

AMENDMENT II (03/24/2011)

1. **Pages 66-67** - Questions and Answers from the Pre-Application Workshop

AMENDMENT I (03/01/2011)

1. **Page 60 –Added language:**

Pre-Application Workshop

CDC South Africa will host three pre-application workshops, as follows:

- Johannesburg: March 9, 2011
- Durban: March 10, 2011
- Cape Town: March 11, 2011

Applicants should contact Katherine Robinson (RobinsonK@sa.cdc.gov) regarding time, venue, and registration details.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

**Support for Strengthening and Expanding HIV/AIDS Surveillance Activities in the
Republic of South Africa under the President’s Emergency Plan for AIDS Relief
(PEPFAR)**

I. AUTHORIZATION AND INTENT

Announcement Type: New

Funding Opportunity Number: CDC-RFA-GH11-1154

Catalog of Federal Domestic Assistance Number: 93.067

Key Dates:

Application Deadline Date: April 25, 2011, 5:00pm U.S. Eastern Standard Time

Authority:

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).

Background:

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. As called for by the PEPFAR Reauthorization Act of 2008, initiative goals over the period of 2009 through 2013 are to treat at least three million HIV infected people with effective combination anti-retroviral therapy (ART); care for twelve million HIV infected and affected persons, including five million orphans and vulnerable children; and prevent twelve million infections worldwide (3,12,12). To meet these goals and build sustainable local capacity, PEPFAR will support training of at least 140,000 new health care workers in HIV/AIDS prevention, treatment and care. The Emergency Plan *Five-Year Strategy* for the five year period, 2009 - 2014 is available at the following Internet address:
<http://www.pepfar.gov>.

With a population of approximately 50 million people (0.7% of the world's population), South Africa accounts for 17% (5.7 million people) of the global burden of disease related to HIV infection. The HIV burden explains a significant portion of the reduction

in life expectancy over the past 15 years which is now 53.5 years for men and 57.2 years for women. The maternal mortality ratio is 625 per 100,000 live births with 43.7% of deaths related to HIV disease. HIV prevalence among people > 2 years old has stabilized at 10.9% while increasing slightly for those aged 15-49 to 16.9% since 2005 (*South African National HIV Prevalence, Incidence, Behavior, and Communication Survey* 2002, 2005, and 2008). However, prevalence among 2-14 year olds has declined over this period from 5.6% to 2.5%. The HIV epidemic is not uniform and varies between and within provinces. Data from the *2008 National Antenatal Sentinel HIV and Syphilis Prevalence Survey* indicates that districts are heterogenous with regard to prevalence; district rates range from over 45% to around 5%.

Currently, different HIV/AIDS data collection systems exist throughout South Africa for various purposes; however, comprehensive national surveillance is unavailable. The information gathered by surveillance systems is essential for the South African government, partners and independent partners in mounting a national response to the HIV/AIDS epidemic. HIV/AIDS surveillance is a crucial part of a comprehensive strategy to monitor the HIV epidemic.

Purpose:

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.
- 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.

The purpose of this program is to develop, implement, and evaluate new HIV surveillance activities, where necessary, or to strengthen current HIV surveillance activities in South Africa. These activities will enable the South African government and its partners to monitor and assess the HIV epidemic through surveys and surveillance to better target resources nationally.

Applicants are expected to respond to one or more of the following program activities and submit a separate application and budget for the program area they intend to implement or work in:

1. National Population-based Household Survey

2. National HIV Drug Resistance Surveillance
3. National Pharmacovigilance Surveillance.
4. Surveillance of HIV Positive pre-ART Persons
5. HIV Surveillance in Underserved Groups at High Risk or Special Populations such as, but not limited to, MSM, intravenous drug users, sex workers, discordant couples, health professionals, migrant workers, military personnel, prisoners, and/or teachers
6. Maternal and Infant Mortality Surveillance
7. Monitoring the use and outcomes of biomedical HIV prevention interventions

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s):

- 1) In the first year, the applicant will be expected to work in collaboration with all stakeholders listed above to provide the following measurable outcomes for the national, population-based household survey:
 - a) Complete a gap analysis to identify areas of the survey to change or strengthen;
 - b) Develop a workplan outlining program activities, targets and outcomes including:
 - i) Begin development of the protocol based on previous survey methodology to ensure the ability to track trends over time
 - ii) Begin to develop methodology, implementation, and analysis plan
 - iii) Begin the process to obtain local IRB approval
 - iv) Begin the process to obtain approval from the CDC Associate Director for Science (ADS).

In subsequent years, the survey will be conducted every three years starting in 2014 and should provide the following outcome measures:

- a) Revise the master sample of households, when necessary after five year or after a census;
- b) Develop spatial maps for selection of households;
- c) Build capacity by selecting and training field workers and other program staff building on existing training curricula from previous surveys;
- d) Modify questionnaire for necessary changes at that time;
- e) Conduct survey in timeframe outlined in protocol;
- f) Develop a monitoring system for quality assurance and accountability towards service delivery;
- g) Data collection and analysis to include the following indicators:
 - i) HIV prevalence
 - ii) HIV incidence
 - iii) Current behavior practices
 - iv) Current HIV knowledge
 - v) Trends over time for incidence, prevalence, behaviors and HIV knowledge
 - vi) Presentation of findings to stakeholders and dissemination to public domains
 - vii) Peer-reviewed publications within one year of the initial report to the national department of health.

- 2) In the first year, the applicant will be expected to work in collaboration with all stakeholders listed above to provide the following measurable outcomes for the national HIV drug resistance surveillance:
- a) Complete a gap analysis to identify areas of need and determine direction;
 - b) Establish the objectives of the system in line with PEPFAR and SAG priorities;
 - c) Begin development of a protocol with methodology and analysis plan;
 - d) Begin the process to obtain local IRB approval;
 - e) Begin the process to obtain approval from CDC ADS;
 - f) Design report forms for data collection;
 - g) Develop SOPs for specimen and data collection; and
 - h) Design data flow structures.

In subsequent years, the applicant will begin implementation of the surveillance on a national scale and should provide the following outcome measures:

- a) Identification and selection of provinces where system will be implemented initially and subsequently;
- b) Meet with national, provincial and CDC stakeholders to present plan;
- c) Build capacity by identifying testing sites and conducting training ;
- d) Perform data collection and analysis routinely
 - i) Prevalence of HIV drug resistance
 - ii) Spectrum of HIV resistance
 - iii) Quarterly trends in resistance overall and specific patterns

- e) Develop a monitoring system for quality assurance and accountability towards service delivery;
 - f) Evaluate the performance of the surveillance system via a formal audit; and
 - g) Disseminate findings nationally and internationally, both reports and peer-reviewed publications
- 3) In the first year, the applicant will be expected to work in collaboration with all stakeholders listed above to provide the following measureable outcomes for national Pharmacovigilence surveillance:
- a) Complete a gap analysis to identify areas of need and determine objectives;
 - b) Establish the objectives of the system in line with PEPFAR and SAG priorities ;
 - c) Develop a workplan outlining program activities, targets and outcomes including:
 - i) Begin development of a protocol with methodology and analysis plan
 - ii) Begin the process to obtain local IRB approval
 - iii) Begin the process to obtain approval from CDC ADS
 - iv) Design report forms for data collection
 - v) Develop SOPs for specimen and data collection
 - vi) Design data flow structures

In subsequent years, the applicant will begin implementation of the surveillance on a national scale and should provide the following outcome measures:

- a) Identification and selection of provinces where system will be implemented initially and subsequently;
 - b) Meet with national, provincial and CDC stakeholders to present plan;
 - c) Build capacity through identifying sites and conducting training;
 - d) Perform data collection and analysis routinely to provide:
 - i) Prevalence of adverse drug reactions in patients on antiretroviral therapy, TB therapy, traditional, complementary and herbal medicines
 - ii) Quarterly trends in adverse drug reactions and/or other patterns
 - e) Develop a monitoring system for quality assurance and accountability towards service delivery;
 - f) Evaluate the performance of the surveillance system via a formal audit; and
 - g) Disseminate findings nationally and internationally, both reports and peer-reviewed publications.
- 4) In the first year, the applicant will be expected work in collaboration with all stakeholders listed above to provide the following measurable outcomes for surveillance of HIV-positive persons for care (ART or pre-ART) services over time:
- a) Complete a gap analysis to identify areas of need and to provide direction in program setup and objectives;
 - b) Ensure the objectives of the system are in line with PEPFAR and SAG priorities;
 - c) Develop a workplan outlining program activities, targets and outcomes including:
 - i) Begin development of a protocol with methodology and analysis plan

- ii) Begin the process to obtain local IRB approval
- iii) Begin the process to obtain approval from CDC ADS
- iv) Design report forms for data collection
- v) Develop SOPs for specimen and data collection
- vi) Design data flow structures

In subsequent years, the applicant will begin implementation of the surveillance activity and should provide the following outcome measures:

- a) Identify and select geographic areas where system will be implemented initially and subsequently;
- b) Meet with national, provincial and CDC stakeholders to present plan;
- c) Build capacity through identifying sites and conducting training;
- d) Track persons with HIV from the time they test positive until they qualify for ART;
- e) Perform data collection and analysis routinely;
 - i) Number of persons testing HIV positive;
 - ii) Proportion of newly diagnosed cases not qualifying for ART and not in care
 - iii) Proportion of newly diagnosed cases qualifying for ART but not in care
 - iv) Proportion of newly diagnosed cases counseled pre-ART
 - v) Proportion of newly diagnosed cases starting ART
- f) Develop a monitoring system for quality assurance and accountability towards service delivery;

- g) Evaluate the performance of the surveillance system via a formal audit; and
 - h) Disseminate findings nationally and internationally, both reports and peer reviewed publications.
- 5) In the first year, the applicant will be expected to work in collaboration with all stakeholders listed above to provide the following measureable outcomes for each underserved groups at high risk or special populations of interest such as, but not limited to, MSM, intravenous drug users, sex workers, discordant couples, health professionals, migrant workers, military personnel, prisoners, and/or teachers:
- a) Complete a gap analysis to identify areas of program need, direction and objectives;
 - b) Ensure the objectives of the survey or surveillance are in line with PEPFAR and SAG priorities; and
 - c) Develop a workplan outlining program activities, targets and outcomes including:
 - i) Begin development of a protocol with methodology and analysis plan
 - ii) Begin the process to obtain local IRB approval
 - iii) Begin the process to obtain approval from CDC ADS
 - iv) Design questionnaires and consent forms for data collection
 - v) Design data flow structures

In subsequent years, the applicant will begin implementation of the surveillance or survey and should provide the following outcome measures for each underserved groups at high risk or special populations population of interest:

- a) Identify and select geographic areas where surveillance or survey will be implemented;
 - b) Meet with national, provincial and CDC stakeholders to present plan;
 - c) Build capacity through identifying sites and conducting training;
 - d) Perform data collection and analysis to provide:
 - i) Prevalence of HIV in the population of interest
 - ii) Identification of risk behaviors and factors
 - e) Develop a monitoring system for quality assurance and accountability towards service delivery; and
 - f) Disseminate findings nationally and internationally, both reports and peer-reviewed publications.
- 6) In the first year, the applicant will be expected to work in collaboration with all stakeholders listed above to provide the following measureable outcomes for maternal and infant mortality surveillance:
- a) Complete a gap analysis to identify areas of need and direction;
 - b) Establish the objectives of the system in line with PEPFAR and SAG priorities;
 - c) Develop a workplan outlining program activities, targets and outcomes including:
 - i) Begin development of a protocol with methodology and analysis plan

- ii) Begin the process to obtain local IRB approval
- iii) Begin the process to obtain approval from CDC ADS
- iv) Design report forms for data collection
- v) Develop SOPs for data collection
- vi) Design data flow structures

In subsequent years, the applicant will begin implementation of the surveillance activity and should provide the following outcome measures:

- a) Identify and select geographic areas where system will be implemented initially and subsequently;
- b) Meet with national, provincial, and CDC stakeholders to present plan;
- c) Build capacity through identifying sites and conducting training;
- d) Perform data collection and analysis routinely to provide:
 - i) Infant mortality rate
 - ii) Maternal mortality rate
 - iii) Proportion of maternal and infants deaths due to HIV
 - iv) Proportion of maternal and infants deaths in hospitals vs. community
- e) Develop a monitoring system for quality assurance and accountability towards service delivery;
- f) Evaluate the performance of the surveillance system via a formal audit; and
- g) Disseminate findings nationally and internationally, both reports and peer reviewed publications.

7) In the first year, the applicant will be expected to work in collaboration with all stakeholders listed above to provide the following measurable outcomes for each biomedical HIV prevention intervention studied:

- a) Complete a gap analysis to identify areas of need and direction;
- b) Establish the objectives of the system in line with PEPFAR and SAG priorities;
- c) Develop a workplan outlining program activities, targets and outcomes including:
 - i) Begin development of a protocol with methodology and analysis plan
 - ii) Begin the process to obtain local IRB approval
 - iii) Begin the process to obtain approval from CDC ADS
 - iv) Design questionnaires and consent forms for data collection
 - v) Design data flow structures

In subsequent years, the applicant will begin implementation of the survey and should provide the following outcome measures:

- a) Identify and select geographic areas where survey will be implemented;
- b) Meet with national, provincial and CDC stakeholders to present plan;
- c) Identify sites and conduct training;
- d) Perform data collection and analysis:
 - i) Prevalence of persons that have used a particular biomedical HIV prevention intervention

- ii) Prevalence of outcomes of persons that have used a particular biomedical HIV prevention intervention
- e) Disseminate findings nationally and internationally, both reports and peer reviewed publications.

This announcement is only for non-research activities supported by the Centers for Disease Control and Prevention within HHS (HHS/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>

II. PROGRAM IMPLEMENTATION

Recipient Activities:

Partners receiving HHS/CDC funding must place a clear emphasis on developing local indigenous capacity to deliver HIV/AIDS related services to the South African population and must also coordinate with activities supported by South African, international or USG agencies to avoid duplication. Partners receiving HHS/CDC funding must collaborate across program areas whenever appropriate or necessary to improve service delivery.

The selected applicant(s) of these funds is responsible for activities in multiple program areas.

The grantee will implement activities both directly and, where applicable, through sub-grantees; the grantee will, however, retain overall financial and programmatic management under the oversight of HHS/CDC and the strategic direction of the Office of the U.S. Global AIDS Coordinator. The grantee must show measurable progressive reinforcement of the capacity of health facilities to respond to the national HIV epidemic as well as progress towards the sustainability of activities.

Applicants should describe activities in detail that reflect the policies and goals outlined in the *Five-Year Strategy* for the President's Emergency Plan and the Partnership Framework for South Africa. The grantee will produce an annual operational plan, which the U.S. Government Emergency Plan team on the ground in South Africa will review as part of the annual Emergency Plan review-and-approval process managed by the Office of the U.S. Global AIDS Coordinator.

The grantee may work on some of the activities listed below in the first year and in subsequent years, and then progressively add others from the list to achieve all of the Emergency Plan performance goals as cited in the previous section. HHS/CDC, under the guidance of the U.S. Global AIDS Coordinator, will approve funds for activities on an annual basis, based on availability of funding and USG priorities, and based on documented performance toward achieving Emergency Plan goals, as part of the annual Emergency Plan for AIDS Relief Country Operational Plan review-and-approval process.

Grantee activities for this program are as follows:

1. To monitor the health of the South African population through a national population-based household survey that specifically estimates HIV prevalence, incidence, and behavior trends.
 - a. Develop, coordinate, conduct, and disseminate findings from the survey to be conducted every three years. Findings should include HIV prevalence and incidence estimates by province as well as changes in trends for various behaviors and knowledge;
 - b. Review and clarify the sample design, content of questionnaire, data collections procedures, and dissemination of findings and recommendations;
 - c. Work closely and in full collaboration with the South African government and CDC South Africa and include representatives from both entities in all survey steering committee meetings, data reviews and launches; and
 - d. Ensure appropriate approval is obtained from CDC South Africa prior to start of survey.

2. To determine the distribution of HIV drug-resistant strains and subtypes and to monitor trends in the transmission of drug-resistant strains and the factors associated with resistance among HIV infected persons.

- a. Establish a national HIV drug resistance surveillance system to estimate the prevalence of mutations associated with HIV drug resistance, resistance patterns, and trends in dissemination of drug-resistant strains;
 - b. Develop laboratory processes, required data elements, data management, data analysis and data dissemination procedures;
 - c. Report, communicate, and disseminate drug resistance data;
 - d. Ensure appropriate approval is obtained from CDC South Africa prior to start of surveillance;
 - e. Collaborate with the South African government, CDC South Africa and others involved in existing HIV drug resistance surveillance to identify current gaps, develop recommendations for strengthening, improving or integrating current surveillance activities in the country (if they exist) or creating new system, and implement the recommendations; and
 - f. Evaluate the performance of the surveillance system.
3. To monitor the burden of drug-related morbidity and mortality in HIV infected persons.
 - a. Establish a national pharmacovigilance surveillance system to collect epidemiologic and clinical information on adverse drug reactions in HIV/AIDS patients who are placed on, but not limited to, antiretroviral therapy, TB therapy, traditional, complementary and herbal medicines;
 - b. Collect, analyze, interpret, and monitor adverse drug reactions with the use of, but not limited to, case control studies, hospital-based monitoring

systems, prescription-based monitoring systems, record linkage systems and epidemiological studies;

- c. Report, communicate, and disseminate epidemiological and clinical information on adverse drug reactions;
- d. Ensure appropriate approval is obtained from CDC South Africa prior to start of surveillance;
- e. Collaborate with the South African government, CDC South Africa and others involved in existing pharmacovigilance surveillance to identify current gaps, develop recommendations for strengthening, improving or integrating current pharmacovigilance activities in the country (if they exist) or creating new system, and implement the recommendations; and
- f. Evaluate the performance of the surveillance system.

4. To determine the prevalence of persons testing HIV positive without accessing ART or pre-ART care:

- a. Develop surveillance in conjunction with the newly initiated HIV Counseling and Testing Campaign to monitor newly diagnosed HIV cases prior to their need to access care/treatment/support to ensure timely access to care/treatment/support when it becomes necessary;
- b. The surveillance should include persons eligible for ART and not in care or ineligible for ART and not in care;

- c. Collect information on persons diagnosed with HIV who have not received care using, but not limited to, pre-ART registries, facility and community-based data;
 - d. Collect, analyze, interpret, and disseminate epidemiological and clinical information;
 - e. Ensure appropriate approval is obtained from CDC South Africa prior to start of surveillance;
 - f. Collaborate with the South African government, CDC South Africa and others involved in existing surveillance to identify current gaps, develop recommendations for strengthening, improving or integrating current surveillance activities in the country (if they exist) or creating new system, and implement the recommendations; and
 - g. Evaluate the performance of the surveillance.
5. To establish HIV Surveillance in Underserved Groups at High Risk or Special Populations.
- a. Implement surveys or surveillance to collect epidemiologic and clinical information on underserved groups at high risk or special populations such as, but not limited to, MSM, intravenous drug users, sex workers, discordant couples, health professionals, migrant workers, military personnel, prisoners, and/or teachers;
 - b. Collect, analyze, interpret, and monitor the prevalence of HIV infection in these populations using, but not limited to, population-based surveillance, facility-based surveillance, and behavioral surveys;

- c. Report, communicate, and disseminate epidemiological and clinical information on the findings;
 - d. Ensure appropriate approval is obtained from CDC South Africa prior to start of surveys or surveillance; and
 - e. Evaluate the performance of the surveillance if this methodology is used.
6. To monitor morbidity and mortality amongst pregnant women and their infants to provide information and influence the health services and policy.
- a. Strengthen maternal and infant mortality surveillance to detect pregnancy-related deaths, identify gaps in services and disseminate findings and recommendations;
 - b. Collect, analyze, interpret, and monitor pregnancy-related deaths of mothers and infants through, but not limited to, review or linkage of vital records, death certificates, medical and hospital records, prenatal and neonatal records;
 - c. Report, communicate, and disseminate epidemiological and clinical information on maternal and infant mortality;
 - d. Ensure appropriate approval is obtained from CDC South Africa prior to start of surveillance;
 - e. Collaborate with the South African government, CDC South Africa and others involved in existing maternal and infant mortality surveillance to identify current gaps, develop recommendations for strengthening, improving or integrating current surveillance activities in the country (if

they exist) or creating new system, and implement the recommendations;
and

f. Evaluate the performance of the surveillance.

7. To establish surveys or surveillance that will monitor the use and outcomes
biomedical HIV prevention interventions.

- a. Develop surveys or surveillance that will monitor biomedical HIV prevention interventions that have been scientifically tested and adopted in South Africa including but not limited to medical male circumcision, combination antiretroviral therapies and microbicides;
- b. Collect, analyze, and interpret data on the prevalence of the use and outcomes of the various biomedical HIV prevention interventions;
- c. Report, communicate, and disseminate epidemiological and clinical information on the prevalence of the use and outcomes of the various biomedical HIV prevention interventions;
- d. Ensure appropriate approval is obtained from CDC South Africa prior to start of surveys;
- e. Collaborate with the South African government, CDC South Africa and others involved in existing biomedical HIV prevention intervention monitoring; and
- f. Evaluate the performance of the surveillance if this methodology is used.

CDC Activities:

The selected applicant of this funding competition must comply with all HHS/CDC management requirements for meeting participation and progress and financial reporting for this cooperative agreement (See HHS/CDC Activities and Reporting sections below for details), and comply with all policy directives established by the Office of the U.S. Global AIDS Coordinator.

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. The in-country CDC office will organize an orientation meeting with the awardee to brief it on applicable U.S. Government, HHS, and Emergency Plan expectations, regulations and key management requirements, as well as provide technical assistance in developing report formats and contents. The orientation may include meetings with staff from HHS agencies and the Office of the U.S. Global AIDS Coordinator.
2. The in-country CDC office will review and make recommendations as necessary to the process used by the awardee 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 Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.
3. The in-country CDC office will provide technical assistance and recommendations to the awardee'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. The in-country CDC office will provide technical assistance and recommendations to the awardee's monitoring-and-evaluation plan, including for compliance with the strategic-information guidance established by the Office of the U.S. Global AIDS Coordinator.
5. The in-country CDC office will meet on a monthly basis with the awardee to assess monthly expenditures in relation to approved work plan and modify plans, as necessary.
6. The in-country CDC office will meet on a quarterly basis with the awardee to assess quarterly technical and financial progress reports and modify plans as necessary.
7. The in-country CDC office will meet on an annual basis with the awardee to review annual progress report for each U.S. Government Fiscal Year, and to review annual work plans and budgets for subsequent year, as part of the Emergency Plan for AIDS Relief review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.
8. The in-country CDC office will provide provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This may include expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, confidential counseling and testing, palliative care, treatment literacy, and adult-learning techniques.

9. The in-country CDC office will provide administrative support to help awardee meet U.S. Government financial and reporting requirements approved by the Office of Management and Budget (OMB) under 0920-0428 (Public Health Service Form 5161).
10. The in-country CDC office will collaborate with the awardee 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. The in-country CDC office provide consultation and scientific and technical assistance based on appropriate, HHS/CDC and Office of the U.S. Global AIDS Coordinator documents to promote the use of best practices known at the time.
12. The in-country CDC office will assist the awardee in developing and implementing quality-assurance criteria and procedures.
13. The in-country CDC office will provide and facilitate in-country planning and review meetings for technical assistance activities.
14. The in-country CDC office will provide technical oversight for all activities under this award.
15. The in-country CDC office will provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters.
16. The in-country CDC office will provide technical assistance with protocols for related evaluations.

17. The in-country CDC office will participate in all stakeholder meetings coordinated by the applicant not only as a donor but as a true stakeholder.
18. The in-country CDC office Act as liaison between applicant and the National Department of Health to ensure alignment with PEPFAR and South African government priorities.
19. The in-country CDC office will assist the awardee in the development of long-term capacity-development plans.
20. The in-country CDC office will provide a designated, in-country CDC point-of-contact (Activity Manager) responsible for liaising with the awardee on a regular basis on matters related to programmatic, financial, and administrative performance. The Activity Manager will regularly review the awardee's financial performance, provide oversight and approval for programmatic activities and make recommendations to the in-country CDC office on the continuation of the award, its supported activities, and associated funding.

Please note: Either HHS staff or staff from organizations that have successfully competed for funding under a separate HHS contract, cooperative agreement or grant will provide technical assistance and training.

III. AWARD INFORMATION AND REQUIREMENTS

Type of Award: Cooperative Agreement.

Award Mechanism: U2G – Global HIV/AIDS Non-Research Cooperative Agreements

Fiscal Year Funds: FY 2011

Approximate Current Fiscal Year Funding: \$2,800,000.00

Approximate Total Project Period Funding: \$20,000,000.00 (This amount is an estimate, and is subject to availability of funds and includes direct costs for international organizations or direct and indirect costs for domestic grantees for all years.)

Approximate Number of Awards: One to Seven

Approximate Average Award: \$400,000.00 (This amount is for the first 12 month budget period, and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)

Floor of Individual Award Range: \$250,000.00

Ceiling of Individual Award Range: None (This ceiling is for the first 12 month budget period and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)

Anticipated Award Date: September 2011

Budget Period Length: 12 Months

Project Period Length: Five Years

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

IV. ELIGIBILITY

Eligible applicants that can apply for this funding opportunity are listed below:

- Nonprofit with 501C3 IRS status (other than institution of higher education)

- Nonprofit without 501C3 IRS status (other than institution of higher education)
- For-profit organizations (other than small business)
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- 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 Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Non-domestic (non-U.S.) entity
- Other (specify)

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 letter from the state or local government as documentation of the status is required. Attach with “Other Attachment Forms” when submitting via www.grants.gov.

SPECIAL ELIGIBILITY CRITERIA: Licensing/Credential/Permits

Cost Sharing or Matching

Cost sharing or matching funds are not required for this program. If applicants receive funding from other sources to underwrite the same or similar activities, or anticipate

receiving such funding in the next 12 months, they must detail how the disparate streams of financing complement each other.

Maintenance of Effort

Maintenance of Effort is not required for this program.

Other

If a funding amount greater than the ceiling of the 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.

Special Requirements:

1. PEPFAR Local Partner definition:

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 within that country:

(1) an individual must be a citizen or lawfully admitted permanent resident of and have his/her principal 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 least 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 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 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 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 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 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 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 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.

Host 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 board may rest with the government.

2. If the application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. The applicant will be notified that the application did not meet submission requirements.

- Late submissions will be considered non-responsive. See section “V.3. Submission Dates and Times” for more information on deadlines.
- If the total amount of appendices includes more than 80 pages, the application 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.
- An HIV/AIDS related funding matrix must be submitted in order for the application to be considered for review. All applicants must indicate whether they are receiving other HIV/AIDS related funding. If the applicant is receiving or has applied for other HIV/AIDS related funding, the following information must be submitted:
 - ✓ Funding mechanism (i.e. contract, CoAg, grant)
 - ✓ Amount of award
 - ✓ Period performance
 - ✓ Funding agency
 - ✓ Contact details for funding agency
 - ✓ Brief description of program activities

- Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive U.S. Government funds constituting a grant, loan, or an award.

Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

V. APPLICATION CONTENT

Unless specifically indicated, this announcement requires submission of the following information:

A Project Abstract must be completed in the Grants.gov application forms. The Project Abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a technically literate lay reader. This abstract must not include any proprietary/confidential information.

The abstract must be submitted in the following format:

- Maximum of 2-3 paragraphs;
- Font size: 12 point unreduced, Times New Roman;
- Single spaced;
- Paper size: 8.5 by 11 inches (preferred), or generally accepted paper size; and
- Page margin size: One inch.

A Project Narrative must be submitted with the application forms. The project narrative must be uploaded in a PDF file format when submitting via Grants.gov. The narrative must be submitted in the following format:

- Maximum number of pages: 25 (If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.);
- Font size: 12 point, unreduced, Times New Roman;
- Double spaced;
- Paper size: 8.5 by 11 inches (preferred), or generally accepted paper size;
- Page margin size: One inch;
- Number all pages of the application sequentially from page one (Application Face Page) to the end of the application, including charts, figures, tables, and appendices; and
- *Project Context and Background (Understanding and Need):* Describe the background and justify the need for the proposed project. Describe the current infrastructure system; targeted geographical area(s), if applicable; and identified gaps or shortcomings of the current health systems and AIDS control projects;
- *Project Strategy - Description and Methodologies:* Present a detailed operational plan for initiating and conducting the project. Clearly describe the applicant's technical approach/methods for implementing the proposed project. Describe the existence of, or plans to establish partnerships necessary to implement the project. Describe linkages, if appropriate, with programs funded by the U.S. Agency for International Development;

- *Project Goals and Objectives:* Describe the overall goals of the project, and specific objectives that are measurable and time phased, consistent with the objectives and numerical targets of the Emergency Plan and for this Cooperative Agreement program as provided in the “Purpose” Section at the beginning of this Announcement;
- *Project Outputs:* Be sure to address each of the program objectives listed in the “Purpose” Section of this Announcement. Measures must be specific, objective and quantitative so as to provide meaningful outcome evaluation;
- *Project Contribution to the Goals and Objectives of the Emergency Plan:* Provide specific measures of effectiveness to demonstrate accomplishment of the objectives of this program;
- *Work Plan and Description of Project Components and Activities:* Be sure to address each of the specific tasks listed in the activities section of this announcement. Clearly identify specific assigned responsibilities for all key professional personnel;
- *Performance Measures:* Measures must be specific, objective and quantitative;
- *Timeline* (e.g., GANTT Chart); and
- *Management of Project Funds and Reporting.*

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. **The total amount of appendices must not exceed 80 pages and can only contain information related to the following:**

- *Project Budget Justification:*

With staffing breakdown and justification, provide a line item budget and a narrative with justification for all requested costs. Be sure to include, if any, in-kind support or other contributions provided by the national government and its donors as part of the total project, but for which the applicant is not requesting funding.

Budgets must be consistent with the purpose, objectives of the Emergency Plan and the program activities listed in this announcement and must include the following: line item breakdown and justification for all personnel, i.e., name, position title, annual salary, percentage of time and effort, and amount requested.

The recommended guidance for completing a detailed budget justification can be found on the HHS/CDC Web site, at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

For each contract, list the following: (1) name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities the contractor will perform; (4) period of performance; (5) method of contractor selection (e.g., competitive solicitation); and (6) methods of accountability. Applicants should, to the greatest extent possible, employ transparent and open competitive processes to choose contractors;

- *Curricula vitae* of current key staff who will work on the activity:

Overall cooperative agreement Principal Investigator and

Activity-specific Principal Investigators;

- ***Job descriptions*** of proposed key positions to be created for the activity;
- ***Applicant’s Corporate Capability Statement;***
- ***Letters of Support*** (5 letters maximum): ***Letters of support should include those from provincial and national departments of health as the activity dictates;***
- ***Evidence of Legal Organizational Structure; and***
- ***If applying as a Local Indigenous Partner,*** provide documentation to self-certify the applicant meets the PEPFAR local partner definition listed in “Special Requirements,” Part IV. ELIGIBILITY section of the FOA.

Additional requirements for additional documentation with the application are listed in Section VII. Award Administration Information, subsection entitled “Administrative and National Policy Requirements.”

APPLICATION SUBMISSION

Registering your organization through www.Grants.gov, the official agency-wide E-grant website, is the first step in submitting an application online. Registration information is located on the “Get Registered” screen of www.Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, the Grants.gov registration process also requires that you register your organization with the Central Contractor Registry (CCR) annually. The CCR registration can require an additional one to two days to complete.

International organizations also require a NATO CAGE Code (NCAGE). The NCAGE request may take from two business days to two weeks to complete. NCAGE is needed before registering with the Central Contractor Registry (CCR). After registering with CCR, the applicant can proceed to register with Grants.gov (See “Other Submission Requirements” session below for more information).

Submit the application electronically by using the forms and instructions posted for this funding opportunity on www.Grants.gov. If access to the Internet is not available or if the applicant encounters difficulty in accessing the forms on-line, contact the HHS/CDC Procurement and Grant Office Technical Information Management Section (PGO-TIMS) staff at (770) 488-2700 for further instruction.

Note: Application submission is not concluded until successful completion of the validation process.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. Applicants are strongly encouraged check the status of their application to ensure submission of their application package is complete and no submission errors exists. To guarantee that you comply with the application deadline published in the Funding Opportunity Announcement, applicants are also strongly encouraged to allocate additional days prior to the published deadline to file their application. Non-validated applications will not be accepted after the published application deadline date.

In the event that you do not receive a “validation” email within two (2) business days of application submission, please contact Grants.gov. Refer to the email message generated at the time of application submission for instructions on how to track your application or the Application User Guide, Version 3.0 page 57.

Other Submission Requirements

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

Dun and Bradstreet Universal Number (DUNS)

The applicant is required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) identifier to apply for grants or cooperative agreements from the Federal government. The DUNS is a nine-digit number which uniquely identifies business entities. There is no charge associated with obtaining a DUNS number. Applicants may obtain a DUNS number by accessing the Dun and Bradstreet website or by calling 1-866-705-5711. This is a requirement for domestic and international organizations.

Central Contractor Registration (CCR)

The applicant is required to have a CCR registration to apply for grants or cooperative agreements from the Federal government. For more information on CCR and how to register go to www.ccr.gov.

Other Submission Requirement for International Organizations:

NATO CAGE Code (NCAGE)

After obtaining DUNS, the applicant is required to have a NATO CAGE Code in order to apply for grants or cooperative agreements from the Federal government. Applicants can complete the request online at www.dlis.dla.mil/forms/Form_AC135.asp. If the organization cannot submit this form by Internet, the organization can obtain an NCAGE by contacting the National Codification Bureau of the country where the organization is located. For a list of addresses, go to www.dlis.dla.mil/nato_poc.asp. Please note that NCAGE code is required for international organizations in order to register with the Central Contractor Registration (CCR) and Grants.gov.

Electronic Submission of Application:

Applications must be submitted electronically at www.Grants.gov. Electronic applications will be considered as having met the deadline if the application has been successfully made available to CDC for processing from Grants.gov on the deadline date.

The application package can be downloaded from www.Grants.gov. Applicants can complete the application package off-line, and then upload and submit the application via the Grants.gov Web site. The applicant must submit all application attachments using a PDF file format when submitting via Grants.gov. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than PDF may result in the file being unreadable by staff.

Applications submitted through Grants.gov (<http://www.grants.gov>), are electronically time/date stamped and assigned a tracking number. The AOR will receive an e-mail notice of receipt when HHS/CDC receives the application. The tracking number serves to document submission and initiate the electronic validation process before the application is made available to CDC for processing.

If the applicant encounters technical difficulties with Grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the

clock, ensuring the best possible customer service is received any time it's needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at support@grants.gov. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Organizations that encounter technical difficulties in using www.Grants.gov to submit their application must attempt to overcome those difficulties by contacting the Grants.gov Support Center (1-800-518-4726, support@grants.gov). After consulting with the Grants.gov Support Center, if the technical difficulties remain unresolved and electronic submission is not possible to meet the established deadline, organizations may submit a request prior to the application deadline by email to PGO TIMS for permission to submit a paper application. An organization's request for permission must: (a) include the Grants.gov case number assigned to the inquiry, (b) describe the difficulties that prevent electronic submission and the efforts taken with the Grants.gov Support Center (c) be submitted to PGO TIMS at least 3 calendar days prior to the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, the applicant will receive instructions from PGO TIMS to submit the original and two hard copies of the application by mail or express delivery service.

Submission Dates and Times

This announcement is the definitive guide on application content, submission, and deadline. It supersedes information provided in the application instructions. If the application submission does not meet the deadline published herein, it will not be eligible for review and the applicant will be notified the application did not meet the submission requirements.

Application Deadline Date: April 25, 2011, 5:00pm U.S. Eastern Standard Time

VI. APPLICATION REVIEW INFORMATION

Eligible applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the “Purpose” section of this announcement. Measures of effectiveness must be objective, quantitative and measure the intended outcome of the proposed program. The measures of effectiveness must be included in the application and will be an element of the evaluation of the submitted application.

Evaluation Criteria

Note: Applicants are expected to respond only to those areas described in this announcement where they have existing expertise or experience. Applicants must submit a separate application for the program area they intend to implement or work in. In addition to the program narrative, the applicant must include a separate budget for each

proposed program and on form SF 424 item number 14, the applicant should state the program area they are applying to work in. Failure to indicate the area of work will make the application non-responsive. Competitive advantage is not given based on the number of activities proposed across program areas. Applicants will be evaluated according to the strength of their responses per program area.

Applicants are expected to respond to one or more of the following program areas:

1. National Population based Household Survey:
 - a. South Africa has conducted three large national population-based household surveys. This activity is meant to be a continuation of those surveys on an ongoing basis every three years;
 - b. The activity should be conducted in collaboration with and under the direction of the South African Government or one of its designated parastatal organizations; and
 - c. The following organizations or stakeholders should be directly involved and represented in the development and implementation of the activity:
South African Department of Health, South African National AIDS Council, and the Human Sciences Research Council.
2. National HIV Drug Resistance Surveillance:
 - a. While some HIV drug resistance activities are happening in South Africa, this activity is considered new and the purpose is to develop, implement and evaluate HIV drug resistance surveillance nationally;

- b. The activity should be conducted in collaboration with and under the direction of the South African Government or one of its designated parastatal organizations; and
 - c. The following organizations or stakeholders should be directly involved or represented in the development, implementation or evaluation of this activity: South African Department of Health, South African National AIDS Council, and the National Health Laboratory Services.
3. National Pharmacovigilance Surveillance:
- a. While pharmacovigilance surveillance is currently ongoing, it requires expansion nationally and strengthening to provide robust epidemiologic information for South Africa;
 - b. This activity should be conducted in collaboration with and under the direction of the South African Government or one of its designated organizations; and
 - c. The following organizations or stakeholders should be directly involved or represented in the expansion and strengthening of this activity: South African Department of Health, the Medical Control Council, and the National Pharmacovigilance Center.
4. Surveillance of HIV Positive pre-ART Persons:
- a. This surveillance activity is new and would entail the development, implementation and evaluation of surveillance of HIV-positive persons to ensure appropriate care (ART or pre-ART) over time and as CD4 count changes; and

- b. This activity should be conducted in collaboration with the South African Government or one of its designated partners.
- 5. HIV Surveillance in Underserved Groups at High Risk or Special Populations such as, but not limited to, MSM, intravenous drug users, sex workers, discordant couples, health professionals, migrant workers, military personnel, prisoners, and/or teachers:
 - a. Various surveys/surveillance activities for these groups/populations have been conducted in the country. These activities need to be continued to track trends, strengthened and continually modified as new data are available;
 - b. This activity should be conducted in collaboration with the South African Government or one of its designated partners; and
 - c. Depending on the group/population under surveillance, the following organizations or stakeholders should be directly involved in the design, implementation and analysis of these activities: South African Department of Health, South African Department of Corrections, South African Department of Education, South African Military Health Services, and/or the South African National AIDS Council.
- 6. Maternal and Infant Mortality Surveillance:
 - a. This surveillance is currently in place at a national level but should be strengthened to include information at the community level and to ensure quality epidemiologic data;

- b. This activity should be conducted in collaboration with and under the direction of the South African Government or one of its designated partners; and
 - c. The following organizations or stakeholders should be directly involved with this activity: South African Department of Health and South African National AIDS Council.
7. Monitoring the use and outcomes of biomedical HIV prevention interventions:
- a. Various surveys/surveillance activities for these biomedical HIV prevention interventions have been conducted in the country. These activities need to be continued to track trends, strengthened and continually modified as new data and interventions are available;
 - b. These activities should be conducted in collaboration with the South African Government or one of its designated partners; and
 - c. The following organizations or stakeholders should be directly involved in the design, implementation and analysis of these activities: South African Department of Health and the South African National AIDS Council.

Eligible applications will be evaluated against the following criteria

Ability to Carry Out the Proposal (20 points):

Does the applicant demonstrate the local experience in South Africa and institutional capacity (both management and technical) to achieve the goals of the project with documented good governance practices? (5 points) Does the applicant have the ability to coordinate and collaborate with 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? (10 points) Is there evidence of leadership support and evidence of current or past efforts to enhance HIV prevention? Does the applicant have the capacity to reach rural and other underserved populations in South Africa? Does the organization have the ability to target audiences that frequently fall outside the reach of the traditional media, and in local languages? (5 points) To what extent does the applicant provide letters of support?

Technical and Programmatic Approach (20 points):

Does the application include an overall design strategy, including measurable time lines, clear monitoring and evaluation procedures, and specific activities for meeting the proposed objectives? (5 points) Does the applicant display knowledge of the strategy, principles and goals of the President's Emergency Plan, and are the proposed activities consistent with and pertinent to that strategy and those principles and goals? (5 points) Does the applicant describe activities that are evidence based, realistic, achievable, measurable and culturally appropriate to achieve the goals of the President's Emergency Plan? (5 points) Does the application propose to build on and complement the current national response in with evidence-based strategies designed to reach underserved populations and meet the goals of the President's Emergency Plan? (5 points) Does the application include reasonable estimates of outcome 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? The reviewers will assess the

feasibility of the applicant's plan to meet the target goals, whether the proposed use of funds is efficient, and the extent to which the specific methods described are sensitive to the local culture.

Capacity Building (15 points):

Does the applicant have a proven track record of building the capacity of indigenous organizations and individuals? Does the applicant have relevant experience in using participatory methods, and approaches, in project planning and implementation? Does the applicant describe an adequate and measurable plan to progressively build the capacity of local organizations and of target beneficiaries to respond to the epidemic?

(10 points) If not a local indigenous organization, does the applicant articulate a clear exit strategy which will maximize the legacy of this project in the intervention communities?

Does the capacity building plan clearly describe how it will contribute to a) improved quality and geographic coverage of service delivery to achieve the "3,12,12"¹ targets of the President's Emergency Plan, and b) (if not a local indigenous organization) an evolving role of the prime beneficiary with transfer of critical technical and management competence to local organizations/sites in support of a decentralized response? (5 points)

Monitoring and Evaluation (15 points):

¹ 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. As called for by the PEPFAR Reauthorization Act of 2008, initiative goals over the period of 2009 through 2013 are to treat at least three million HIV infected people with effective combination anti-retroviral therapy (ART); care for twelve million HIV infected and affected persons, including five million orphans and vulnerable children; and prevent twelve million infections worldwide.

Does the applicant demonstrate the local experience and capability to implement rigorous monitoring and evaluation of the project? (5 points) Does the applicant describe a system for reviewing and adjusting program activities based on monitoring information obtained by using innovative, participatory methods and standard approaches? Does the plan include indicators developed for each program milestone, and incorporated into the financial and programmatic reports? Are the indicators consistent with the President's Emergency Plan Indicator Guide? Is the 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? (10 points) Is the plan to measure outcomes of the intervention, and the manner in which they will be provided, adequate? Is the monitoring and evaluation plan consistent with the principles of the "Three Ones"²? "Applicants must define specific output and outcome indicators must be defined in the proposal, and must have realistic targets in line with the targets addressed in the Activities section of this announcement.

Understanding of the Problem (10 points):

² The Emergency Plan supports the multi-sectoral national responses in host nations, adapting U.S. support to the individual needs and challenges of each nation where the Emergency Plan is at work. Countries and communities are at different stages of HIV/AIDS response and have unique drivers of HIV, distinctive social and cultural patterns (particularly with regard to the status of women), and different political and economic conditions. Effective interventions must be informed by local circumstances and coordinated with local efforts. In April 2004, OGAC, working with UNAIDS, the World Bank, and the U.K. Department for International Development (DfID), organized and co-chaired a major international conference in Washington for major donors and national partners to consider and adopt key principles for supporting coordinated country-driven action against HIV/AIDS. These principles became known as the "Three Ones": - **one national plan, one national coordinating authority, and one national monitoring and evaluation system** in each of the host countries in which organizations work. Rather than mandating that all contributors do the same things in the same ways, the Three Ones facilitate complementary and efficient action in support of host nations.

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 Five-Year Strategy and goals of the President's Emergency Plan? (5 points) To what extent does the applicant justify the need for this program within the target community?

Personnel (10 points):

Does the organization employ staff fluent in local languages who will work on this project? Are the staff roles clearly defined? As described, will the staff be sufficient to meet the goals of the proposed project? If not an indigenous organization, does the staff plan adequately involve local individuals and organizations? Are staff involved in this project qualified to perform the tasks described? Curricula vitae provided should include information that they are qualified in the following: management of HIV/AIDS prevention activities, especially confidential, voluntary counseling and testing; and the development of capacity building among and collaboration between Governmental and non-governmental partners.

Administration and Management (10 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? Is the management structure for the project sufficient to ensure speedy implementation of the project? If appropriate, does the applicant have a proven track

record in managing large laboratory budgets; running transparent and competitive procurement processes; supervising consultants and contractors; using subgrants or other systems of sharing resources with community based organizations, faith based organizations or smaller non-governmental organizations; and providing technical assistance in laboratory or pharmacy management? The grantee must demonstrate an ability to submit quarterly reports in a timely manner to the HHS/CDC office.

Budget (Reviewed, but 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?

Funding Preferences (10 Points)

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

- **Local Indigenous Organization:**

Applicants registered in the country as a local indigenous organization and in compliance with the definition given in the FOA for “Local partner” will receive **10 points** in addition to the points established in the Evaluation Criteria.

Funding Restrictions

Restrictions, which must be taken into account while writing the budget, are as follows:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care.
- Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Recipients may purchase equipment and complete minor renovations if deemed necessary to accomplish program objectives in accordance with applicable federal law and HHS/CDC policy; however, recipients must request prior approval by HHS/CDC officials in writing and conduct procurements in a transparent and competitive manner.
- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Reimbursement of pre-award costs is not allowed.
- 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.

- 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 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.
- Foreign grantees are subject to audit requirements specified in 45 CFR 74.26(d). A non-Federal audit is required, if during the grantees fiscal year, the grantee expended a total of \$500,000.00 or more under one or more HHS awards (as a direct grantee and/or as a sub-grantee). The grantee either may have (1) A financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those case where the grantee receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (2) An audit that meets the requirements contained in OMB Circular A-133.

- A fiscal Grantee Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

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) 2011, the limit is no more than 8 percent of the country's FY 2011 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 RFA/APS/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 RFA/APS/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 RFA/APS/FOA.**

For example, the proposal should state that the applicant has \$_____ in FY 2011 grants and cooperative agreements (for as many fiscal years as applicable) in South Africa. For additional information concerning this RFA/APS/FOA, please contact the Grants Officer for this RFA/APS/FOA.

Prostitution and Related Activities

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document (“recipient”) cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the

preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any “exempt organizations” (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization and its six Regional Offices, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. § 7102(9).

All recipients must insert provisions implementing the applicable parts of this section, “Prostitution and Related Activities,” in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, must acknowledge that compliance with this section, “Prostitution and Related Activities,” is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization’s compliance with this section, “Prostitution and Related Activities.”

All prime recipients that receive U.S. Government funds (“prime recipients”) in connection with this document must certify compliance prior to actual receipt of such funds in a written statement that makes reference to this document (e.g., “[Prime recipient's name] certifies compliance with the section, ‘Prostitution and Related Activities.’”) addressed to the agency’s grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, “Prostitution and Related Activities,” is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term.

The recipient shall refund to HHS the entire amount furnished in connection with this document in the event HHS determines the recipient has not complied with this section, “Prostitution and Related Activities.”

Any enforcement of this clause is subject to Alliance for Open Society

International v. USAID, 05 Civ. 8209 (S.D.N.Y., orders filed on June 29, 2006 and August 8, 2008)(orders gaining preliminary injunction) for the term of the Orders.

The List of the members of GHC and InterAction is found at:

http://www.usaid.gov/business/business_opportunities/cib/pdf/GlobalHealthMemberlist.pdf

Application Review Process

All eligible applications will be initially reviewed for completeness by the Procurement and Grants Office (PGO) staff. In addition, eligible applications will be jointly reviewed for responsiveness by HHS/CDC Global AIDS Program staff and PGO. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified the application did not meet eligibility and/or published submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in Section VI. Application Review Information, subsection entitled “Evaluation Criteria”. The panel may include both U.S. Federal Government and non-U.S. Federal Government participants.

Applications Selection Process

Applications will be funded in order by score and rank determined by the review panel unless funding preferences or other considerations stated in the FOA apply.

The following “funding preference” may affect the funding decision:

- Applicants registered in the country as a local indigenous organization and in compliance with the definition given in the FOA for “Local partner” working with the South African population will receive an additional ten points.

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

Pre-Application Workshop

CDC South Africa will host three pre-application workshops, as follows:

- **Johannesburg: March 9, 2011**
- **Durban: March 10, 2011**
- **Cape Town: March 11, 2011**

Applicants should contact Katherine Robinson (RobinsonK@sa.cdc.gov) regarding time, venue, and registration details.

VII. AWARD ADMINISTRATION INFORMATION

Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management

Officer and e-mailed to the program director. A hard copy of the NoA will be mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate. The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-6 Patient Care
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-21 Small, Minority, and Women-Owned Business
- AR-23 States and Faith-Based Organizations
- AR-24 Health Insurance Portability and Accountability Act Requirements
- AR-25 Release and Sharing of Data
- AR-27 Conference Disclaimer and Use of Logos

- AR-29 Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009
- AR-30 Section 508 Compliance

Additional information on the requirements can be found on the CDC Web site at the following Internet address: http://www.cdc.gov/od/pgo/funding/Addtl_Reqmnts.htm.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

CDC Assurances and Certifications can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>

TERMS AND CONDITIONS

Reporting Requirements

Each funded applicant must provide CDC with an annual Interim Progress Report submitted via www.grants.gov:

1. The interim progress report is due no less than 90 days before the end of the budget period. The Interim Progress Report will serve as the non-competing continuation application, and must contain the following elements:
 - a. Standard Form (“SF”) 424S Form.
 - b. SF-424A Budget Information-Non-Construction Programs.

- c. Budget Narrative.
- d. Indirect Cost Rate Agreement.
- e. Project Narrative.
- f. Activities and Objectives for the Current Budget Period;
- g. Financial Progress for the Current Budget Period;
- h. Proposed Activity and Objectives for the New Budget Period Program;
- i. Budget;
- j. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for South Africa ; and
- k. Additional Requested Information;

Additionally, funded applicants must provide CDC with an original, plus two hard copies of the following reports:

- 2. Annual progress report due 90 days after the end of the end of the budget period.
The annual progress report should include activity-specific detailed narratives of the project achievements as well as particular success and challenges with the development, implementation and data dissemination;
- 3. Financial Status Report (SF 269) and annual progress report, no more than 90 days after the end of the budget period;
- 4. Final performance and Financial Status Reports, no more than 90 days after the end of the project period.

These reports must be submitted to the attention of the Grants Management Specialist listed in the Section VIII below entitled “Agency Contacts”.

VIII. AGENCY CONTACTS

CDC encourages inquiries concerning this announcement.

For programmatic technical assistance, contact:

Katherine Robinson, Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

CDC South Africa, PO Box 9536, Pretoria, 0001, South Africa

Telephone: +27-12-424-9000

E-mail: robinsonk@sa.cdc.gov

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

Dionne Bounds, Grants Management Specialist

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, MS: K-75

Atlanta, GA 30341

Telephone: 770-488-2082

E-mail: DBounds@cdc.gov

For **assistance with submission difficulties**, contact Grants.gov:

Phone: 1-800-518-4726

Email: support@grants.gov

Hours of Operation: 24 hours a day, 7 days a week. Closed on Federal holidays.

For **application 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 the hearing impaired or disabled is available at:

TTY 1-888-232-6348

Other Information

Other CDC funding opportunity announcements can be found on Grants.gov Web site,

Internet address: <http://www.grants.gov>.

Questions and Answers from the Pre-Application Workshop:

1. Regarding the local partner preference: would an international organization partnering with a local organization as put forth in an application benefit from this preference?

ANSWER: Yes.

2. Can an organization apply for one program area or all program areas as defined in the FOA?

ANSWER: Yes, each applicant must apply for at least one program area, but may apply for additional program areas up to the total of seven as defined in the FOA.

3. Some programs mention national surveillance and some do not, how broad should this be? Does it extend down to the provincial, district, sub-district, and community level?

ANSWER: It depends on the program area. For example, the HIV-positive, pre-ART patient surveillance program may be on the clinic level but could also extend up to the national level. The FOA gives specifications regarding desired level on the individual surveys and surveillance program areas.

4. How would the grantee identify a designated partner?

ANSWER: The awardee is expected to collaborate with the South African Government (SAG) as outlined in the FOA. In some cases, SAG may identify a partner organization or parastatal with whom the grantee would need to consult.

5. The budgets are to be prepared in US Dollars, but the funds will likely be spent in South African Rands. How should an applicant set the exchange rate in the application's budget?

ANSWER: Generally the CDC Procurements and Grants Office (PGO) will advise that the applicant select an exchange rate that is close to the current rate near the time of application, factoring in the historical stability of the local currency. For the South African Rand it would be reasonable to select an exchange rate around \$1=R7.

6. In terms of the pharmacovigilance program area, there are already several pharmacovigilance programs currently functioning within South Africa. How does this FOA relate to those programs?

ANSWER: As stated in the FOA, the awardee will conduct a gap analysis and assesses where there are gaps and take into account existing programs to strengthen pharmacovigilance surveillance.

7. In area five (HIV Surveillance in Underserved Groups at High Risk or Special Populations), did you mention the prison population?

ANSWER: Yes, but note that the populations listed in the FOA are only examples.