Funding Opportunity Announcement (FOA)

Enhancing the Government of India's Capacity to Scale Up and Improve Comprehensive HIV Service Package Quality for People Who Inject Drugs under the President's Emergency Plan for AIDS Relief (PEPFAR)

CDC-RFA-GH15-1542

Division of Global HIV/AIDS
Center for Global Health
Centers for Disease Control and Prevention

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-GH15-1542. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name

Centers for Disease Control and Prevention

B. Funding Opportunity Title

Enhancing the Government of India's Capacity to Scale Up and Improve Comprehensive HIV Service Package Quality for People Who Inject Drugs under the President's Emergency Plan for AIDS Relief (PEPFAR)

C. Announcement Type:

New-Type 1

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-GH15-1542

E. Catalog of Federal Domestic Assistance Number

93.067 Global AIDS program

F. Dates

1. **Letter of Intent Deadline Date:** N/A

Application Deadline Date: October 15, 2014, 11:59 p.m. U.S. Eastern Standard Time, on www.grants.gov

Informational conference call or pre-application workshop if held in person for potential applicants: N/A

G. Executive Summary

1. **Summary Paragraph**

Despite the scale up of interventions among People Who Inject Drugs (PWID), HIV prevalence continues to be high in India at 7.1%. Most worrisome is the continued high HIV prevalence in the North Eastern states (NE) of Manipur (12.9%), Mizoram (12.0%) and Meghalaya (6.4%). A qualitative study (2011) carried out to assess gaps in the national PWID program revealed that PWID interventions in India and especially NE states where the epidemic lies are lagging in terms of intensity and coverage of interventions, continued barriers to accessing services, stigma and discrimination, and lack of skills in dealing with PWID among service providers. Another observation by the qualitative study is that most PWIDs have transitioned from non-injecting modes of administration (e.g., smoking or chasing heroin) to injecting (e.g., injecting pharmaceuticals or heroin). Analysis of national program data revealed that Opioid Substitution Therapy (OST) coverage in NE states was 12% (planned target 20%) and retention was also low (59%). Similarly, HIV testing coverage was also low (48%) in NE states. There is scant information on the extent of female PWID and the challenges this group faces accessing services. The estimated number of female PWID is 10,000 and they are concentrated in NE states. HIV testing facility data reveals a prevalence of 7-25% among female PWID. Similarly, HIV prevalence has been reported to

be high among spouses of PWID (2.5% to 5%). There are also concerns regarding high reported spousal violence among this population (55%).

The overarching goal of the India PWID Collaborative Project is to enhance institutional and human capacity to scale up and improve the quality of the comprehensive package of services for this population in high burden PWID states in the NE region. The key activities of the project include:

a) Targeted technical assistance to state-level institutions to scale up coverage and quality of PWID comprehensive package of services,
b) Effective monitoring systems including establishment of an inter-linked biometric system to track coverage and quality of OST services,
c) Piloting models to provide OST to non-injecting opioid dependent users,
d) Training of the harm reduction workforce in health care institutions on comprehensive PWID service packages and sensitization of law enforcement officials, and
e) Scaling up gender sensitive HIV services for female PWID and spouses of PWID.

Primary expected outcomes of the project are increases in: coverage of OST; coverage of PWID using sterile injecting equipment; condom usage; HIV testing coverage; Antiretroviral Treatment (ART) coverage of HIV-positive PWID; coverage of female PWID with comprehensive package of services and coverage of spouses with psychosocial support services.

a.	**Eligible Applicants:** Fully Competitive
b.	**FOA Type:** Cooperative Agreement
c.	**Approximate Number of Awards:** 1
d.	**Total Project Period Funding:** None
e.	**Average One Year Award Amount:** $1,800,000.00
f.	**Number of Years of Award:** 5 Years
g.	**Approximate Date When Awards will be Announced:** February 2015
h.	**Cost Sharing and /or Matching Requirement:** N/A

Part II. Full Text

A. Funding Opportunity Description

1. Background:

The HIV burden among People Who Inject Drugs (PWID) is expanding in India. The estimated number of PWIDs in India ranges from 170,000 to 200,000. HIV prevalence among PWIDs continues to be high in India at 7.1%. Most worrisome is the high HIV prevalence in the North Eastern (NE) states of Manipur (12.9%), Mizoram (12.0%) and Meghalaya (6.4%). In some districts in this region, the HIV prevalence is as high as 30%. The Department of AIDS Control (DAC) responded to the epidemic by establishing 268 Targeted Interventions (>50% in NE states) and reaching about 80% of the PWID population in the country. Despite the scale up, prevalence among this population continues to be high and coverage and quality of services inadequate. Studies assessing challenges scaling up PWID interventions are scant and there is limited quantitative data available to measure coverage and quality. A qualitative study (2011) carried out to assess gaps in the national PWID program revealed that PWID interventions in India, particularly NE states where the epidemic lies, are lagging in terms of intensity and coverage of interventions, continued barriers to accessing services, stigma and discrimination, and a lack of skills among service providers to deal with PWID. Another observation made is that most PWIDs have transitioned from non-injecting modes of administration (e.g., smoking or chasing heroin) to injecting (e.g., pharmaceuticals or heroin) and this is facilitated by several factors: increasing cost of heroin,

impurity of heroin, easy availability of pharmaceutical drugs, user knowledge related to various pharmaceuticals and their potential benefits alleviating opioid withdrawal and changing peer norms.

The number of Opioid Substitution Therapy (OST) sites and coverage increased from 52 centers/5,000 OST clients in 2010 to 150 centers/15,000 OST clients nationally with the majority in NE states. Analysis of national program data reveals that OST coverage in NE states is 12% (below the target of 20%) with heightened concern about low retention rates (59%). Similarly, HIV testing coverage was also low (48%) in NE states. The other major concern is the inadequate dosage of OST given to PWIDs. This is based on program experience only as no study has been carried out to evaluate dosage quality. Planning for such a study assessing dosage quality is currently underway by DAC. To date, no surveys have been carried out to document the magnitude of female PWID in India including their injecting risk behaviors and problems accessing services. According to DAC, the estimated number of female PWID is about 10,000 and they are concentrated in NE states. HIV testing facility data reveals a prevalence of 7-25% among female PWIDs in this region. DAC has recently initiated six Targeted Interventions (TIs) among female PWID reaching about 1,200; however, this coverage is too low and much needs to be done to scale up interventions among this population. Studies have reported high HIV prevalence among spouses of PWID who are non-injecting, ranging from 2.5% to 5%. Furthermore, a high level (55%) of intimate partner violence—verbal, sexual and physical—has been reported among spouses of PWID in India.

PWID programming gaps in high burden NE states call for concerted action to address the epidemic in this region. DAC has requested PEPFAR/CDC to support their efforts in accelerating the response by enhancing the capacity of local institutions and individuals in scaling up the comprehensive package[1] of services for PWID in the NE region.

This proposed activity is linked to PEPFAR India Strategy Goal 1 (Improved Access to Quality Services) and Goal 4 (Health Systems Strengthening). It is also aligned with the PEPFAR Blueprint[2], as well as Strategy One of the National AIDS Control Program, Phase IV (Intensifying and consolidating prevention services, with a focus on key and vulnerable populations)[3].

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

[1] Comprehensive Package of services includes Needle Syringe Exchange Program (NSP), OST, targeted outreach including condom promotion, STI care and linkages to HIV testing, ART and diagnosis and treatment of HBV, HCV and TB.
[2] PEPFAR Blueprint: Creating an AIDS-free Generation, available at: http://www.pepfar.gov/documents/organization/201386.pdf.
[3] India National AIDS Control Programme Phase-IV (2012-2017), available at: http://www.naco.gov.in/upload/NACP%20-%20IV/NACP-IV%20Strategy%20Document%20.pdf.

monitoring and evaluation, field evaluation of diagnostic tests, etc.) may be funded through this mechanism.

b. Healthy People 2020:

Healthy People 2020 provides national health objectives for improving the health of all persons by encouraging collaborations across sectors, guiding individuals toward making informed health decisions, and measuring the impact of prevention activities. Additional information on Healthy People 2020 is available at http://www.healthypeople.gov.

c. PEPFAR Priorities and Strategies

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. Other National Public Health Priorities and Strategies:
N/A
e. Relevant Work:
N/A

2. CDC Project Description
a. Approach:

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
Activities, outputs and outcomes for all objectives pertain to NE states				
Objective 1: Enhance capacity of DAC and state level institutions in high burden PWID states in NE region to increase coverage and quality of the comprehensive package [Needle Syringe Program (NSP) +OST+HIV testing +ART) of services for PWID].				
Conduct a situational analysis of PWID interventions to identify programmatic gaps in high burden PWID states in NE region	Desk review of published articles and reports on PWID epidemic and response in NE states conducted Secondary analysis of PWID program data conducted for the period 2010 to 2014 Qualitative study conducted to report on the PWID program status including identifying barriers and service delivery issues in NE states Dissemination workshop conducted to share the findings to PWID technical resource group, DAC and state level officers of high burden NE states. Finalize recommendations for implementations	**Skills of DAC and state level institutions of NE states enhanced in conducting a situational analysis of the PWID intervention to identify programmatic gaps** **Policy level decisions and recommendations made to strengthen the response to PWID epidemic in high burden NE states**	**Increased regular coverage of PWID by targeted intervention (TI) programs over the last 12 months in NE states** **Increased coverage of PWID reporting using sterile injecting equipment at last injection** **Increased number of cities/towns in NE states where injecting drug users are located and where OST is available** **Increased number of PWID reporting given condoms through an outreach service, drop-in center or health facility during the last 12 months**	**Reduction in HIV incident cases among PWID in high burden NE states** **Increased OST coverage of opioid-dependent PWID on OST** **Increased ART treatment coverage of all eligible HIV-positive PWID (MER TX_New, TX_CURR)**
Develop a Technical Support Program to strengthen the PWID program in high burden NE	Analytical reports developed based on data captured in DAC strategic information unit for high burden PWID states in the NE region	**Increased awareness of stakeholders in NE states to scale up comprehensive package of PWID services**		

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
states based on situational assessment findings and programmatic gaps Introduction and piloting of innovative interventions such as Low Dead Space Needles and Syringes to further PWID service improvements and reduction of HIV transmission among PWID	Targeted technical assistance provided to state level institutions to implement plan for scaling up comprehensive package of services Experience Sharing and Review Meetings conducted every six months among State AIDS Control Societies (SACS), PWID TIs and other partners in high burden NE states on lessons learned and challenges in PWID interventions Ongoing supportive supervision and mentoring activities carried out for all PWID TIs and OST centers in NE states Quarterly performance grading of PWID and OST centers carried out as per DAC's TI grading system[4] Performance improvement plan implemented as per the findings of the quarterly performance review Protocol developed in consultations with DAC	**Increased utilization of analytical reports for strategic planning in high burden PWID states in NE region.** **Increased knowledge and skills of SACS and their partners in scaling up comprehensive package of services** **Increased number of high burden PWID states implementing comprehensive package of services** **Skills of SACS and state technical team enhanced to conduct supportive supervision and quarterly performance grading of PWID TIs and OST centers as per DAC's grading system** **Increased knowledge and skills of outreach team of all PWID TIs in NE states supported by DAC to effectively implement the comprehensive package of services** **Increased knowledge and skills of outreach teams of all OST centers in NE states to effectively implement**	**Increased coverage of PWID reporting use of condoms at last sex** **Increased coverage of PWID receiving HIV testing in the last 12 months and knew their result (MER HTC_TST)** **Increased number of TIs in NE states receiving an "A" (Very Good) per DAC TI grading system***	

[4] TIs are graded as per the DAC Grading System which is based on a set of TI performance indicators. They are judged on performance during quarterly assessments: C poor, B- below average, B average B+ above average A good, A+ very good, A++excellent.

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
	State level consultations held among DAC, SACS, PWID TIs, and state technical team to implement the Low Dead Space Needles and Syringes intervention Staff of all PWID TIs in NE states trained on Low Dead Space Needles and Syringes intervention Formative and Summative evaluation conducted to assess the effectiveness of Low Dead Space Needles and Syringes intervention Findings of the evaluation disseminated to experts and DAC	**services** **Increased support from DAC and SACS by formulating policies to implement the Low Dead Space Needles and Syringes intervention** **Increased skills of SACS, OST centers and PWID TI staff to implement the Low Dead Space Needles and Syringes intervention**		
Objective 2: Establish effective monitoring systems by developing tools, technology (inter-linked biometric system) and skills training to increase coverage, retention and quality of OST services in high burden PWID states in NE region and scale up lessons nationally.				
Design and implement a Quality Assessment tool to monitor the quality of OST services	Quality assurance/quality improvement experts hired for developing a quality improvement program for OST services Quality Assessment Tool developed for key components of OST in consultations with experts, DAC TI team and program implementers State level consultations held among SACS and their partners to implement quality assessment program in high burden NE states	**Increased support from DAC and SACS by formulating policies to implement quality assessment program** **Increased skills of SACS and state technical team in using the Quality Assessment Tool to track quality of OST program**	**Increased OST sites in NE states adhering to quality standards** **Increase in the coverage of PWID receiving maintenance dose of OST greater than or equal to the recommended minimum dose**	**Increase in the coverage of PWID receiving OST treatment for at least 6 months (MER, KP_MAT)** **Reduction in HIV incident cases among PWID in high burden NE**

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
	Monthly/quarterly quality assessment meeting conducted to assess the progress and make recommendations for program refinement			**states** **Increased OST coverage of opioid-dependent PWID on OST** **Increased ART treatment coverage of all eligible HIV-positive PWID (MER TX_New, TX_CURR)**
Inter-linked bio-metric system between PWID NGOs and OST centers for tracking OST clients including dosage	Inter-linked bio-metric system protocol developed in consultations with DAC Inter-linked bio-metric system software developed by the Software Agency contracted by awardee State level consultations held among OST centers, PWID TIs, SACS and state technical team to implement the Inter-linked bio-metric system Staff of all PWID TIs OST centers in NE states trained on Inter-linked bio-metric system Formative and Summative evaluation conducted to assess the effectiveness of Inter-linked bio-metric system Findings of the evaluation disseminated to experts and DAC	**Increased support from DAC and SACS by formulating policies to implement Inter-linked bio-metric system** **Increased skills of SACS, OST centers and PWID TI staff to implement the Inter-linked bio-metric system for tracking OST clients**		
Scale up OST monitoring system in all high burden PWID states in the	National Guidelines developed for scaling up OST monitoring system Module developed to train SACS, and	**Increased support from DAC and SACS by formulating policies to implement the OST monitoring system nationally**	**Increased OST sites nationally adhering to quality standards**	

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
country (Fourth and Fifth year)	state technical team on OST monitoring system Conduct Training of Trainers (TOT) of Technical Support Units (TSUs), SACS and State Training Resource Centers (STRC) staff on OST monitoring system nationally Staff of OST centers, PWID TI and SACS, trained on OST monitoring system in all high burden PWID states nationally	**Increased skills of SACS-state technical team (TSU and STRC) in high burden PWID states in using the Quality Assessment Tool to track quality of OCT program nationally** **Increased skills of SACS, OST centers and PWID TI staff in all high burden PWID states nationally to implement the Inter-linked bio-metric system for tracking OST clients**	**Increase in the coverage of PWID receiving maintenance dose of OST greater than or equal to the recommended minimum dose nationally**	
Objective 3: Pilot a model to provide OST to non-injecting opioid dependent users in one NE PWID high burden state.				
Conduct a pilot intervention strategy providing OST to non-injecting opioid dependent users	Protocol developed in consultations with DAC State level consultations held among OST centers, PWID TIs and SACS to implement the pilot on OST among non-injecting opioid dependent users All outreach staff of NE states trained on OST intervention among non-injecting opioid dependent users Monitoring system established to track OST intervention among non-injecting opioid dependent users Pilot evaluated (formative and summative) and findings disseminated to experts and DAC	**Increased support from DAC and SACS of the selected state by formulating policies to conduct a pilot on OST among non-injecting opioid dependent users** **Increased skills of PWID TI outreach staff to implement OST intervention among non-injecting opioid dependent users** **Monitoring system accurately tracks OST intervention among non-injecting opioid dependent users**		**Reduction in drug users transitioning from non-injecting to injecting**

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
Objective 4: Improve quality of PWID package of services through training of harm reduction workforce (staff of Outreach, OST and Medical) and sensitization of law enforcement officials in high burden NE states.				
Capacity Building of Harm Reduction Force on improving quality of PWID package of services Development and implementation of a Sensitization workshop of law enforcement officials	Training needs assessment[5] of Harm Reduction Force conducted on issues related to the implementation of PWID package of services Task analysis[6] of the Harm Reduction Force in implementing the PWID package of services conducted Revised training module adopting a systematic approach to curriculum development TOT training of SACS and state level training institution staff conducted for all high burden NE PWID states Sensitization module developed for law enforcement officials TOT of state level training institution on Sensitization Module for law enforcement officials conducted in high burden PWID states	**Increased knowledge of DAC on training needs of Harm Reduction Force on issues related to the implementation of PWID package of services** **Increased knowledge and skills of the Harm Reduction Force to effectively implement the PWID package of services** **Increased awareness amongst law enforcement officials of PWID as a public health issue**	**Increased number of Health Care Providers providing stigma free PWID package of services** **Increased number of law enforcement officials having knowledge of PWID being a public health issue and not a legal problem**	**Reduction in HIV incident cases among PWID in high burden NE states** **Increased OST coverage of opioid-dependent PWID on OST** **Increased ART treatment coverage of all eligible HIV-positive PWID (MER TX_New, TX_CURR)**
Objective 5: Improve coverage of gender sensitive HIV services for female PWID and spouses of PWID by providing technical support to institutions				

[5] Training needs assessment of Harm Reduction Force will be conducted to identify their present level of knowledge, attitude and skills on the package of PWID services.
[6] Task Analysis is the method of listing the tasks to be performed by the staff to implement the project and then analyze what knowledge, attitude and skills is required to effectively perform the tasks. This is a scientific approach of conducting good training.

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
through development of tools, guidelines, innovative strategies and skills training in high burden NE states.				
Technical support program through development of tools, guidelines and time bound HR support (experts) to state level institution on interventions among Female PWID in high burden NE states	National level and state level consultations held with DAC, SACS, NGOs and female PWID community to design strategies for scaling up female PWID program Ongoing mentoring and supportive supervision for scaling up Female PWID program in high burden NE states Innovative approaches in providing gender sensitive services such as formation of female PWID network and placement of female PWID volunteers in HIV/health facilities demonstrated	**Increased support from DAC and SACS by formulating policies to scale up the comprehensive package of services for female PWID** **Knowledge and skills of SACS and state level technical team increased on innovative approaches in gender sensitive services for female PWID**	**Increased coverage of comprehensive package for Female PWID** **Increased coverage of female PWID reporting using sterile injecting equipment at last injection** **Increased coverage of female PWID reporting use of condoms at last sex** **Increased coverage of female PWID receiving HIV testing in the last 12 months and knew their result (MER HTC_TST)**	**Increased OST coverage of opioid-dependent female PWID on OST** **Increased ART treatment coverage of all eligible HIV-positive female PWID (MER TX_New, TX_CURR)**
Technical support program through development of tools, guidelines and time bound HR support (experts) to state level institutions on interventions among spouses of PWID in high burden NE states	Situational assessment carried out to identify spousal violence and gender concerns of the spouses of PWID Program strategies and tools designed to address the gender concerns and spousal violence Gender based program for PWID and their spouses piloted in one state Technical assistance plan developed to scale up PWID Spousal intervention	**Increased support from DAC and SACS by formulating policies to implement a program to address the concerns of the spouses of PWID** **Knowledge and skills of SACS and state technical team increased on implementing strategies to address gender concerns and spousal violence** **Increased support from DAC by formulating policies to scale up PWID Spousal intervention program**	**Increased number of spouses reached by PWID spousal program (MER, GEND_NORM)**	**Decreased PWID spousal violence**

Activities	Outputs	Outcomes		
		Short Term Outcomes (1-2 Years)	Intermediate Outcomes (3-4 Years)	Long Term Outcomes (5+ Years)
	program nationally based on lessons learned from these activities in NE states	**nationally**		

i. Problem Statement:

HIV prevalence continues to be high in the NE states of Manipur (12.9%), Mizoram (12.0%) and Meghalaya (6.4%). Despite the progress attained in scaling up outreach services including condom distribution and the NSP (80% reached), there are issues of quality affecting the uptake of the comprehensive package of services among PWID populations. The coverage of OST (12%), HIV testing (48%) and linkage to ART services is low. Besides, the OST retention rate is also low (59%) at three months. The other major concern is inadequate dosage of OST given to PWIDs, though this is based on program experience as no data is available to measure the extent of this problem.

There is a dearth of data on the magnitude of the female PWID burden in India. According to DAC, the estimated number of female PWID is about 10,000 and they are concentrated in NE states. HIV testing facility data reveals a prevalence of 7-25% among female PWIDs in this region. HIV prevalence was also observed to be high among spouses of PWID. Studies report high HIV prevalence among spouses of PWID who are non-injecting to range from 2.5% to 5%. Additionally, a high level of intimate partner violence (55%) including sexual and physical violence is reported among spouses of PWID in India.

Gaps identified in the PWID program in high burden NE states calls for a concerted action to address the epidemic in this region. DAC has requested PEPFAR/CDC to support their efforts in accelerating the response by enhancing the capacity of local institutions and individuals in scaling up the comprehensive package of services for PWID in the NE region. To sustain these efforts, PEPFAR/CDC will build on existing interventions by leveraging government infrastructure and maximize resources already being invested by integrating project interventions within existing programs. This approach will ensure a seamless transition of project activities to the government.

ii. Purpose

The purpose of this FOA is to enhance institutional and human capacity to scale up and improve the quality of the comprehensive package of services for PWID population in high burden PWID states in the NE region. The objectives of this FOA are as follows:

- Enhance capacity of DAC and state level institutions in high burden PWID states in the NE region to increase coverage and quality of the comprehensive package (NSP+OST+HIV testing +ART) of services for PWID.
- Establish effective monitoring systems by developing tools, technology (inter-linked biometric system) and skills training to increase coverage, retention and quality of OST services in high burden PWID states in NE region and scale up lessons nationally. Pilot models to provide OST to non-injecting opioid dependent users in one NE PWID high burden state.
- Improve the quality of PWID package of services through training of harm reduction workforce (Staff of Outreach, OST and Medical) and sensitization of law enforcement officials in high burden NE states.
- Improve coverage of gender sensitive HIV services for female PWID and spouses of PWID by providing technical support to institutions through development of tools, guidelines, innovative strategies and skills training in high burden NE states.

iii. Outcomes

The following are key outcomes awardees are expected to achieve by the end of the project period:

Key Outcomes (all pertains to NE states):

- 30 to 40% reduction in HIV incident cases among PWID over baseline (6-12% in 2013).
- 50 to 60% increase in opioid-dependent PWID on OST over baseline (12% in 2014).
- *60% of all eligible HIV-positive PWID receiving ART.
- 60% of PWID were regularly reached by TIs over the last 12 months.
- 80% of PWID receive targeted IEC provided by TIs and OST centers.
- 20 to 30 increase over baseline (60% in 2014) of PWID reporting using sterile injecting equipment at last injection.
- PWID reporting use of condoms at last sex increased from 40% to 75%.
- 50 to 60% increase over baseline (48% in 2014) of PWID who received HIV testing in the last 12 months and knew their results.
- 90% of TIs receive A grade (Very Good) as per DAC TI grading system.
- 70% of the OST centers adhering to the quality standards.
- *40 to 50% of patients receiving maintenance dose of OST greater than or equal to the recommended minimum dose.
- *40 to 50% of patients receiving OST who received treatment for at least 6 months ((MER, KP_MAT).
- 30% OST sites providing OST to non-injecting opioid dependent users.
- *50% of Health Care Providers providing stigma free/PWID friendly services.
- *50 to 60% increase in opioid-dependent Female PWID on OST over baseline in NE states.
- *50 to 60% increase of female PWID report using sterile injecting equipment at last injection.
- *50 to 60% increase over baseline of female PWID who received HIV testing in the last 12 months and knew their results in NE states.
- *60% of all eligible HIV-positive female PWID receiving ART.
- 40 to 50% decrease in PWID spousal violence over baseline (55.5% in 2011)

*Currently no baseline is available and it would be critical to reach this target. A national Integrated Bio-Behavioral Survey is underway and will be completed by the end of 2014. Baseline for all measures will be obtained from this survey.

The monitoring tools and materials piloted to track PWID patients on Opioid Substitution Therapy (OST) to ensure retention will be retained by MOH for scaling up throughout the country. Similarly, the training modules, tools, and materials developed under this project for enhancing the skills of outreach workers to effectively reach male and female PWID will be retained by MOH for replication throughout the country.

iv. Funding Strategy

N/A

v. Strategies and Activities

Objective 1: Enhance capacity of DAC and state level institutions in high burden PWID states in the NE region to increase coverage and quality of the comprehensive package (NSP+OST+HIV testing +ART) of services for PWID.

- Conduct a situational analysis of the PWID intervention to identify programmatic gaps in high burden PWID states in NE region.
  - The awardee will develop a protocol in consultation with DAC for conducting a situational analysis of PWID interventions. The awardee should contract an agency or a

team of consultants to carry out the following tasks: a) Desk review of published articles and reports on PWID epidemic and response, b) Secondary analysis of PWID program data for the period 2010 to 2014, c) Qualitative study to assess PWID program status including identifying barriers and service delivery issues and d) Dissemination workshop to share the findings to PWID technical resource group, DAC and state level officers of high burden NE states. Finalize recommendations for implementations

- Develop a Technical Support Program to strengthen the PWID program in high burden NE states based on situational assessment findings and programmatic gaps.
  - Based on the findings of a situational assessment study, the awardee will develop a Technical Assistance plan and provide ongoing support to strengthen state level institutions in high burden NE states to effectively implement the complete package of PWID services. In addition, the awardee needs to coordinate with CDC technical assistance partner to DAC on strategic information to carry out periodic analysis of PWID data of high burden NE states. The awardee needs to prepare analytical reports and provide strategic guidance and mentoring support to SACS and associated state level institutions for scaling up the comprehensive package of services. The awardee needs to be able to provide technical assistance for the design and establishment of integrated models of PWID service provision, where ideally OST, ART, TB, Prevention of Mother to Child Transmission (PMTCT) and Sexually Transmitted Infections (STI) treatment can be provided at one site together. The awardee needs to also organize Experience Sharing and Review Meetings every six months among SACS, state level institutions and PWID Community Based Organizations of high burden PWID states on lessons learned and challenges in PWID interventions. Finally, the awardee should carry out need based training programs for staff of SACS and its partners.
  - Every quarter the team will carry out a performance review of PWID TIs and OST centers in these high burden NE states as per DAC's TI grading system. The team has to develop a performance improvement plan and provide ongoing mentoring support for TIs and OST centers that fall below the average category.

- Introduction and piloting of innovative interventions such as Low Dead Space Needles and Syringes to further PWID service improvements and reduction of HIV transmission among PWID.
  - The awardee will also provide technical support for the potential introduction and piloting of innovative interventions such as Low Dead Space Needles and Syringes that contribute to further PWID service improvements and reduction of HIV transmission among PWID. The awardee will develop the protocol in consultations with DAC, SACS and the PWID community. The staff of the PWID TIs will be trained to implement the Low Dead Space Needles and Syringes intervention.
  - A monitoring system needs to be established to track the intervention. Finally, the pilot needs to be evaluated (both formative-baseline and summative) and findings disseminated to experts and DAC.

Objective 2: Establish effective monitoring systems by developing tools, technology (inter-linked biometric system) and skills training to increase coverage, retention and quality of OST services in high burden PWID states in NE region and scale up lessons nationally.

- Design and implement a Quality Assessment tool to monitor the quality of OST services.
  - The awardee needs to hire quality assurance/quality improvement experts for

developing a quality improvement program for OST services. The experts should develop a Quality Assessment Tool for key components of OST in consultations with DAC TI team and program implementers.
    - The awardee, along with experts, should organize a State level consultation with the SACS and their partners for taking their inputs to implement the quality assessment program. The awardee is required to organize monthly/quarterly quality assessment meetings to assess the progress and make recommendations for program refinement.

- Inter-linked bio-metric system between PWID NGOs and OST centers for tracking OST clients including dosage.
    - As a first step, the awardee needs to hire a Software Agency and develop a protocol on Inter-linked bio-metric system in consultations with DAC. Following the development of the software, the awardee needs to hold state level consultations among OST centers, PWID TIs and SACS to implement the Inter-linked bio-metric system. The awardee should also conduct a training of staff at OST centers, PWID TIs and SACS to implement the Inter-linked bio-metric system. The effectiveness of the Inter-linked bio-metric system needs to be evaluated and findings disseminated to DAC to scale up nationally.

- Scale up OST monitoring system in all high burden PWID states in the country (Fourth and Fifth year).
    - The awardee should develop national guidelines for scaling up the OST monitoring system based on findings from the pilot project. The awardee should develop a training module on OST monitoring system. The awardee should conduct a TOT program to train the staff of SACS, STRC and OST centers on OST monitoring system.

Objective 3: Pilot models to provide OST to non-injecting opioid dependent users in one NE PWID high burden state.

- Conduct a pilot on providing OST to non-injecting opioid dependent users.
    - The awardee should develop a protocol on OST intervention to non-injecting opioid dependent users through consultations with DAC. The awardee should hold state level consultations among OST centers, PWID TIs, and SACS to implement the pilot on OST among non-injecting opioid dependent users. Besides, the awardee needs to train staff of OST centers and PWID TI projects to implement OST intervention among non-injecting opioid dependent users. A monitoring system needs to be established to track OST intervention among non-injecting opioid dependent users. Finally, the pilot needs to be evaluated (both formative-baseline and summative) and findings disseminated to experts and DAC.

Objective 4: Improve quality of PWID package of services through training of harm reduction workforce (staff of Outreach, OST and Medical) and sensitization of law enforcement officials in high burden NE states.

- Capacity Building of Harm Reduction Force on improving quality of PWID package of services.
    - The awardee needs to carry out training needs assessment of Harm Reduction Force on issues related to the implementation of PWID package of services. They will need to do conduct a task analysis of the Harm Reduction Force in implementing the PWID package of services. Based on the findings of the needs assessment and the task analysis, the training curriculum and training module need to be revised. The awardee needs to follow a systematic approach to curriculum development. Following the development of

the curriculum and the module, the awardee needs to conduct a TOT training of SACS and state level training institution staff of all high burden PWID states. In addition to training, the awardee needs to facilitate develop a Quality Improvement (QI) plan, providing TA to the DAC for PWID program quality assurance and QI, and for monitoring QI as needed over the duration of the cooperative agreement and prior to the final program evaluation.

- Development and implementation of a Sensitization workshop of law enforcement officials.
  - The awardee should develop a sensitization module for law enforcement officials. They need to conduct a TOT training of SACS and state level training institution staff on the Sensitization Module who in turn will conduct sensitization workshops among law enforcement officials in high burden PWID states.

Objective 5: Improve coverage of gender sensitive HIV services for female PWID and spouses of PWID by providing technical support to institutions through development of tools, guidelines, innovative strategies and skills training in high burden NE states.

- Technical support program through development of tools, guidelines and time bound HR support (experts) to state level institution on interventions among Female PWID in high burden NE states.
  - The awardee needs to conduct national and state level consultations with DAC, SACS and female PWID community to design strategies for scaling up female PWID program. The awardee needs to design strategies including tools and guidelines and provide ongoing mentoring and supportive supervision to SACS for scaling up Female PWID program. The awardee also needs to design and implement innovative approaches such as formation of female PWID network and placement of female PWID volunteers in HIV/health facilities in providing gender sensitive services for Female PWID.

- Technical support program through development of tools, guidelines and time bound HR support (experts) to state level institution on interventions among spouses of PWID in high burden NE states.
  - The awardee needs to carry out a situational assessment to identify gender concerns of PWID spouses. Based on the findings of this assessment, program strategies and tools should be designed to address gender concerns and spousal violence including spouse/partner HIV testing and disclosure. The awardee needs to provide technical assistance to SACS and their partners through time bound support of experts to implement the gender based program for PWID and their spouses. Based on lessons learned from this pilot, the awardee should develop a technical assistance plan and support DAC in scaling up the PWID Spousal intervention program nationally.

1. **Collaborations:**

The awardee will seek technical guidance from CDC partners implementing strategic information activities to design demonstration projects and in establishing management information systems. It will also seek their guidance in designing a baseline and end line evaluation.

The awardee will also coordinate with USAID partner implementing HIV prevention to care and treatment continuum activities among Key Populations to avoid duplication. At the time of COP 14 planning, CDC held discussions with USAID and mutually agreed upon activities that both agencies would support on prevention to care and treatment continuum activities

	among Key Populations. USAID is not carrying out any demonstration projects or technical assistance activities with DAC on PWID interventions. USAID is focusing on female sex workers (FSW), men who have sex with men (MSM), and transgender populations (TG). Efforts will be put to identify overlaps among the key populations (PWID, FSW, MSM and TG) intervened through CDC and USAID partners especially when the lessons learned on PWID intervention is being scaled up nationally through the CDC partner. All the PWID intervention activities planned under this project will be designed and implemented in collaboration with DAC and SACS.
2. Target Populations:	
	The project will carry out interventions among Male PWID, non-injecting drug users, Female PWID and Spouses of PWID.
	Inclusion:
	N/A

b. Evaluation and Performance Measurement:

i. CDC Evaluation and Performance Measurement Strategy:

The monitoring and evaluation framework will be designed to assess project effectiveness as measured by intermediate and long term outcome indicators.

Key evaluation questions for the project are:

- How effective was the technical support program in scaling up coverage and quality of the comprehensive package of PWID services in high burden NE states?
- How accurate/effective was the Quality Assessment tool in monitoring the quality of OST services?
- How effective was the Inter-linked bio-metric system between PWID NGOs and OST centers in tracking OST clients including dosage?
- Did the training of Harm Reduction Force lead to improvement in the quality of PWID package of services? Did it reduce stigma and discrimination against PWID?
- How effective were the strategies and technical support activities in scaling up coverage and quality of services for female PWID and spouses of PWID?

The Targeted Intervention Division of DAC will be involved in developing the monitoring and evaluation framework. The technical officers (PWID) of the Targeted Intervention Division will be members of the various evaluations carried out under this project. Where appropriate USAID will be engaged in the design and conduct of evaluations.

Public Domains

The baseline and final evaluation reports will be placed in the websites of DAC and CDC. The final evaluation report will be printed and distributed as necessary. Scientific articles based on the findings of this will be prepared and submitted to peer reviewed journals. Where appropriate, the findings of this project will be disseminated in national and international conferences including seminars.

Project Monitoring

The Technical Officer assigned to this activity will provide management and technical oversight including evaluations to this project. S/he will be responsible for tracking project progress as per the approved yearly action plan and in accordance with PEPFAR, DAC and Project level indicators. The Technical Officer will be the key member of the various project committees at the national and state level. S/he, as CDC representative, will provide policy level guidance as appropriate in these committees. S/he will undertake field visits to assess the quality of the interventions. The Technical Officer will also monitor the quality of data collected by the project. CDC will carry out a quarterly review of the technical and financial progress.

Evaluation Budget (10 to 12% of the overall budget)
A formative study ($100,000) is being conducted to assess the PWID program status including identifying barriers and service delivery issues in NE states. The findings of this study will inform DAC in strengthening the program strategies. As regards to evaluation of the project, the awardee will be accessing data from the strategic management information unit of DAC to measure the quantitative aspects of the evaluation questions listed in the evaluation matrix. The cost involved will be in carrying out the analysis of the data ($300,000). In addressing the qualitative aspects of the evaluation questions, the awardee needs to carry out studies ($400,000) among providers and the community (listed in the matrix). The awardee needs to also allocate $50,000 for dissemination of evaluation findings through seminars and workshops. A budget of $200,000 needs to be allocated for routine program monitoring which includes field visits and monthly/quarterly reviews.

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
How effective was the technical support program in scaling up coverage and quality of the comprehensive package of PWID services in high burden NE states?	All high burden PWID states implementing comprehensive package of services. (quantitative)	DAC Strategic Management Information System	Data Abstraction	Monthly by SACS of each state	Present progress every quarter to DAC and SACS of concerned states on implementation of the comprehensive package of services Develop improvement plans to support SACS
	60% of PWID regularly reached by TI program. (quantitative)	DAC Strategic Management Information System	Data Abstraction	Routinely by TI program	Present progress every quarter to DAC and SACS of concerned states on coverage of PWIDs Develop scale up plans to achieve targets
	Knowledge of all SACS and their partners increased in scaling up comprehensive package of services. (qualitative)	Staff of SACS and their partners	Interview Program review	Annually	Retraining on comprehensive package if there are knowledge gaps
	Knowledge and skills of 80% of the outreach team of 115 PWID TIs and 80 OST centers supported by DAC	Peer Educators and Outreach Workers of PWID TIs	Interview Program Review	Quarterly	Retraining on comprehensive package if there are knowledge and skills gap

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
	increased to effectively implement the comprehensive package of services. (qualitative)				
	90% of TIs receiving an "A" per DAC TI grading system. (quantitative)	SACS monitoring records	Program Review	Quarterly	Develop scale up plans to achieve targets Develop plans to improve quality
	50 to 60% increase in opioid-dependent PWID on OST over baseline (12% in 2014). (quantitative)	DAC Strategic Management Information System	Data Abstraction	Routinely on OST registration and daily administration of OST dosage	Present progress every quarter to DAC and SACS of concerned states on coverage of OST Develop scale up plans to achieve targets Develop plans to improve quality
	20 to 30 increase over baseline (60% in 2014) of PWID reporting using sterile injecting equipment at last injection. (quantitative) PWID reporting use of condoms at last sex increased from 40% to 75%. (quantitative)	PWID	Integrated Biological and Behavioral Surveillance Survey (IBBA)	Baseline and end line	Develop Evaluation Results Meet with DAC and SACS to discuss findings at baseline Incorporate findings to strengthen intervention strategies Discuss findings of end line and recommendations for further scale up or quality improvement.
	50 to 60% increase over baseline (48% in 2014) of PWID who received HIV testing in the last 12 months and knew their results. (quantitative)	DAC Strategic Management Information System	Data Abstraction	Routinely data will be recorded of every HIV testing and counseling	Present progress every quarter to DAC and SACS of concerned states on coverage of HIV testing Develop scale up plans to achieve targets

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
				encounter at DAC supported HIV testing facilities	Develop plans to improve quality
	*60% of all eligible HIV-positive PWID receiving ART (quantitative)	DAC Strategic Management Information System	Data Abstraction	Routinely data will be recorded of every eligible HIV-positive PWID receiving ART at DAC designated ART centers	Present progress every quarter to DAC and SACS of concerned states on coverage of ART Develop scale up plans to achieve targets Develop plans to improve quality
How accurate and effective was the Quality Assessment tool in monitoring the quality of OST services?	Knowledge and skills of 80 % of the SACS and state technical team from NE states increased in using the Quality Assessment Tool to track quality of OST program. (qualitative)	Staff of SACS and their partners	Interview Quality Assessment Reports	Quarterly	Implementation of the recommendations of quality assessment reviews by SACS
	70% of the OST centers adhering to quality standards. (quantitative) All the performance measures of evaluation question one apply to evaluation question two.	Staff of OST centers PWID TI peer educators Male and Female PWID community	Quality Assessment Reports Program Review Qualitative study	Quarterly One time	Discuss findings of OST quality assessment with DAC, SACS and community Develop plans to improve quality
How effective was the Inter-linked bio-metric system	Knowledge and skills of 80 % of the SACS, OST centers and PWID TI staff from NE	Staff of SACS, OST centers and PWID TIs	Interview Program Review	Quarterly	Meet with DAC and SACS to discuss progress of the Inter-linked Biometric System

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
between PWID NGOs and OST centers in tracking OST clients including dosage?	states increased to implement the Inter-linked Biometric System. (qualitative)				
	*40 to 50% of patients receiving OST who received treatment for at least 6 months. (quantitative) *40 to 50% of patients receiving maintenance dose of OST greater than or equal to the recommended minimum dose. (quantitative)	Inter-linked Biometric System records PWID TI peer educators	Data Abstraction Interview	Routinely patients registered and receiving OST services will be recorded in Inter-linked Biometric System	Implement recommendations to strengthen coverage of OST patients and to maintain adequate dosage of OST
Did the training of Harm Reduction Force lead to improvement in the quality of PWID package of services? Did it reduce stigma and discrimination against PWID?	* Knowledge and skills of 80 % of the Harm Reduction Force increased to effectively implement the PWID package of services. (qualitative) *Reduction in stigma and discrimination in providing services to PWID by Health Care Providers. (qualitative)	Staff of SACS, PWID TI, OST centers Health Care Providers at HIV Testing, STI, ART and other Medical facilities PWID peer educators and community PWID community	Interview Program review with facilities Community Study- Peer Educators and PWID Community Qualitative study	Quarterly Annually Baseline and end line	Retraining of staff based on the findings of the review Share the findings of the study with DAC Formulate and implement recommendations
	80% of law enforcement officials have knowledge of	PWID community	Qualitative study	Baseline and end line	Meet with DAC and SACS to discuss findings at baseline.

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
	PWID being a public health issue and not a legal problem. (qualitative)	Law enforcement officials			Incorporate findings to strengthen intervention strategies Discuss findings of end line and recommendations for improvement
How effective were the strategies and technical support activities in scaling up coverage and quality of services for female PWID and spouses of PWID?	Knowledge and skills of 80% of the SACS and state level technical team of NE states increased on innovative approaches in gender sensitive services for female PWID. (qualitative)	Staff of SACS and their partners	Interview Program review	Annually	Retraining on innovative approaches in gender sensitive services for female PWID if gaps in knowledge and skills persist
	*50 to 60% increase in opioid-dependent Female PWID on OST over baseline in NE states. (quantitative)	DAC Strategic Management Information System	Data Abstraction	Routinely at every OST registration and daily administration	Present progress every quarter to DAC and SACS of concerned states on coverage of OST Develop scale up plans to achieve targets Develop plans to improve quality
	*50 to 60% increase of female PWID report using sterile injecting equipment at last injection. (quantitative)	PWID	Integrated Biological and Behavioral Surveillance Survey (IBBA)	Baseline and end line	Develop Evaluation Results Meet with DAC and SACS to discuss findings at baseline. Incorporate findings to strengthen intervention strategies Discuss findings of end line and recommendations for further scale up or quality improvement
	*50 to 60% increase over	DAC Strategic	Data	Routinely data	Present progress every quarter to

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
	baseline of female PWID who received HIV testing in the last 12 months and knew their results in NE states. (quantitative)	Management Information System	Abstraction	will be recorded of every HIV testing and counseling encounter at DAC supported HIV testing and counseling facilities	DAC and SACS of concerned states on coverage of HIV testing Develop scale up plans to achieve targets Develop plans to improve quality
	*60% of all eligible HIV-positive female PWID receiving ART. (quantitative)	DAC Strategic Management Information System	Data Abstraction	Routinely data will be recorded of every eligible HIV-positive female PWID receiving ART at DAC designated ART centers.	Present progress every quarter to DAC and SACS of concerned states on coverage of ART Develop scale up plans to achieve targets Develop plans to improve quality
	Knowledge and skills of 80% of SACS and state level technical team of NE states increased on implementing strategies to address gender concerns and spousal violence. (qualitative)	Staff of SACS and their partners	Interview Program review	Annually	Retraining on strategies to address gender concerns and spousal violence if gaps in knowledge and skills persist
	*50 to 60% of the spouses receiving psychosocial support services. (quantitative)	SACS monitoring records	Program Review	Quarterly	Develop scale up plans to achieve targets Develop plans to improve quality
	40 to 50% decrease in PWID	PWID Spouse	Integrated	Baseline and	Develop Evaluation Results

Evaluation Question	Performance Measure	Data Source	Collection Method	Collection Frequency	Dissemination and Utilization
	spousal violence over baseline (55.5% in 2011) (quantitative)		Biological and Behavioral Surveillance Survey (IBBA) Or Qualitative Study	end line	Meet with DAC and SACS to discuss findings at baseline. Incorporate findings to strengthen intervention strategies Discuss findings of end line and recommendations for further scale up or quality improvement
*Currently no baseline is available and it would be critical to reach this target. A national Integrated Bio-Behavioral Survey is underway and will be completed by the end of 2014. Baseline for all measures will be obtained from this survey.					

ii. Applicant Evaluation and Performance Measurement Plan:

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.

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 awardees 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 timelines.
- 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.

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 monitoring and evaluation plan, including for compliance with the strategic information guidance established by the OGAC.

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.

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 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 process, outcome or impact.
    A. Process Evaluation: measures how the intervention was delivered, what worked/did not, differences between the intended population and the population served, and access to the intervention.
    B. Outcome Evaluation: determines effects of intervention in target population(s) (e.g., change in knowledge, attitudes, behavior, capacity, etc.).
    C. Impact Evaluation: measures net effects of program and prove of causality

18. Supply the awardee with protocols for related evaluations.

B. Award Information

1.	**Type of Award:**
	Cooperative Agreement: CDC's substantial involvement in this program is indicated in the "CDC program Support to Awardees" section of this document.
2.	**Award Mechanism:**
	U2G-Global HIV/AIDS Non-Research Cooperative Agreements
3.	**Fiscal Year:**
	2015
4.	**Approximate Total Fiscal Year Funding:**
	$1,800,000.00
5.	**Approximate Total Project Period Funding:**
	None

6.	**Total Project Period Length:**
	5 Years
7.	**Approximate Number of Awards:**
	1
8.	**Approximate Average Award:**
	$1,800,000.00
9.	**Floor of Individual Award Range:**
	None
10.	**Ceiling of Individual Award Range:**
	$1,800,000.00 (This amount is subject to the availability of funds).
11.	**Anticipated Award Date:**
	April 1, 2015
12.	**Budget Period Length:**
	12 months 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: Applicants 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.***
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 will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities). The CDC will not reimburse indirect costs unless the recipient has an indirect cost rate covering the applicable activities and period.

C. Eligibility Information

1.	**Eligible Applicants:**
	Eligible applicants that can apply for this FOA are listed below: Government Organizations:

- National Ministries of Health
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)[7] .
- American Indian/Alaska Native tribal governments (federally recognized or state-recognized)
- Political subdivisions of States (in consultation with States)

Non-government Organizations:

- American Indian/Alaska native tribally designated organizations
- Alaska Native health corporations
- Tribal epidemiology centers
- Urban Indian health organizations
- Nonprofit with 501C3 IRS status (other than institution of higher education)
- Nonprofit without 501C3 IRS status (other than institution of higher education)
- Research institutions (that will perform activities deemed as non-research)

Colleges and Universities

Community-based organizations

Faith-based organizations

For-profit organizations (other than small business)

Hospitals

Small, minority, and women-owned businesses

All Other eligible organizations

PEPFAR Local Partner definition:
To be considered eligible as a local partner under this Funding Opportunity Announcement, the applicant must submit supporting documentation demonstrating how their organization meets one of the three criteria listed below under the "PEPFAR Local Partner definition." The supporting documentation must be included in the Appendices of the application and must be labeled as "Eligibility Documentation for PEPFAR Local Partner Definition." Applicants that do not provide and/or label the supporting documentation required to meet the PEPFAR Local Partner definition above will not be considered eligible for review.

Under PEPFAR, a "local partner" may be an individual or sole proprietorship, an entity, or a joint venture or other arrangement. However, to be considered a local partner in a given country served by PEPFAR, the partner must meet the criteria under paragraph (1), (2), or (3) below:

(1) an individual must be a citizen or lawfully admitted permanent resident of and have his/her principal

[7] A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required.

place of business in the country served by the PEPFAR program with which the individual is or may become involved, and a sole proprietorship must be owned by such an individual; or

(2) an entity (e.g., a corporation or partnership):
   a) must be incorporated or legally organized under the laws of, and have its principal place of business in, the country served by the PEPFAR program with which the entity is or may become involved;
   b) must be at 75% for FY2015 beneficially owned by individuals who are citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), or by other corporations, partnerships or other arrangements that are local partners under this paragraph or paragraph (3);
   c) at least 75% for FY 2015 of the entity's staff (senior, mid-level, support) must be citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), and at least 75% for FY 2015 of the entity's senior staff (i.e., managerial and professional personnel) must be citizens or lawfully admitted permanent residents of such country; and
   d) where an entity has a Board of Directors, at least 51% of the members of the Board must also be citizens or lawfully admitted permanent residents of such country; or

(3) a joint venture, unincorporated association, consortium, or other arrangement in which at least 75% for FY 2015 of the funding under the PEPFAR award is or will be provided to members who are local partners under the criteria in paragraphs (1) or (2) above, and a local partner is designated as the managing member of the organization. Partner government ministries (e.g., Ministry of Health), sub-units of government ministries, and parastatal organizations in the country served by the PEPFAR program are considered local partners. A parastatal organization is defined as a fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations. However, ultimate control over the organization rests with the government.

Note: To be considered a local partner, the applicant must submit supporting documentation demonstrating their organization meets at least one of the three criteria listed above.

2. Special Eligibility Requirements:

All applications will be initially reviewed for completeness by the Procurement and Grants Office (PGO) staff. Applications that do not include a budget narrative and project narrative will be determined non-responsive. Complete applications will be jointly reviewed for responsiveness by HHS/CDC Division of Global HIV/AIDS and PGO. Non-responsive applications will not advance through the review process. Applicants will be notified the application did not meet eligibility and/or published submission requirements.

Non-Responsive Criteria

The list below contains criteria for determining responsiveness to this FOA:

- Late submissions will be determined non-responsive. Please see section D, "Application and Submission Information," Part 4, "Submission Dates and Times" for the application deadline date. Please also see Section 16, "Other Submission Requirements" for information on technical difficulties and paper submission. All requests to submit a paper application must be received at least three calendar days prior to the application deadline.
- The applicant's proposed budget for year one must not exceed the ceiling of the individual award range listed in Section B, "Award Information." If a funding amount greater than the ceiling of the individual award range is requested for year one, the application will be considered non-responsive and will not be entered into the review process.

Page Limitations

- Applicants must abide by the page number limitation listed in Section D, #10 Project Narrative. Any pages submitted beyond the number of pages listed for the project narrative will not be reviewed.
- If the total amount of appendices includes more than 90 pages, any pages after page 90 of the appendix will not be considered for review. For this purpose, all appendices must have page numbers and must be clearly identified in the Table of Contents as appendices.

3. Justification for Less than Maximum Competition:

N/A

4. Other:

N/A

5. Cost Sharing or Matching:

Cost sharing or matching funds are not required for this program. Although there is no statutory match requirement for this FOA, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

6. Maintenance of Effort:

Maintenance of Effort is not required for this program.

D. Application and Submission Information

Additional materials that may be helpful to applicants:
http://www.cdc.gov/od/pgo/funding/docs/FinancialReferenceGuide.pdf.

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 follow the instruction 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 (CCR)	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will 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:

Download the application package from 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 1-888-32-6348.

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.

a. **Letter of Intent (LOI) Deadline Date**: (must be postmarked by): N/A

b. **Application Deadline Date:** October 15, 2014, 2014, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. Late submissions will be considered non-responsive.

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.

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/od/pgo/funding/grants/foamain.shtm

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. Content and Form of Application 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):

A letter of intent is not applicable to this funding opportunity announcement.

8. Table of Contents:

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. There is no page limit. The table of contents is not included in the project narrative page limit

9. Project Abstract Summary:

(Maximum of 1 page)
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**

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).

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

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. In addition to the project period outcomes required by CDC, applicants should include any additional outcomes they anticipate.

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[8] (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).

1. **Collaborations:** Applicants must describe how they will collaborate with CDC funded programs as well as with organizations external of CDC.

2. **Target Populations:** Applicants must describe the specific target population(s) to be addressed in their jurisdiction to allocate limited resources, target those at greatest health risk, and achieve the greatest health impact. Applicants should use data, including social determinants data, to identify communities within their jurisdictions or community served that are disproportionately affected by the public health problem, and plan activities to reduce or eliminate these disparities. Disparities by race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions (e.g., tribal communities) should be considered.

   Inclusion: N/A

c. **Applicant Evaluation and Performance Measurement Plan:** Applicants must provide an overall jurisdiction or community-specific 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.

[8] http://www.thecommunityguide.org/index.html

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 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 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 six months of the project, as outlined in the reporting section of the FOA.

d. **Organizational Capacity of Awardees to Execute the Approach:**
Applicant must address the organizational capacity requirements as described in the CDC Project Description. Applicants must submit CVs/Resumes of the Principal Investigator (PI)/Project Director and Business Service Official, as well as detailed job descriptions of key positions to be created necessary for program development and implementation. Please distinguish between existing vs. new staff resources dedicated to this project. Applicants must also submit Organizational Charts. These items must be submitted as part of the appendix, clearly named "CVs/Resumes," "Job Descriptions," and "Organizational Charts," and uploaded as PDF files at www.grants.gov.

11. Work Plan:

(Included in the Project Narrative- 18 page limit)
Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies, and activities, evaluation and performance measurement, including key milestones.

12. Budget Narrative:

Applicants must submit an itemized, line-item budget and narrative with staffing breakdown (i.e., name, position title, annual salary, percentage of time and effort, and amount requested) and justification for all requested costs for the first budget period. Budgets must be consistent with the purpose, objectives of the Emergency Plan, and the program activities listed in this announcement. When developing the budget narrative, applicants should 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

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).

When developing the budget narrative, applicants should consider whether the proposed budget is reasonable and consistent with the purpose, outcomes and program strategy outlined in the project narrative. All budget justification pages must be numbered.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

Applicants should name this "Budget Narrative" and upload 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 should name this file "Indirect Cost Rate" and upload to www.grants.gov.

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. The applicant will be notified that the application did not meet the eligibility requirements.

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 can be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. This builds upon the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Tobacco Policies:

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

Nutrition Policies:

1. Healthy food service guidelines should at a minimum, align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf)
2. The following are resources for healthy eating and tobacco free workplaces:
   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.
- Pre-award costs may be allowable for successful applicants under this FOA prior to award.
- 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-GH15-1542."

- **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 India. 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.

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

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 include the following three items:

1. Include the www.grants.gov case number assigned to the inquiry;
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, 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:
Applications will be reviewed in three phases

a. Phase I Review:

All applications will be reviewed initially for completeness by the CDC's Procurement and Grants Office (PGO) staff and will be reviewed jointly for eligibility by the CDC Division of Global HIV/AIDS and PGO. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance to Phase II review. Applicants will be notified that the application did not meet eligibility and/or published submission requirements.

b. Phase II Review:

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

Ability to Carry Out the Proposal (15 points):
Does the applicant demonstrate the local experience in India and institutional capacity (both management and technical) to achieve the goals of the FOA with documented good governance practices? (5 points)
Does the applicant have the ability to coordinate and collaborate with Host Country Government, existing Emergency Plan partners and other donors, including the Global Fund and other U.S. Government Departments and agencies involved in implementing the President's Emergency Plan, including the U.S. Agency for International Development? (5 points)
Is there evidence of current or past efforts in supporting PWID interventions in the country? Where applicable, does the applicant have the capacity to expand comprehensive package of PWID services in hard to reach areas and in locations where there is high burden of PWID? Where applicable, does the organization have the ability to target audiences that frequently fall outside the reach of the traditional media, and in local languages? To what extent does the applicant provide letters of support? (5 points)

Technical and Programmatic Approach (25 points):
Does the application include an overall strategy, including measurable time lines, clear monitoring

and evaluation procedures, and specific activities for meeting the proposed outcomes? (8 points)
Does the applicant display knowledge of the strategy, principles and goals of the PWID program of the Indian National AIDS Control Program (NACP)? (6 points)
Does the applicant describe activities that are evidence based, realistic, achievable, measurable and culturally appropriate to achieve the PWID program goals of NACP? (6 points)
Does the application propose to build on and complement the current national response with evidence-based strategies designed to meet the goals of the NACP? Does the application include reasonable estimates of output targets? (For example, the numbers of sites to be supported, number of clients the program will reach.) To what extent does the applicant propose to work with other organizations? (5 points)
The reviewers will assess the feasibility of the applicant's plan to meet the outcomes, congruency of application with the logic model, whether the proposed use of funds is efficient, and the extent to which the specific methods described are appropriate for the local culture.

Understanding of the Problem (10 points):
Does the applicant demonstrate a clear and concise understanding of the current national HIV/AIDS response and the cultural and political context relevant to the programmatic areas targeted? (5 points)
Does the applicant display an understanding of the PWID prevention, care and treatment (comprehensive package) efforts in the country including the gaps in the program? (5 points)

Capacity Building (15 points):
Does the applicant have a proven track record of building the capacity of government and non-governmental organizations and individuals? (5 points)
Does the applicant have relevant experience in using participatory methods, and approaches, in project planning and implementation? (5 points)
Does the applicant describe an adequate and measurable plan to progressively strengthen the capacity of government and non-governmental organizations to respond to the epidemic? (5 points)

Monitoring and Evaluation (15 points):
Does the applicant demonstrate the local experience and capability to implement performance monitoring and rigorous evaluation of the project? (5 points)
Does the evaluation and performance measurement plan appropriately address the components specified in this announcement (i.e. key evaluation questions, types of evaluations to be conducted, performance measures (i.e., indicators), how often performance measures must be reported, how evaluation and performance measurement will track how target populations are affected by FOA strategies, how evaluation findings and performance measures will be used and yield findings to demonstrate the value of the FOA, and how results will be disseminated)? (5 points)
Does the applicant describe a performance monitoring system used to routinely review data and adjust program activities accordingly? Are performance measures (i.e., indicators) developed for each program milestone, and incorporated into the financial and programmatic reports? (3 points)
Does the applicant demonstrate a system able to generate financial and program reports to show disbursement of funds, and progress towards achieving the numerical objectives of the President's Emergency Plan and HHS/CDC priorities? (2 points)

Personnel (15 points):
Does the organization employ staff fluent in local languages who will work on this project? (3 points)
Are the staff roles clearly defined? (5 points)
As described, will the staff be sufficient to meet the goals of the proposed project? (3 points)

Is staff involved in this project qualified to perform the tasks described? Curricula vitae provided should include information that they are qualified in the following: Strengthening the national PWID response in the country. (4 points)

Administration and Management (5 points):
Does the applicant provide a clear plan for the administration and management of the proposed activities, and to manage the resources of the program, prepare reports, monitor and evaluate activities, audit expenditures and produce collect and analyze performance data? (3 points)
Is the management structure for the project sufficient to ensure speedy implementation of the project? (2 points)
The grantee must demonstrate an ability to submit quarterly reports in a timely manner to the HHS/CDC office.

Budget (Reviewed Not Scored)
Is the itemized budget for conducting the project, along with justification, reasonable and consistent with stated objectives and planned program activities? Is the budget itemized, well justified and consistent with the goals of the President's Emergency Plan for AIDS Relief? If applicable, are there reasonable costs per client reached for both year one and later years of the project?

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

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:

Funding Preferences (30 points):
In addition to direct consideration of findings from the Objective Review Panel, funding under this award will be subject to several preferences based on programmatic needs and in-country strategic priorities. Applicants meeting the criteria set forth in these funding preferences will receive additional points beyond the possible total of 100 as follows:

Funding Preference 1: Preference to local and indigenous organizations. (20 points)
Deliverable 1: Letter from the PI clearly demonstrating how the organization meets one of the published criteria of a PEPFAR local partner, as listed in Section C.1 above
Label for Deliverable 1: Funding Preference as Local Indigenous Organization

Funding Preference 2: Preference to organizations that demonstrate experience conducting similar work in India. (10 points)
Deliverable 2: At least one annual report describing similar work in India and the outcomes of that work
Label for Deliverable 2: Funding Preference for demonstrated experience

Each funding preference deliverable must be submitted as part of the appendix, clearly named using the label for the deliverable above, and uploaded as a PDF file at www.grants.gov. Funding preference points will not be awarded to applicants who do not provide the required deliverable for the applicable funding preference. Funding preference points will not be awarded to applicants who

fail to label the supporting documentation as required to certify the deliverable for the funding preference.

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

2. Anticipated Announcement and Award Dates:

The anticipated announcement date is February 2015. The award date will be April 1, 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 administrative requirements outlined 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/od/pgo/funding/grants/additional_req.shtm

The following administrative requirements apply to this project:

Generally applicable administrative requirements (ARs):

- AR-9: Paperwork Reduction Act
- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving," October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR- 32: Executive Order 131410: Promoting Quality and Efficient Health Care in Federal Government (If applicable applicants should be aware of the program's current business needs and how they align with nationally adopted Public Health Information Network (PHIN) standards, services, practices, and policies when implementing, acquiring, and updating public health information systems.)
- AR-33: Plain Writing Act of 2010
- AR-34: Patient Protection and Affordable Care Act (e.g. a tobacco-free campus policy and a lactation policy consistent with S4207)

ARs applicable to HIV/AIDS Awards:

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

Organization Specific ARs:

- AR-8: Public Health System Reporting (Community-based non-governmental organizations)
- AR-15: Proof of Non-profit Status (Non-profit organizations)
- AR 23: Compliance with 45 C.F.R. Part 87 (Faith-based organizations)

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

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 to determine 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.

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:

(due no later than 120 days before the end of the budget period and serves as a continuation application).

This report must not exceed 35 pages excluding work plan and administrative reporting. Attachments are not permitted, but web links are allowed. The awardee must submit the Annual Performance Report via www.grants.gov no later than 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 should 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 should describe how CDC could assist them in overcoming any 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 IV. Content and Form of Application Submission, Budget Narrative Section
  - ✓ Indirect Cost Rate Agreement
  - ✓ 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 India 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.

iv. Monitoring Reporting and Evaluation:

CDC programs must ensure that grantee's Evaluation and Performance Measurement Plan is aligned with the strategic information guidance established by OGAC and other HHS/CDC requirements, including PEPFAR's Monitoring Reporting and Evaluation (MER) strategy and CDC's Data for Partner Monitoring Program (DFPM).

v. Federal Financial Reporting:

The annual FFR form (SF-425) is required and must be submitted through eRA Commons[9] 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.

vi. 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. The page limit for this report is not to exceed 40 pages.

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.

[9] https://commons.era.nih.gov/commons/

- 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 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.

5. Programmatic Impact Reporting and Monitoring:

A. The recipient is responsible for managing and monitoring each project, program, subaward, function or activity supported through this Agreement. Recipients must monitor subawards to ensure that subrecipients have met the programmatic impact requirements as set forth in the subrecipient's agreement.

B. The recipient must submit the original and two copies of annual and quarterly Performance reports and quarterly pipeline analysis reports. Annual reports must be due 90 calendar days after the award year and quarterly reports must be due 30 days after the reporting period. The final performance reports are due 90 calendar days after the expiration or termination of this Agreement.

C. Performance reports must generally contain, for each award, brief information on each of the following:

- A comparison of actual accomplishments with the goals and objectives previously established for the period, including metrics outlined in the monitoring and evaluation plan (section on M&E), any findings of an external entity, or both. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data must be included in the reports and be related to cost data for computation of unit costs. Also included should be a brief description of the methods used to assure and assess the quality of the quantitative data, including any remediation taken to improve findings of poor data quality.

- Reasons why established goals for the performance period were not met, if appropriate.
- Other pertinent information including, when appropriate, statutory or Congressional reporting requirements, analysis and explanation of cost overruns or high unit costs reported in financial reports.
- The recipient must immediately notify the awarding agency of developments that have a significant impact on the award-supported activities. Also, recipients must give notification immediately in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification must include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.
- The Pipeline Analysis report must contain expenditures versus budget as identified in work plan, description of challenges, and explanation of unexpected pipeline (high or low).

The recipient is required to submit in a timely manner both quarterly and annual program results for all relevant programmatic indicators in accordance with U.S. government guidance.

6. Monitoring and Evaluation:

A. The recipient must submit a monitoring and evaluation plan for approval, and carry out monitoring and evaluation activities in accordance with the approved monitoring and evaluation plan. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC or other guidance otherwise applicable to this Agreement.

B. HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the Activities and use of HHS/CDC funding under this Agreement, must require a provision to this effect in all sub-awards or contracts financed by funds under this Agreement. Where applicable, this includes support for, and response to, activities associated with the Site Monitoring System and implementation of Data and Service Quality Assessments.

7. Expenditure Analysis

Recipients of PEPFAR funds are required to report annually on program expenditures. Specifically, annual completion of PEPFAR Program Expenditures (Form DS-4213, approved by OMB 1405-0208, or the relevant OMB-approved format) will be required in conjunction with the PEPFAR Annual Progress Report at the completion of the USG fiscal year.

8. Audit, Books, and Records Clause:

A. Reports and Information. The recipient must furnish HHS/CDC accounting records and such other information and reports relating to the Agreement as HHS/CDC may reasonably request.

B. The Recipient Agreement Books and Records. The recipient must maintain accounting books, records, documents and other evidence relating to the Agreement, adequate to show, without limitation, all costs incurred by the recipient, the receipt and use of goods and services acquired by the recipient, agreed-upon cost sharing requirements, the nature and extent of solicitations of prospective suppliers of goods and services acquired by the recipient, the basis of award of recipient contracts and orders, and the overall progress of the Agreement toward completion ("Agreement books and records"). The recipient must maintain Agreement books and records in accordance with generally accepted accounting principles prevailing in the United States, or at the recipient's option, with approval by HHS/CDC, other accounting principles, such as those (1) prescribed by the

International Accounting Standards Committee (an affiliate of the International Federation of Accountants), or (2) prevailing in the country of the recipient. Agreement books and records must be maintained for at least three years after the date of last disbursement by HHS/CDC or for such longer period, if any, required to resolve any litigation, claims or audit findings.

C. Partner Government Audit. If $300,000 or more of US Government funds are expended by the recipient in its fiscal year under the Agreement, the recipient must have financial audits made of the expenditures in accordance with the following terms, except as the Parties may otherwise agree in writing:

   i. The recipient must use its Supreme Audit Institution (SAI), if the SAI is approved by HHS/CDC, or select an independent auditor to perform the audit in accordance with the guidelines issued by HHS/CDC.
   ii. The audit must determine whether the receipt and expenditure of the funds provided under the Agreement are presented in accordance with generally accepted accounting principles agreed to in Section 2 above and whether the recipient has complied with the terms of the Agreement. Each audit must be submitted to HHS/CDC no later than nine months after the close of the recipient's year under audit.

D. Sub-recipient Audits. The recipient, except as the Parties may otherwise agree in writing, must ensure that "covered" sub-recipients, as defined below, are audited, and submit to HHS/CDC, no later than the end of the recipient's year under audit, in form and substance satisfactory to HHS/CDC, a plan for the audit of the expenditures of "covered" sub-recipients, as defined below, that receive funds under this Agreement pursuant to a direct contract or agreement with the recipient.

   i. "Covered" sub-recipient is one who expends $300,000 or more in its fiscal year in "US Government awards" (i.e. as recipients of US Government cost reimbursable contracts, grants or cooperative agreements).
   ii. The plan must describe the methodology to be used by the recipient to satisfy its audit responsibilities for covered sub-recipients. The recipient may satisfy such audit responsibilities by relying on independent audits of the sub-recipients; expanding the scope of the independent financial audit of the recipient to encompass testing of sub-recipients' accounts; or a combination of these procedures.
   iii. The plan must identify the funds made available to sub-recipients that will be covered by audits conducted in accordance with audit provisions that satisfy the recipient's audit responsibilities.
   iv. The recipient must ensure that covered sub-recipients under direct contracts or agreements with the recipient take appropriate and timely corrective actions; consider whether sub-recipients' audits necessitate adjustment of its own records; and require each such sub-recipient to permit independent auditors to have access to records and financial statements as necessary.

E. Audit Reports. The recipient must furnish or cause to be furnished to HHS/CDC an audit report for each audit arranged for by the recipient in accordance with this Section within 30 days after completion of the audit and no later than nine months after the end of the period under audit.

F. Cost of Audits. Subject to HHS/CDC approval in writing, costs of audits performed in accordance with the terms of this Section may be budgeted for, and charged to, the Agreement so long as such costs are allowable, allocable, and reasonable as defined in the Cost Allowability section of this Agreement.

G. Audit by HHS/CDC. HHS/CDC retains the right to perform the audits required under this Agreement on behalf of the recipient conduct a financial review, or otherwise ensure accountability of organizations expending US Government funds regardless of the audit requirement.

H. Opportunity to Audit or Inspect. The recipient must afford authorized representatives of HHS/CDC the opportunity at all reasonable times to audit or inspect activities financed under the Agreement, the utilization of goods and services financed by HHS/CDC, and books, records and other documents relating to the Agreement.

I. Sub-recipient Books and Records. The recipient will incorporate paragraphs (1), (2), (4), (5), (6), (7) and (8) of this provision into all sub-agreements with non-U.S. organizations which meet the $300,000 threshold of paragraph (3) of this provision. Sub-agreements with non-U.S. organizations, which do not meet the $300,000 threshold, must, at a minimum, incorporate paragraphs (7) and (8) of this provision. Sub-agreements with U.S. organizations must state that the U.S. organization is subject to the audit requirements contained in OMB Circular A-133.

9. Reporting of Foreign Taxes

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

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

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

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

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

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

5) Contents of Reports: The reports must contain:
   a. grantee name;
   b. contact name with phone, fax, and e-mail;
   c. agreement number(s) if reporting by agreement(s);
   d. reporting period;
   e. amount of foreign taxes assessed by each foreign government;
   f. amount of any foreign taxes reimbursed by each foreign government;
   g. amount of foreign taxes unreimbursed by each foreign government.

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

10. Human Subjects Restrictions:

Data collection protocols required for release of human subjects funding restrictions must be submitted to the DGHA Science Office within 6 months of notification of such restrictions, 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 subsequent budget period after the award or continuation has been made, provided that the Grantee has not been granted an exception to the deadlines specified above.

G. Agency Contacts

CDC encourages inquiries concerning this announcement.

For **programmatic technical assistance**, contact:

Ronald Peterson , Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
U.S. Embassy,
Chanakyapuri, New Delhi – 110 021, India
Telephone: +91-11-2419-8649 or +1-404-553-8546
Email: EAQ7@cdc.gov

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

Steward Nichols, Grants Management Officer
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS K75
Atlanta, GA 30341
Telephone: 770-488-2788
Email: shn8@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 must 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, that document will not be reviewed.

- Project Abstract (required form)
- CDC Assurances and Certifications (required form)
- Table of Contents for Entire Submission (no page limit)
- Project Narrative/Work Plan (maximum 18 pages)
- Budget Narrative (no page limit)
- SF424 (required form)
- SF424A (required form)

Applicants may submit additional information in an Appendix. The appendices will not be counted toward the project narrative page limit. **The total amount of appendices must not exceed 90 pages**. Any pages after page 90 of the appendix will not be considered for review. The following documents must be included in the application appendices:

- **Resumes/CVs of current key staff** who will work on the activity, including, but not limited to: Principal Investigator, Business Official, Project Manager
  - **Please refer to Section D, #10, part d, "Organizational Capacity of Awardees to Execute the Approach" for specific job descriptions required in this FOA, as applicable**
- **Job Descriptions** of proposed key positions to be created for the activity, including, but not limited to: Principal Investigator, Business Official, Project Manager
  - **Please refer to Section D, #10, part d, "Organizational Capacity of Awardees to Execute the Approach" for specific job descriptions required in this FOA, as applicable**
- **Letters of support:** See Collaborations section and Funding Preference section, as applicable
- **Memorandums of Understanding/Agreements (MOU/MOA):** See Collaborations section and Funding Preference section, as applicable
- **Organizational Chart**
- **Negotiated Indirect Cost Rate Agreement,** if applicable
- **Non-profit organization IRS status forms,** if applicable
- ***Funding Preference deliverables:*** See Funding Preference section in Section E, as applicable
  - ***If applying for the funding preference for local partner,*** the applicant must submit documentation to self-certify how the applicant meets the PEPFAR local partner definition listed in Section C, Eligibility Information in this FOA. The applicant must label the supporting documentation as "Eligibility Documentation for **PEPFAR Local Partner Definition**" and must clearly identify which criteria under paragraph 1, 2, or 3 their organization meets, and provide sufficient documentation

to certify how their organization meets that criterion. Funding preference points will not be awarded to applicants who do not provide and/or label the supporting documentation required to meet the PEPFAR Local Partner definition.

Any additional information submitted via www.grants.gov must be uploaded in a PDF file format, and should be clearly labeled (i.e.: Letters of support should be named "letters of support").

Amendments, Questions and Answers (Q&As)

Applicants must submit their Q&As, if any, to the Project Officer listed under the Agency Contacts Section of this announcement no later than 15 days after the publication date in www.grants.gov. All Q&As will be published on the DGHA Website http://www.cdc.gov/globalaids/global-hiv-aids-at-cdc/FOA.html.

All changes, updates, and amendments to the FOA will be posted to www.grants.gov following the approval of CDC.

For additional information on reporting requirements, visit the CDC website at: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

Other CDC funding opportunity announcements can be found on Grants.gov website, at the following internet address: http://www.grants.gov.

I. Glossary

Administrative and National Policy Requirements, Additional Requirements (ARs): outline 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/od/pgo/funding/grants/additional_req.shtm.

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=0bebbc3b3261e255dc82002b83094717&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 similar staff 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.