions which require submission of protocols will be submitted within six months of notification of such requirement, but no later than the end of the first budget year. Requests for exceptions to these deadlines will need to be submitted in writing to the Grants Management Officer. All protocol approvals should be obtained no later than the end of the second budget period after the award or Continuation has been made, provided that the Grantee submits their protocol no later than the deadline.

- Needle Exchange – No funds made available under this award may be used for needle exchange programs.

- The recipient must use funds provided under the agreement for costs incurred in carrying out the purposes of the award which are reasonable, allocable, and allowable in accordance with applicable cost principles. Unallowable costs will be determined in accordance with the applicable cost principles.

- "Reasonable" means the costs do not exceed those that would ordinarily be incurred by a prudent person in the conduct of normal business.

- "Allocable" means the costs are necessary to the award.

- “Allowable” means the costs are reasonable and allocable, and conform to any limitations set forth in the award.

- The recipient is encouraged to obtain the Grants Management Officer’s written determination in advance whenever the recipient is uncertain as to whether a cost will be allowable.

- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

- Public Financial Management Assessment Clause: The Parties acknowledge that HHS/CDC has assessed the recipient’s systems required to manage the activities supported with US Government funds under this Agreement and that this Agreement is expressly conditioned upon that assessment, as well as any measures, mitigation or means by which the recipient has or will address the vulnerabilities or weaknesses, if any, found in that assessment. The recipient agrees to take the necessary action(s) to address the recommendations or requirements of the assessment as agreed separately in writing with HHS/CDC in accordance with an action plan to be jointly developed to address such recommendations or as otherwise contained in this agreement.

- It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities designated for United Nations Security Council sanctions. In accordance with this policy, the applicant agrees to use reasonable efforts to ensure that none of the funds provided under this grant are used to provide support of individuals or entities designated for UN Security Council sanctions (compendium of Security Council Targeted Sanctions Lists at: http://www.un.org/sc/committees/list_compend.shtml). This provision must be included in all sub-agreements, including contracts and sub-awards, issued under this award.

- **Prohibition on Assistance to Drug Traffickers**

- HHS/CDC reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by HHS/CDC who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.

- The Applicant agrees not to disburse, or sign documents committing the Applicant to disburse funds to a sub-recipient designated by HHS/CDC ("Designated Sub-recipient") until advised by HHS/CDC that: (1) any United States Government review of the Designated Sub-recipient and its key individuals has been completed; (2) any related certifications have been obtained; and (3) the assistance to the Designated Sub-recipient has been approved.

- The Applicant shall insert the following clause, or its substance, in its agreement with the Designated Sub-recipient:

- The Applicant reserves the right to terminate this Agreement or take other appropriate measures if the [Sub-recipient] or a key individual of the [Sub-recipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.

- **Conference Costs and Fees**

U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by

the CDC in writing.

- Definitions:

- A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.

- An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.

- A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

- **Using PEPFAR funds for Implementing Partners (IPs) and Partner Government Officials**

IPs are required to notify their Project Officer immediately upon abstract acceptance. Once accepted, IPs are required to submit a written justification to their Project Officer stating the rationale for seeking support to attend the conference. IPs with accepted oral posters or oral abstracts for presentations that give clear attribution to PEPFAR may be authorized to use PEPFAR funds for travel providing that funds are available for travel. Funds for travel must be drawn from an existing agreement with the IP and not from PEPFAR country program management and operations budget. IPs must obtain prior approval from their respective Project Officer for participation and on availability and use of funds.

PEPFAR partner government officials who wish to attend any large conference using PEPFAR funds must submit requests to the Project Officer, who will work with this PEPFAR Coordination office in-country, or to the designated PEPFAR Point of Contact in countries without Coordinators. Final decisions will be made in collaboration with the PEPFAR Deputy Principals and responses will be circulated to Post.

- **Attribution to PEPFAR**

- All PEPFAR-related accepted abstracts presented by implementing partners during any conference (regardless of conference/meeting size) must be attributed to PEPFAR. All posters must include the PEPFAR logo as well as the following language: “This research has been supported by the President’s Emergency Plan for AIDS Relief (PEPFAR) through HHS/CDC under the terms of CDC-RFA-GH15-1625.”

- **Abortion and Involuntary Sterilization Restrictions**

- Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

- Prohibition on Abortion-Related Activities:

- No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate”, as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

- No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as

a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded

- **Prostitution and Sex Trafficking**

- A standard term and condition of award will be included in the final notice of award; all applicants will be subject to a term and condition that none of the funds made available under this award may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. In addition, non-U.S. nongovernmental organizations will also be subject to an additional term and condition requiring the organization's opposition to the practices of prostitution and sex trafficking.

- **Trafficking in Persons Provision**

- No contractor or subrecipient under this Agreement that is a private entity may, during the period of time that the award is in effect:

- engage in trafficking in persons, as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime;

- procure any sex act on account of which anything of value is given to or received by any person; or

- use forced labor in the performance of this award.

- If HHS/CDC determines that there is a reasonable basis to believe that any private party contractor or subrecipient has violated paragraph 1 of this section or that an employee of the contractor or subrecipient has violated such a prohibition where that the employee's conduct is associated with the performance of this award or may be imputed to the contractor or subrecipient, HHS/CDC may, without penalty, (i) require the Grantee to terminate immediately the contract or subaward in question or (ii) unilaterally terminate this Agreement in accordance with the termination provision.

- For purposes of this provision, "employee" means an individual who is engaged in the performance in any part of the Project as a direct employee, consultant, or volunteer of any private party contractor or subrecipient.

- The Applicant must include in all subagreements, including subawards and contracts, a provision prohibiting the conduct described in subsection a by private party subrecipients, contractors, or any of their employees

- **Requirements for Voluntary Family Planning Projects**

- A family planning project must comply with the requirements of this paragraph.

- A project is a discrete activity through which a governmental or nongovernmental organization or Public International Organization (PIO) provides family planning services to people and for which funds obligated under this award, or goods or services financed with such funds, are provided under this award, except funds solely for the participation of personnel in short-term, widely attended training conferences or programs.

- (3) Service providers and referral agents in the project must not implement or be subject to quotas or other numerical targets of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning. Quantitative estimates or indicators of the number of births, acceptors, and acceptors of a particular method that are used for the purpose of budgeting, planning, or reporting with respect to the project are not quotas or targets under this paragraph, unless service providers or referral agents in the project are required to achieve the estimates or indicators.

- (4) The project must not include the payment of incentives, bribes, gratuities or financial rewards to (i) any individual in exchange for becoming a family planning acceptor, or (ii) any personnel performing functions under the project for achieving a numerical quota or target of total number of births, number of family planning acceptors, or acceptors of a particular method of contraception. This restriction applies to

salaries or payments paid or made to personnel performing functions under the project if the amount of the salary or payment increases or decreases based on a predetermined number of births, number of family planning acceptors, or number of acceptors of a particular method of contraception that the personnel affect or achieve.

- (5) A person must not be denied any right or benefit, including the right of access to participate in any program of general welfare or health care, based on the person's decision not to accept family planning services offered by the project.

- The project must provide family planning acceptors comprehensible information about the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method. This requirement may be satisfied by providing information in accordance with the medical practices and standards and health conditions in the country where the project is conducted through counseling, brochures, posters, or package inserts.

- The recipient must notify CDC when it learns about an alleged violation in the requirements for voluntary family planning projects described in paragraphs (3), (4), or (5), above.

- The recipient must investigate and take appropriate corrective action, if necessary, when it learns about an alleged violation and must notify CDC about violations in a project affecting a number of people over a period of time that indicate there is a systemic problem in the project.

- The recipient must provide CDC such additional information about violations as CDC may request.

- **Investment Promotion**

- No funds or other support provided hereunder may be used to provide a financial incentive to a business enterprise currently located in the United States for the purpose of inducing such an enterprise to relocate outside the United States if such incentive or inducement is likely to reduce the number of employees of such business enterprise in the United States because United States production is being replaced by such enterprise outside the United States.

- In the event the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.

- The Applicant must ensure that its employees and subcontractors and sub-recipients providing investment promotion services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.

- **Worker's Rights**

- No funds or other support provided hereunder may be used for any activity that contributes to the violation of internationally recognized workers' rights of workers in the recipient country.

- In the event the Applicant is requested or wishes to provide assistance in areas that involve workers' rights or the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.

- The Applicant must ensure that all employees and subcontractors and sub-recipients providing employment-related services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.

- The term "internationally recognized worker rights" includes-- the right of association; the right to organize and bargain collectively; a prohibition on the use of any form of forced or compulsory labor; a

minimum age for the employment of children, and a prohibition on the worst forms of child labor; and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health.

- The term "worst forms of child labor" means-- all forms of slavery or practices similar to slavery, such as the sale or trafficking of children, debt bondage and serfdom, or forced or compulsory labor, including forced or compulsory recruitment of children for use in armed conflict; the use, procuring, or offering of a child for prostitution, for the production of pornography or for pornographic purposes; the use, procuring, or offering of a child for illicit activities in particular for the production and trafficking of drugs; and work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety, or morals of children, as determined by the laws, regulations, or competent authority of the country.

- **Contract Insurance Requirement**

To the extent that a host government partner enters into contracts expressly approved by the U.S. government, the host country government partner shall ensure that its contractors or subcontractors (a) provide, before commencing performance under any contracts or subcontracts funded under this agreement, such workers' compensation insurance or security as required by HHS/CDC and (b) continue to maintain such insurance until performance is completed. The host country government partner shall insert, in all contracts and subcontracts under this agreement, a clause similar to this clause (including this sentence) imposing upon those contractors and subcontractors the obligation to obtain workers' compensation insurance or security as required by HHS/CDC.

- No funds or other support provided under the award may be used for support to any military or paramilitary force or activity, or for support to any police, prison authority, or other security or law enforcement forces without the prior written consent of HHS/CDC.

- **Conscience Clause**

An organization, including a faith-based organization, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care—

- Shall not be required, as a condition of receiving such assistance—
- To endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
- To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
- Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described above.

- **Medically Accurate Information About Condoms**

Information provided about the use of condoms as part of projects or activities funded under the award must be medically accurate and must include the public health benefits and failure rates of such use.

- **Financing of Terrorism**

Consistent with numerous United Nations Security Council resolutions, including UNSCR 1267 (1999) (http://www.undemocracy.com/S-RES-1269(1999).pdf), UNSCR 1368 (2001) (http://www.undemocracy.com/S-RES-1368(2001).pdf), UNSCR 1373 (2001) (http://www.undemocracy.com/S-RES-1373(2001).pdf), and UNSCR 1989 (2011), both HHS/CDC and the Applicant are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities associated with terrorism. In accordance with this policy, the Applicant agrees to use reasonable efforts to

ensure that none of the HHS/CDC funds provided under this Agreement are used to provide support to individuals or entities associated with terrorism, including those identified on the U.S. Department of Treasury Office of Foreign Assets Control Specially Designated Nationals List. This provision must be included in all subagreements, including contracts and subawards, issued under this award.

- **Source and Nationality and Other Procurement Restrictions**

- Disbursements will be used exclusively to finance the costs of goods and services required for this Agreement [in accordance with 22 CFR 228, and] having their source and nationality in countries [included in Geographic Code [937 or 935]] OR [identified in subsection 6 below], except as HHS/CDC may otherwise agree in writing and as follows:

- Ocean transportation costs must be financed under the Agreement only on vessels under flag registry of [countries included in Code 935] OR [the following countries: LIST. Also see subsection 7 below on use of U.S.-flag vessels.

- Any motor vehicles financed under the Agreement will be of United States manufacture, except as HHS/CDC may otherwise agree in writing.

- The nationality of the contractor providing ocean and air shipping services will be deemed to be the ocean vessel's or aircraft's country of registry at the time of shipment.

- Provisions concerning restricted and ineligible goods and services may be provided in subsequent written communications between the parties. Special procurement rules apply to agricultural commodities, pharmaceuticals, pesticides, and fertilizer, none of which may be procured without advance written consent of HHS/CDC.

- Transportation by air of property or persons financed under this agreement will be on carriers holding United States certification; to the extent service by such carriers is available under the Fly America Act. This requirement may be further described by HHS/CDC in subsequent written communications between the parties.

- Eligibility Date. No goods or services may be financed under the Agreement which are procured pursuant to orders or contracts firmly placed or entered into prior to the date of this Agreement, except as the Parties may otherwise agree in writing.

- Eligible countries for procurement: HHS/CDC to identify for specific agreement.

- Transportation

- In addition to the requirements in subsection 1 above, costs of ocean or air transportation and related delivery services may not be financed under this Agreement, if the costs are for transportation under an ocean vessel or air charter which has not received prior HHS/CDC approval.

- Unless HHS/CDC determines that privately owned U.S. -flag commercial ocean vessels are not available at fair and reasonable rates for such vessels, or otherwise agrees in writing:

- At least fifty percent (50%) of the gross tonnage of all goods (computed separately for dry bulk carriers, dry cargo liners and tankers) financed by HHS/CDC which may be transported on ocean vessels will be transported on privately owned U.S.-flag commercial vessels; and

- At least fifty percent (50%) of the gross freight revenue generated by all shipments financed by HHS/CDC and transported to the territory of the Grantee on dry cargo liners shall be paid to or for the benefit of privately owned U.S.-flag commercial vessels. Compliance with the requirements of (1) and (2) of this subsection must be achieved with respect to both any cargo transported from U.S. ports and any cargo transported from non-U.S. ports, computed separately.

- **Environmental Impact Statement**

HHS/CDC and the Applicant agree to implement the Project in conformance with the regulatory and legal

requirements of the Partner Country's environmental legislation and HHS/CDC's environmental policies.

- The Applicant is required to create and follow an environmental mitigation plan and report (EMPR) for each thematic area covered by this agreement. The EMPR shall include the following:
- Coversheet;
- Narrative with project specific information, including level of effort;
- Annexes:
- Environmental Screening Form (Table 1);
- Identification of Mitigation Plan (Table 2);
- Environmental Monitoring and Tracking Table (Table 3);
- Photos and Maps, as appropriate.
- The EMPR will capture potential environmental impacts and also inform whether a supplemental Initial Environmental Examination (IEE) is required and should be completed and submitted to HHS/CDC.
- **Branding**

All PEPFAR-funded programs or activities must adhere to PEPFAR branding guidance, which includes guidance on the use of the PEPFAR logo and/or written attribution to PEPFAR. PEPFAR branding guidance can be found at http://www.pepfar.gov/reports/guidance/branding/index.htm

- **The 8% Rule**

The President's Emergency Plan for AIDS Relief (PEPFAR) seeks to promote sustainability for programs through the development, use, and strengthening of local partnerships. The diversification of partners also ensures additional robust capacity at the local and national levels.

To achieve this goal, the Office of the Global AIDS Coordinator (OGAC) establishes an annual funding guideline for grants and cooperative agreement planning. Within each annual PEPFAR country budget, OGAC establishes a limit for the total amount of U.S. Government funding for HIV/AIDS activities provided to a single partner organization under all grant and cooperative agreements for that country. For U.S. Government fiscal year (FY) 2015, the limit is no more than 8 percent of the country's FY 2015 PEPFAR program funding (excluding U.S. Government management and staffing costs), or $2 million, whichever is greater. The total amount of funding to a partner organization includes any PEPFAR funding provided to the partner, whether directly as prime partner or indirectly as sub-grantee. In addition, subject to the exclusion for umbrella awards and drug/commodity costs discussed below, all funds provided to a prime partner, even if passed through to sub-partners, are applicable to the limit. PEPFAR funds provided to an organization under contracts are not applied to the 8 percent/$2 million single partner ceiling. Single-partner funding limits will be determined by PEPFAR after the submission of the COP(s). Exclusions from the 8 percent/$2 million single-partner ceiling are made for (a) umbrella awards, (b) commodity/drug costs, and (c) Government Ministries and parastatal organizations. A parastatal organization is defined as a fully or partially state-owned corporation or government agency. For umbrella awards, grants officers will determine whether an award is an umbrella for purposes of exception from the cap on an award-by-award basis. Grants or cooperative agreements in which the primary objective is for the organization to make sub-awards and at least 75 percent of the grant is used for sub-awards, with the remainder of the grant used for administrative expenses and technical assistance to sub-grantees, will be considered umbrella awards and, therefore, exempted from the cap. Agreements that merely include sub-grants as an activity in implementation of the award but do not meet these criteria will not be considered umbrella awards, and the full amount of the award will count against the cap. All commodity/drug costs will be excluded from partners' funding for the purpose of the cap. The remaining portion of awards, including all overhead/management costs, will be counted against the cap.

Applicants should be aware that evaluation of proposals will include an assessment of grant/cooperative agreement award amounts applicable to the applicant by U.S. Government fiscal year in the relevant country. An applicant whose grants or cooperative agreements have already met or exceeded the maximum, annual single-partner limit may submit an application in response to this FOA. However, applicants whose total PEPFAR funding for this country in a U.S. Government fiscal year exceeds the 8 percent/$2 million single partner ceiling at the time of award decision will be ineligible to receive an award under this FOA unless the U.S. Global AIDS Coordinator approves an exception to the cap. Applicants must provide in their proposals the dollar value by U.S. Government fiscal year of current grants and cooperative agreements (including sub-grants and sub-agreements) financed by the Emergency Plan, which are for programs in the country(ies) covered by this FOA. For example, the proposal should state that the applicant has $_____ in FY 2015 grants and cooperative agreements (for as many fiscal years as applicable) in South Africa. For additional information concerning this FOA, please contact the Grants Management Officer for this FOA.

16. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded from www.grants.gov. Applicants can complete the application package off-line, and then submit the application by uploading it at www.grants.gov website. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO TIMS staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity on www.grants.gov.

If Internet access is not available or if the forms cannot be accessed on-line, applicants may contact the PGO TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 am–4:30 pm Eastern Standard Time (EST), except federal government holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

Do not use "special characters (i.e. %, &, * etc.) on the cover page of your application (form SF 424 – Application for Federal Assistance) as special characters are not recognized by the electronic system. Use of special characters may result in your application being rejected. When copy/paste is used on application documents, the grantee should ensure that text only is pasted. When extra, blank spaces at the end of the original are pasted into the new document it causes the system to reject the document.

b. Tracking Number: Applications submitted through www.grants.gov, are time/date stamped electronically and assigned a tracking number. The Authorized Organization Representative (AOR) will receive an email notice of receipt when www.grants.gov receives the application. The tracking number serves to document that the application has been submitted and initiates the electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until successful completion of the validation process. After submission of the application package, applicants will receive a "submission receipt" email generated by www.grants.gov. A second email message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two (2) business days. Applicants are strongly encouraged to check the status of their application to ensure submission of their package is complete and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Application User Guide, Version 3.0, page 57.

d. Technical Difficulties: If the applicant encounters technical difficulties with www.grants.gov, the applicant should contact www.grants.gov Customer Service. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of Federal Holidays. You can reach the www.grants.gov Contact Center at 1-800-518-4726 or by email at support@www.grants.gov. Submissions sent by email, fax, CD's or thumb drives of applications will not be accepted. Please note that www.grants.gov is managed by HHS.

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

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

1. Include the www.grants.gov case number assigned to the inquiry;
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be postmarked at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Application Review Information

1. Review and Selection Process

a. Phase I Review

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the "Criteria" section of the FOA.

Not more than 30 days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

Single Eligibility - no objective review panel

NONE	Maximum Points: 100

c. Phase III Review

Applications will be funded in order by score and rank determined by the review panel unless funding preferences or other considerations stated in this FOA apply. Final selection and approval of activities will be prioritized in collaboration with CDC.

In addition, the following factors may affect the funding decision:

N/A

CDC will provide justification for any decision to fund out of rank order.

2. Anticipated Announcement and Award Dates

The anticipated announcement date is March 2, 2015. The award date will be in May 2015

F. Award Administration Information

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NoA) from the CDC PGO. The NoA shall be the only binding, authorizing document between the awardee and CDC. The NoA will be signed by an authorized GMO and emailed to the awardee program director.

Any application awarded in response to this FOA will be subject to the DUNS, SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of the results of the application review by email with delivery receipt or by mail.

2. Administrative and National Policy Requirements

Awardees must comply with the administration requirements outline in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate. To view brief descriptions of relevant provisions visit the CDC website at: http://www.cdc.gov/grants/additionalrequirements/index.html

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The following administrative requirements apply to this project:

Potentially Applicable Public Policy Requirements

- False or Misleading Information
- Taxes: Certification of Filing and Payment of Taxes
- Fly America Act/ U.S. Flag Air Carriers
- National Environmental Policy Act

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will have a condition of award that applies to 48 CFR section 3.908 requiring grantees to inform their employees in writing of employee whistleblower rights and protections under 41. U.S.C 4712 in the predominant native language of the workforce.

If applicable, award recipients will be required to submit an electronic version of the final, peer-reviewed manuscript of any work developed under this award upon acceptance for publication. Additional information will be provided in the award terms.

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will have a condition of award that applies to 48 CFR section 3.908 requiring grantees to inform their employees in writing of employee whistleblower rights and protections under 41. U.S.C 4712 in the predominant native language of the workforce. If applicable, award recipients will be required to submit an electronic version of the final, peer-reviewed manuscript of any work developed under this award upon acceptance for publication. Additional information will be provided in the award terms. For more information on the Code

of Federal Regulations, visit the National Archives and Records Administration at:
http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

3. Reporting

a. CDC Reporting Requirements

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

- Helps target support to applicants, particularly for cooperative agreements;
- Provides CDC with periodic data to monitor awardee progress towards meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous program improvement throughout the project period and todetermine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables the assessment of the overall effectiveness and impact of the FOA.

As described in the following text, awardees must submit an annual performance report, ongoing performance measures data, administrative reports, and a final performance and financial report. A detailed explanation of any additional reporting requirements will be provided in the Notice of Award to successful applicants.

See above

b. Specific Reporting Requirements

i. Awardee Evaluation and Performance Measurement Plan

Awardees must provide a more detailed evaluation and performance measurement plan within the first six months of the project. This more detailed plan should be developed by awardees as part of first-year project activities, with support from CDC. This more detailed plan should build on the elements stated in the initial plan, and should be no more than 25 pages. At a minimum, and in addition to the elements of the initial plan, this plan must:

- Indicate the frequency that evaluation and performance data are to be collected.
- Describe how data will be reported.
- Describe how evaluation findings will be used to ensure continuous quality and program improvement.
- Describe how evaluation and performance measurement will yield findings that will demonstrate the value of the FOA (e.g., effect on improving public health outcomes, effectiveness of FOA as it pertains to performance measurement, cost-effectiveness, or cost-benefit).
- Describe dissemination channels and audiences (including public dissemination).
- Describe other information requested and as determined by the CDC program.

When developing evaluation and performance measurement plans, applicants are encouraged to use the Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide, available at:
http://www.cdc.gov/eval/guide/index.htm

ii. Annual Performance Report

This report must not exceed 45 pages excluding administrative reporting; attachments are not allowed, but web links are allowed.The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period. In addition, the awardee must submit an annual Federal Financial Report within 90 days after the end of the calendar quarter in which the budget year ends.

This report must include the following:

- **Performance Measures (including outcomes)** – Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results** – Awardees must report evaluation results for the work completed to date (including any impact data).
- **Work Plan (maximum of 25 pages)** – Awardees must update work plan each budget period.
- **Successes**
  - Awardees must report progress on completing activities outlined in the work plan
  - Awardees must describe any additional successes (e.g., identified through evaluation results or lessons learned) achieved in the past year
  - Awardees must describe success stories
- **Challenges**
  - Awardees should describe any challenges that hinder achievement of both annual and project period outcomes, performance measures, or their ability to complete the activities in the work plan
  - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year
- **CDC Program Support to Awardees**
  - Awardees describe how CDC could assist them in overcoming the challenges to achieve both annual and project period outcomes and performance measures, and complete activities outlined in the work plan
- **Administrative Reporting** (not subject to page limits)
  - SF-424A Budget Information-Non-Construction Programs
  - Budget Narrative – Must use the format outlined in Section D. Content and Form of Application Submission, Budget Narrative Section
  - Indirect Cost Rate Agreement

The deadline date for submitting the Annual Performance Report is 120 days before the end of the budget period. Send an electronic copy to CDC Project Officer (PO) with attention to the GMS and PO. The contact information for the GMS and PO is listed in the "Agency Contacts" section of the FOA

Administrative Reporting (not subject to page limits)

- Pipeline Analysis – Expenditures versus budget as identified in work plan, description of challenges, and explanation of unexpected pipeline (high or low).

Measures of Effectiveness

- Include progress against the numerical goals of the President's Emergency Plan for AIDS Relief for South Africa and HHS/CDC guidance

iii. Performance Measure Reporting

CDC programs must require awardees to submit performance measures annually at a minimum, and may require reporting more frequently. Performance measure reporting should be limited to the collection of data. When funding is awarded initially, CDC programs should specify reporting frequency, required data fields, and format.

See above

iv. Federal Financial Reporting
The annual FFR form (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 year ends. The report should include only those funds authorized and disbursed during the timeframe covered by the report. The final report must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. The final FFR expenditure data and the Payment Management System's (PMS) cash transaction data must correspond; no discrepancies between the data sets are permitted. Failure to submit the required information by the due date may affect adversely the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation and include the date by which the information will be provided.

v. Final Performance and Financial Report
At the end of the project period, awardees must submit a final report to include a final financial and performance report. This report is due 90 days after the end of the project period.

At a minimum, this report must include the following:

- Performance Measures (including outcomes) – Applicants must report final performance data for all performance measures for the project period.
- Evaluation results – Applicants must report final evaluation results for the project period
- Impact of Results – Applicants must describe the effects or results of the work completed over the project period, including success stories.
- Additional forms as described in the Notice of Award, including Equipment Inventory Report and Final Invention Statement.
- FFR (SF-425)

Awardees should e-mail the report to the CDC PO and the GMO listed in the "Agency Contacts" section of the FOA.

Awardees should e-mail the report to the CDC PO and the GMS listed in the "Agency Contacts" section of the FOA.

4. Federal Funding Accountability and Transparency Act of 2006
Federal Funding Accountability And Transparency Act Of 2006 (FFATA), 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 awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, www.USASpending.gov.

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

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

- http:// frwebgate.access.gpo.gov/ cgi-bin/getdoc.cgi? dbname=109_cong_bills&docid= f:s2590enr.txt.pdf
- https:/ /www.fsrs.gov/ documents/ffata_legislation_110_252. pdf
- http:// www.hhs.gov/asfr/ ogapa/aboutog/ Grants%20Management% 20Information/ffata_guidelines.html.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Courtney Emerson, Project Officer
CDC
HIV Care & Treatment Branch
1600 Clifton Rd.
MS E04
Atlanta, GA 30329
Phone: (404) 639-2058
Email: iud6@cdc.gov

Grants Staff Contact

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

Dionne Bounds
CDC
Procurement & Grants Office (PGO)
2920 Brandywine Road
KOGR Bldg COLGA Rm 2607, MS K75
Atlanta, GA 30341
Phone: (770) 488-2082
Email: vhv5@cdc.gov

For assistance with **submission difficulties related to www.grants.gov,** contact:

www.grants.gov Contact Center: 1-800-518-4726.
Hours of Operation: 24 hours a day, 7 days a week. Closed on Federal holidays.

For all other **submission** questions, contact:

Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
Email: pgotim@cdc.gov

CDC Telecommunications for individuals with hearing loss is available at: TTY 1.888.232.6348.

H. Other Information

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

- Project Abstract
- Project Narrative

- Budget Narrative
- CDC Assurances and Certifications
- Work Plan
- Table of Contents for Entire Submission

Listed above

I. Glossary

Administrative and National Policy Requirements, Additional Requirements (ARs): The Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements as mandated by statute or CDC policy. CDC programs must indicate which ARs are relevant to the FOA. All ARs are listed in the template for CDC programs. Awardees must then comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions visit the CDC website at:

http://www.cdc.gov/grants/additionalrequirements/index.html

Authority: Legal authorizations that outline the legal basis for the components of each individual FOA. An Office of Global Council (OGC) representative may assist in choosing the authorities appropriate to any given program.

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

Budget Period/Year: the duration of each individual funding period within the project period. Traditionally, budget period length is 12 months or 1 year.

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

Catalog of Federal Domestic Assistance (CFDA): A catalog published twice a year which describes domestic assistance programs administered by the federal government. This government-wide compendium of Federal programs lists projects, services, and activities which provide assistance or benefits to the American public. https:// www.cfda.gov/index?s= agency&mode =form&id= 0bebbc3b3261e25 5dc82002b83094717&tab= programs&tabmode= list&subtab=list& subtabmode=list.

CDC Assurances and Certifications: Standard government-wide grant application forms.

CFDA Number: The CFDA number is a unique number assigned to each program/FOA throughout its lifecycle that enables data and funding tracking and transparency.

Competing Continuation Award: An award of financial assistance which adds funds to a grant and extends one or more budget periods beyond the currently established project period.

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

Contracts: An award instrument establishing a binding legal procurement relationship between CDC and a recipient obligating the latter to furnish a product.

Cooperative Agreement: An award of financial assistance that is used to enter into the same kind of relationship as a grant; and is distinguished from a grant in that it provides for substantial involvement between the Federal agency and the awardee in carrying out the activity contemplated by the award.

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

Direct Assistance: assistance given to an applicant such as federal personnel or supplies. See http:// www.cdc.gov/ stltpublichealth/ GrantsFunding/ direct_assistance.html.

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

Fiscal Year: The year that budget dollars are allocated to fund program activities. The fiscal year starts October 1st and goes through September 30th.

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

Grants.gov: A "storefront" web portal for use in electronic collection of data (forms and reports) for Federal grant-making agencies through the www.grants.gov site, www.grants.gov.

Health Disparities: are differences in health outcomes and their determinants between segments of the population, as defined by social, demographic, environmental, and geographic attributes.

Healthy People 2020: Provides national health objectives for improving the health of all Americans by encouraging collaborations across sectors, guiding individuals toward making informed health decisions, and

measuring the impact of prevention activities.

Inclusion: Inclusion refers to both the meaningful involvement of community members in all stages of the program process, and maximum involvement of the target population in the benefits of the intervention. An inclusive process assures that the views, perspectives, and needs of affected communities, care providers, and key partners are actively included.

Indirect Costs: Those costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, program, or activity but are nevertheless necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries are generally treated as indirect costs.

International public health work: For purposes of this template, is defined as work conducted internationally for the benefit of a foreign entity or jurisdiction.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions or Executive Orders ("legislation or other orders"), or other similar deliberations at all levels of government through communications that directly express a view on proposed or pending legislation or other orders and which are directed to members of staff, or other employees of a legislative body or to government officials or employees who participate in the formulation of legislation or other orders. Grass Roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the Federal, State or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

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

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

New FOA: Any FOA that is not a continuation or supplemental award.

Non-Governmental Organization: A non-governmental organization (NGO) is any non-profit, voluntary citizens' group which is organized on a local, national or international level.

Notice of Award: The only binding, authorizing document between the recipient and CDC confirming issue of award funding. The NoA will be signed by an authorized Grants Management Officer, and provided to the recipient fiscal officer identified in the application.

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

OGC: Office of the General Counsel (OGC) is the legal team for the Department of Health and Human Services (HHS), providing representation and legal advice on a wide range of national issues. OGC supports the development and implementation of HHS's programs by providing legal services to the Secretary of HHS and the organization's various agencies and divisions.

Outcome: The observable benefits or changes for populations and/or public health capabilities that will result from a particular program strategy.

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

Plain Writing Act of 2010: The Plain Writing Act requires federal agencies to communicate with the public in plain language to make information and communication more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. www.plainlanguage.gov

Procurement and Grants Office (PGO): PGO is the only entity within CDC which can obligate federal funds. PGO provides non-programmatic management for all CDC financial assistance activities (grants and cooperative agreements) and manages and awards all CDC contracts.

Program Strategies: Public health interventions or public health capabilities.

Program Official: The person responsible for developing the FOA – whether a project officer, program manager, branch chief, division leadership, policy official, center leadership, or similarstaff member.

Project Period Outcome: An outcome that will result by the end of the FOA period of funding.

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

Statute: An act of a legislature that declares, proscribes, or commands something; a specific law, expressed

in writing. A statute is a written law passed by a legislature on the state or federal level. Statutes set forth general propositions of law that courts apply to specific situations.

Statutory Authority: A legal statute that provides the authority to establish a Federal financial assistance program or award.

Technical Assistance: The providing of advice, assistance, and training pertaining to the development, implementation, maintenance, and/or evaluation of programs.

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