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### Part 1. Overview Information

<b>Participating Organization(s)</b>	Centers for Disease Control and Prevention ( <a href="#">CDC</a> )
<b>Components of Participating Organizations</b>	Center for Global Health (CGH)
<b>Funding Opportunity Title</b>	<b>Operations Research (Implementation Science) for Strengthening Program Implementation through the President's Emergency Plan for AIDS Relief (PEPFAR)</b>
<b>Mechanism of Support</b>	<a href="#">U01</a> Research Project Cooperative Agreements  This funding opportunity will use the U01 activity code. The HHS/CDC U01 is a cooperative agreement assistance instrument. Under the U01 assistance instrument, the Recipient Organization retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, and with HHS/CDC staff is substantially involved as a partner with the Recipient Organization, as described in Section VI.2., "Cooperative Agreement Terms and Conditions of Award."
<b>Announcement Type</b>	New
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>RFA-GH-12-008</b>

<b>Catalog of Federal Domestic Assistance (CFDA) Number(s)</b>	93.067
<b>Category of Funding Activity</b>	Health
<b>FOA Purpose</b>	This FOA will directly support host-country investigators working at public and nonprofit private institutions and agencies in PEPFAR-supported countries (“PEPFAR Local Partners”) for the conduct of operations research (implementation science) essential for strengthening activities in the areas of prevention, care, and treatment of HIV/AIDS. The overall purpose of these research activities is to yield knowledge that will help to optimize the delivery of services and maximize the population-level impact of HIV/AIDS prevention, care, and treatment services provided in PEPFAR-supported countries.

### Key Dates

<b>Publication Date</b>	January 3, 2012  To receive notification of any changes to RFA-GH-12-008, return to the synopsis page of this announcement at <a href="http://www.grants.gov">www.grants.gov</a> and click on the “Send Me Change Notification Emails” link. An email address is needed for this service.
<b>Letter of Intent Due Date</b>	<b>March 1, 2012, by 5:00 PM U.S. Eastern Time.</b>
<b>Application Due Date</b>	<b>March 29, 2012, by 5:00 PM U.S. Eastern Time.</b> On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. <b>Note:</b> HHS/CDC grant submission procedures <b>do not</b> provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

<b>Scientific Merit Review</b>	June, 2012
<b>Secondary Review</b>	July, 2012
<b>Start Date</b>	September, 2012
<b>Expiration Date</b>	March 30, 2012
<b>Due Dates for E.O. 12372</b>	Executive Order 12372 does not apply to this program.

### **Required Application Instructions**

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

**Note:** The Research Strategy component of the Research Plan is limited to 15 pages.

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

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

## **Part 2. Full Text**

### **Section I. Funding Opportunity Description**

#### **Statutory 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>.

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 activities that include the following:

- 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.
- Develop, validate and/or evaluate 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.

The PEPFAR Reauthorization Act of 2008 calls for expanding the integration of timely and relevant operational research within the prevention, care, and treatment of HIV/AIDS for the purposes of improving program quality and efficiency, ascertaining cost effectiveness, assessing population-based impact, and optimizing delivery of services. The purpose of this funding announcement is to support operational research (implementation science) to strengthen PEPFAR program implementation. In this context, implementation science is the study of methods to improve the uptake, implementation, and translation of research findings into routine and common practices (the “know-do” or “evidence to program” gap). The scope is broader than typical biomedical research; it seeks to improve program effectiveness and optimize efficiency, including the effective transfer of interventions from one setting to another. The methods of implementation science facilitate making evidence-based choices between competing or combined interventions and improving the delivery of effective and cost-effective programs.

The PEPFAR Reauthorization Act of 2008 identifies as key research collaborators public and nonprofit private institutions and agencies in foreign countries. This funding announcement will directly support host-country investigators working at public and nonprofit private institutions and agencies in PEPFAR-supported countries (“PEPFAR Local Partners”) for the conduct of implementation science essential for strengthening activities in the areas of prevention, care, and treatment of HIV/AIDS.

#### **Purpose**

The overall purpose of these research activities is to yield knowledge that will help to optimize the delivery of services and maximize the population-level impact of HIV/AIDS prevention, care, and treatment services provided in PEPFAR-supported countries. This program addresses the “Healthy People 2020” focus area of Global Health by improving public health and strengthen U.S. national security through global disease detection, response, prevention, and control strategies.

#### **Objectives**

The PEPFAR Reauthorization Act of 2008 calls for carrying out and expanding biomedical research, health services research, impact evaluation research, and operations research and for disseminating the findings globally through mechanisms developed by the Office of the Global AIDS Coordinator in coordination with CDC. The overall purpose of these research activities is to yield knowledge that will help to optimize the delivery of services and maximize the population-level impact of HIV/AIDS prevention, care, and treatment services provided in PEPFAR-supported countries.

Essential for the conduct of these research activities is the institutional and investigator capacity necessary to perform this research. Understanding that research capacity in many PEPFAR-funded countries is limited, applicants are encouraged to request support for the development of local research capacity necessary for the conduct of the proposed study, and to propose studies that are feasible given the limits of research capacity.

Investigators funded through this announcement may partner with other local public and nonprofit private institutions, and may subcontract with technical assistance providers locally or based in other countries, including the United States. For a given application, subcontracts to non-local entities are limited to less than 50% of the entire award, unless a specific justification is provided. If a portion of the award is provided to a non-local entity to support research activities, the applicant should specify how research capacity will also be strengthened at the local institutions during the project period.

Through the cooperative agreement mechanism, CDC staff will be responsible for collaborating with funded institutions on these projects. For this reason, eligibility is limited to investigators working in PEPFAR-supported countries with CDC Global AIDS Program (GAP) offices or PEPFAR-supported countries that already have other CDC GAP-supported projects.

The Global Health Initiative (GHI) principles are reflected in this announcement through the emphasis on research capacity-building and many of the potential research topics described below.

#### **Specific areas of research**

The applicant may propose an implementation science research project focusing on one of the topics described below, to the extent that it can be justified within the context of the country PEPFAR program. The topics described below provide examples of priority research areas that would be considered responsive to this funding announcement. The topics were identified in consultation with multiple stakeholders and selected because they reflect urgent needs in countries where PEPFAR is active and seeks to optimize service delivery. It is not an exhaustive list, nor is the list intended to limit studies to these areas of investigation. However, investigators who submit applications outside of these areas of emphasis should demonstrate the importance of their research and how the results will inform delivery of HIV prevention, care, and treatment in PEPFAR-funded sites.

#### **HIV Prevention: Increasing the proportion of persons who know their HIV status and are linked to appropriate HIV prevention services**

Many prevention interventions designed to reduce HIV acquisition and transmission and consequently HIV incidence require knowledge of one's HIV status. Since the advent of PEPFAR, the expansion of HIV testing and counseling (HTC) services through antenatal clinics, provider-initiated testing and counseling strategies, and home-based counseling and testing programs have improved knowledge of HIV status among women more than men.

Implementation research is needed to develop innovative methods for further improving access to and uptake of HIV testing and counseling, particularly among men.

Innovative HIV testing interventions also need to be developed to increase uptake of counseling and testing services for couples. Despite evidence suggesting that the majority of new HIV

infections in sub-Saharan Africa occur within stable cohabiting relationships, and that > 45% of cohabiting HIV-positive individuals have HIV-negative partners, HIV prevention programs targeting discordant couples remain lacking. Couples HIV counseling and testing (CHCT), whereby couples receive joint HTC and support for mutual disclosure of their HIV status, is one HIV prevention intervention addressing this gap. CHCT has been associated with increased condom use and reduced HIV transmission among discordant couples, but it has not been widely implemented. The identification of discordant couples at all health system entry points (e.g. antenatal clinics, voluntary counseling and testing centers, and HIV care and treatment sites) presents opportunities for averting new infections.

Implementation research is also needed to inform programs on how best to assure linkage of those tested to appropriate prevention interventions, e.g., individuals identified as HIV-infected to care and treatment programs; couples identified as HIV-discordant to effective interventions; and men identified as HIV-negative to male circumcision services.

Accordingly, priority research questions to be addressed in one or more defined populations include but are not limited to the following:

- What interventions improve male uptake of HIV testing and counseling?
- What interventions increase the uptake of couples' HIV counseling and testing?
- What sustainable interventions within the clinical setting prevent HIV transmission within sero-discordant couples?
- What interventions ensure early enrollment and retention into HIV care and treatment programs after testing HIV positive?

#### **HIV Prevention: Evaluating the Implementation of Male Circumcision**

Accumulating evidence has demonstrated the partial protective effect of male circumcision (MC) in reducing male acquisition of HIV from an HIV-infected female sex partner. Several decades of observational and ecological evidence have established that widespread male circumcision is correlated with lower HIV prevalence and vice versa. A meta-analysis of 28 observational studies supported the protective effect of MC. Finally, prospective studies have verified the causal relationship between MC and HIV protection. Three randomized controlled trials involving more than 10,000 men in sub-Saharan Africa conclusively demonstrated a 60% risk reduction for men from acquiring HIV from women. Based on the cumulative evidence, WHO and UNAIDS are promoting MC as a key HIV prevention strategy in generalized epidemics where HIV prevalence and incidence are high and MC prevalence is low.

Programs to provide MC for HIV prevention differ from programs such as care and treatment services in that large capacity is not required for the long term. Once intensive service provision accomplishes “catch-up” circumcision for current adolescent and adult males, sustainable services need to reach only successive cohorts of, for example, 14 year old males, or of newborn males, depending on the host country strategy. Nonetheless, challenges remain in determining the most efficient, cost-effective approach to providing safe medical MC for up to 30 million adolescent and adult males in southern and eastern Africa. Priority implementation research questions to be addressed include but are not limited to the following:

- What strategies increase uptake of MC services among different populations?
- What approaches increase HIV testing and counseling uptake among clients in MC programs?

- Through unlinked, de-identified (anonymous) testing of blood from the excised foreskin, what proportion of men who decline pre-op HTC is HIV positive?
- What approaches to HIV care and treatment referral improve linkage from the MC program? If HIV clinical staging were performed at the MC site, would that motivate people to go for care?
- What non-surgical efficiencies can be introduced into MC service delivery programs to increase volume while maintaining safety?

### **HIV Prevention: Linkages Required for Combination Prevention and Treatment as Prevention**

New strategies for HIV prevention, labeled “combination prevention” and “treatment as prevention” are being recommended by public health experts. The first strategy involves implementing multiple prevention interventions with known efficacy in a geographic area at a scale, quality, and intensity to impact the epidemic. The interventions with high efficacy are HIV testing and counseling (HTC), adult male circumcision (MC), anti-retroviral therapy (ART), and prevention of mother-to-child HIV transmission (PMTCT). Modeled simulations suggest that very high coverage (for example, 70% or more) of all four components is necessary to reduce HIV incidence at the population level in a short time period. The second strategy involves treating HIV-infected persons at higher CD4 counts than currently recommended (>350 CD4 <550, as demonstrated in the HPTN 052 study) to reduce their transmission risk. To achieve high coverage for either or both strategies, an additional step beyond implementing programs is necessary: assuring that persons are appropriately linked from one program to another. Priority research questions to be addressed include but are not limited to the following:

- What strategies improve linkage of HIV-negative males who are tested in medical-care (e.g., inpatient wards and outpatient clinics) or community-based settings (home-based HTC or mobile outreach) to MC services?
- What interventions increase the proportion of newly HIV-diagnosed persons tested in medical-care (including MC) or community-based settings who enroll in HIV care and treatment?
- What approaches assure that HIV-infected pregnant women who currently receive PMTCT services enroll in HIV care and treatment?
- Are interventions such as point-of-diagnosis CD4 assessment; provision of escort, travel voucher or transportation services; brief linkages case-management services, or enrollment incentives such as conditional cash or commodity transfers more or less effective in linking persons to appropriate services?
- How can linkages from one program to another be effectively monitored?

### **HIV Prevention: High Risk Marginalized Populations**

In many countries, persons who engage in illicit or socially stigmatized behaviors, including sex work, drug use, and male-male sexual behavior are at disproportionately high risk for HIV. HIV may spread rapidly in these populations due to frequent participation in high risk behaviors, such as unprotected anal and vaginal sex with partners of unknown HIV-status and sharing of injection equipment. HIV spread may be further facilitated because risk behaviors and the sexual networks of persons who engage in these behaviors often overlap (e.g. sex workers [SW] who use drugs, men who have sex with men [MSM] who sell sex). Because these populations are often hidden, they can be difficult to reach and have limited access to services, or may not

make use of services when available due to fear of being stigmatized or criminalized. Priority research questions include but are not limited to the following:

- Among sex workers, MSM, and IDUs who have HIV seroconverted, do HIV risk behaviors change? Does risk increase, decrease or remain the same and why? What are implications for HIV positive prevention programs?
- Among sex workers, MSM, and IDUs who have HIV seroconverted, what is the feasibility and impact on HIV transmission or community viral load of starting ART earlier (at higher CD4 counts)?

#### **Prevention of Mother-to-Child HIV Transmission (PMTCT) Services: Improving Access to Care, PMTCT Coverage, and Integrated Service Delivery**

Delivering PMTCT services requires a prolonged period of health supervision for pregnant women, mothers, and infants. However, many women access antenatal services and PMTCT services late in pregnancy, if at all, and relatively few attend the 4 antenatal care (ANC) visits recommended by the World Health Organization (WHO). Home deliveries by traditional birth attendants and late presentation to clinic with sick children are common. Reasons and effective approaches to increase delivery of HIV services during pregnancy, delivery, and postnatally may vary in different areas. Approaches could include interventions at community and/or facility level, as well as incentives, enablers, and reducing disincentives for patients, health care and community workers, and others. Incentives for patients might include offering packages of integrated services (e.g., linkages to HIV care and treatment, safe delivery, family planning, immunizations, nutrition, malaria prophylaxis, and syphilis testing). Supporting the integration of HIV prevention, care, and treatment with maternal, newborn, and child health services at the levels of policy, program administration, and service delivery offers an opportunity for PEPFAR to use limited resources to leverage other key programs and strengthen these services. However, the practical logistics as well as the science and evidence to support integrated service delivery is still emerging. Priority questions that may be addressed in one or more defined districts include but are not limited to the following:

- What factors influence decisions of HIV infected and uninfected women to attend maternal and child health services, including antenatal care (ANC), delivery with skilled birth attendants, and routine post-partum and post-natal care for themselves and their newborns/infants?
- What package of sustainable interventions is most effective in improving rates of ANC, skilled birth attendance, and post-partum/ post-natal continuity of care for pregnant HIV infected and uninfected women, mothers, and infants with goals of improving PMTCT coverage and effectiveness and survival of mothers and infants?
- Which community outreach interventions are beneficial?
- What is the impact on health service delivery and patient care of integrating PMTCT into maternal, newborn, and child health services and into sexual and reproductive health services?
- What are the most effective health service delivery models and systems for delivering integrated services?

#### **PMTCT Services: Implications of New Approaches: 2010 WHO Guidelines, Elimination of Mother-to-Child HIV Transmission (MTCT), and Treatment for Prevention**

In 2010, WHO issued revised guidelines for PMTCT and infant feeding; additional updates are under consideration. Some countries plan to implement modified WHO guidelines, e.g., ART for HIV-infected pregnant women regardless of CD4 count. In 2011, the HPTN 052 study

demonstrated the benefits of early ART in preventing sexual HIV transmission from persons with CD4 counts of 350- 550. This finding is potentially relevant to PMTCT by supporting early treatment of HIV+ partners of HIV- pregnant women to avoid incident infections in pregnancy and breastfeeding that pose a high risk of MTCT. However best practices for implementing these new approaches and their field impact are uncertain. Priority research questions include but are not limited to the following:

- What are operational challenges, impact, and cost of implementing WHO PMTCT guidelines or modifications? Challenges include implementation of effective HIV testing strategies to identify HIV-positive pregnant women earlier in pregnancy and ensure repeat HIV testing during pregnancy and breastfeeding, initiating ART in pregnant and breastfeeding women for their own health, ARV prophylaxis for women not needing ART for their own health, ensuring adherence and retention, and implementing infant feeding recommendations. What models of care best address these challenges in countries with high ANC HIV prevalence rates? In countries with a high HIV burden but relatively low ANC HIV prevalence rates?
- What is the correlation between PMTCT ARV prophylaxis coverage and transmission rates, subsequent treatment outcomes of mothers (after they become eligible for ART) and HIV-infected infants, and measured HIVDR levels.
- What strategies improve identification of discordant couples in PMTCT settings and ensure that the infected partner is initiated and retained on treatment to reduce the risk of HIV transmission?
- What are useful methods for countries to measure impact and effectiveness of a PMTCT program?
- What is the observed impact of implementing WHO guidelines on the following parameters:
  - HIV-free survival of children 12-18 months
  - Survival of mothers (and impact on orphans)
  - Health care costs and cost-effectiveness of interventions
  - Drug resistance in HIV-infected women and children
  - Infant feeding practices

### **TB-HIV Services**

HIV epidemics in resource-constrained settings have fueled pre-existing TB epidemics, and TB is the most common cause of death and morbidity among HIV-infected patients. Thus, coordination of TB-HIV clinical services is needed to control both epidemics. Two key interventions supported in PEPFAR I to improve TB-HIV coordination were scale-up of HIV testing in TB clinics and TB screening (also called TB intensified case finding or TB ICF) in HIV clinics. Whereas progress was made in implementation of both interventions in several PEPFAR focus countries, challenges and questions remain for scaling up these two interventions and would benefit from well-conducted operational research. Examples of operational research needs that are pertinent to TB ICF in HIV care and treatment settings include development of efficient ways to scale up intensified TB ICF in HIV clinics, and the evaluation of TB ICF scale-up in HIV clinics, the appropriate and practical use of isoniazid preventive therapy (IPT) in HIV clinical settings, and the implementation of TB infection control practices. Implementation challenges facing HIV prevention, care and treatment interventions in TB clinics include: further scale-up of provider-initiated HIV counseling and testing (PITC) in TB clinics, especially in difficult-to-reach populations (e.g., children with TB); scaling up HIV prevention interventions (e.g., prevention-with-positives) in TB clinics; improving uptake of HIV care (including co-

trimoxazole prophylaxis) and antiretroviral therapy (ART) services by TB patients who are found to be HIV-positive through PITC in TB clinics; and providing co-trimoxazole and ART for HIV-infected TB patients in TB clinics while they are undergoing TB treatment.

Given the issues described above, priority questions in the field of adult and pediatric TB-HIV services include but are not limited to the following:

- What are ways to improve scale-up of TB screening and diagnostic testing in HIV clinical settings?
- How can we improve monitoring and evaluation of scale-up of TB intensified case-finding in HIV clinics?
- How should HIV testing in TB clinics in countries with small budgets (i.e., former “non-focus” countries) be scaled up?
- What can be done to increase HIV testing in difficult-to-reach populations of TB patients, e.g., infants and children?
- What is needed to improve uptake of HIV care and treatment services among HIV-infected TB patients?
- What is the most feasible and appropriate use of new TB diagnostics (e.g., point-of-care molecular diagnostics)? What impact does implementation of new TB diagnostics have on important clinical outcomes (e.g., number of patients receiving appropriate treatment, time to initiation of appropriate treatment, number of patients lost-to-follow-up in the diagnostic pathway)?
- Can and should ART be provided in TB clinics while patients are receiving TB treatment? What are successful models for providing ART in TB clinics?
- What are optimal ways to scale-up TB infection control in busy HIV clinical settings?
- When and how should IPT be used in adult and pediatric populations in resource-limited settings?

### **Adult Care and Support**

As access to HIV care and treatment has expanded, implementation challenges have included: difficulties linking patients from HIV counseling and testing (HTC) services to HIV care and treatment services; difficulties retaining patients in pre-ART care; operational barriers to provision of co-trimoxazole prophylaxis and other elements of a “basic care package” (e.g., safe water intervention, insecticide-treated nets); difficulties linking nutritional interventions to HIV care and treatment services; and, implementing and evaluating interventions which reduce risk of HIV transmission.

Poor linkage-to-care for recently diagnosed HIV-infected persons is a challenge in resource-rich and resource-constrained settings. Interventions to improve linkage-to-care in resource-rich settings may not be suitable for resource-constrained settings, and further implementation research is needed to identify best practices.

The limited data available show high rates of loss-to-follow-up (LTFU) among individuals during pre-antiretroviral care. Death may account for a significant proportion of LTFU patients, but other non-biological reasons are also important. Further research to identify strategies that improve pre-ART care retention is urgently needed.

Despite significant progress, coverage of the affordable drug cotrimoxazole among HIV-infected persons in both pre-ART care and ART remains low in many settings. Research to identify cost-effective delivery strategies, integrated within existing health care systems, is needed. In addition, research to identify new interventions that slow HIV disease progression, reduce risk of opportunistic infections and cancers, and reduce risk of HIV transmission is urgently needed.

Malnutrition is common among HIV-infected patients and predicts poor outcomes. Multiple causative factors, which probably vary by setting, contribute to the high prevalence of HIV-associated malnutrition. Although some progress has been made, significant gaps in knowledge of how to design and implement programs to prevent and treat HIV-associated malnutrition remain. Further implementation research is needed to identify the most cost-effective, sustainable models of nutritional care for HIV-infected persons.

Given the issues described above, priority questions in the field of adult care and support include but are not limited to:

- What are the most effective and cost-effective strategies to link newly diagnosed HIV-infected adults to HIV care and treatment services?
- What are the most effective and cost-effective strategies to retain patients in pre-ART care?
- What are the barriers to provision of co-trimoxazole prophylaxis and what are the best models to overcome these barriers?
- What are new strategies to reduce morbidity and mortality in persons with HIV by prevention and/or treatment of opportunistic infections and cancers, and how can existing strategies be improved?
- What is the impact of prevention and/or treatment of opportunistic infections and cancers on the risk of HIV disease progression?
- What is the impact of prevention and/or treatment of opportunistic infections and cancers on the risk of HIV transmission?
- How can current WHO guidelines for nutrition be implemented and what impact can they have on health outcomes for HIV-infected adults?
- What minimal elements are needed in a nutritional package for adults in HIV care settings, and how should the package differ for pregnant and lactating women?

### **Adult HIV Treatment**

During 2004-2009, the number of persons receiving antiretroviral therapy (ART) in middle- and low-income countries increased more than 10-fold, from less than 100,000 to more than 5 million. Despite success in scale-up, certain implementation challenges threaten the goals of future PEPFAR-supported treatment programs. These challenges include: static annual ART program funding in countries where universal access to ART has not yet been achieved; late initiation of ART; early mortality; loss to follow-up; poor long-term adherence; difficulties detecting and appropriately managing virologic treatment failure; potential for development of HIV drug resistance; difficulties in effectively integrating ART services into national combination prevention programs; and lack of sustainable health systems.

Most countries, especially in sub-Saharan Africa, have enrolled less than 80% of the ART-eligible population on therapy. Research aimed at identifying best practices for HIV testing and

linkage to care; and the most successful, feasible, and cost-effective models of ART service delivery are needed to ensure continued scale-up at a time when ART funding is static.

In most countries, a high proportion of patients initiate ART with advanced HIV disease. Advanced disease at ART initiation is predictive of poor outcomes. Research to identify service models which facilitate earlier initiation of therapy is urgently needed. Such models could include, but are not limited to innovations for earlier HIV diagnosis, earlier linkage to care, and retention in pre-ART care. Partly due to late ART initiation, rates of mortality during ART are highest within the first 90 to 180 days of therapy. Research to identify service delivery models or interventions, which complement earlier ART initiation and reduce early mortality is urgently needed.

In many countries, attrition of patients on ART is increasing as the ART program matures. Loss to follow-up (LTFU) accounts for the majority of attrition. Interventions, appropriate for resource-constrained settings, are urgently needed to improve retention of adults on ART.

Several studies have demonstrated that adherence to ART declines with therapy duration. Poor adherence is a risk factor for treatment failure, morbidity, mortality and emergence and spread of HIV drug resistant virus. Implementation research to identify new interventions, which improve adherence, is needed.

As access to HIV care and treatment expands, there is opportunity to use adult ART service infrastructure to facilitate national combination prevention programs; further implementation research to identify innovative combination prevention strategies that incorporate ART is urgently needed. Similarly, ART service infrastructure can facilitate health systems strengthening; further research to identify the best way to use this infrastructure to build capacity of national health systems and improve global health status indicators, is needed.

Given the issues described above, priority questions in the field of adult ART in resource-constrained settings include but are not limited to the following:

- What are the most successful, feasible, sustainable and cost-effective models of ART service delivery? Can wide-spread use of these models achieve efficiencies that allow continued scale-up despite static funding?
- What is the best way to diagnose and link HIV-infected persons to care and treatment services early, so that prognosis of care and treatment is improved?
- How can ART programs reduce early mortality?
- Which interventions or models of care improve retention on ART in resource-constrained settings?
- How can patient adherence to ART be improved in resource-constrained settings?
- What are the most successful and cost-effective strategies for clinical monitoring of ART patients?
- What are the best models of ART service delivery in resource-constrained settings to maximize the prevention effectiveness of ART?
- How can PEPFAR's adult ART service infrastructure facilitate health system strengthening with clear measurement of progress towards improved global health status indicators?

### **Pediatric HIV Care and Treatment**

Over the past few years great advances have been made to increase access to diagnostic, care and treatment services for HIV-exposed and infected infants, children and adolescents. Studies in resource poor settings have shown that HIV- infected children receiving optimal care and treatment can remain healthy indefinitely. Successful treatment outcomes are largely dependent on early diagnosis and prompt initiation of ART. Many gaps remain in our knowledge on how best to provide services for exposed and infected pediatric populations and sustain long-term HIV or AIDS free outcomes. More work is needed to understand how programs in resource-limited settings can operationalize recent testing, prevention, care and treatment guidelines for infants and children. Priority research questions regarding HIV-exposed infants and HIV-infected children include but are not limited to the following:

- What are effective models of service delivery to improve identification and provide appropriate follow-up for HIV-exposed infants?
- What are optimal approaches to scale-up provider initiated HIV testing and counseling and linkage to care for children and adolescents in high, medium and low prevalence settings?
- What are effective models of service delivery to improve retention in care of HIV-exposed and infected infants and children and retrieve patients lost to follow-up?
- What are optimal approaches to enable age-appropriate disclosure of HIV status to children by health care providers and caregivers?
- What are effective models of monitoring and retaining HIV-infected children not eligible for treatment, (2 years and older) to ensure adherence to co-trimoxazole prophylaxis, timely treatment initiation and reduction in losses to follow-up?
- What are innovative approaches to measure and support long-term adherence in various pediatric age groups (infancy, toddlers/pre-school, school-age and adolescents)?
- What factors contribute to losses to follow-up of HIV-exposed and infected children and what facility and/or community-based interventions are useful to reduce these losses?
- What are the long-term treatment outcomes (rates and causes of mortality, treatment failure, and common opportunistic infections, as well as developmental outcomes, etc) of children and how can they be improved?
- What interventions can help reduce early mortality of infants, children, and adolescents initiated on ART?
- What is the optimal way to monitor treatment of infants and children in resource-limited settings?
- What are the strengths and weaknesses of existing or newly developed models to meet the transitioning needs of adolescents with HIV?
- What are the strengths and weaknesses of existing or newly developed models of providing a comprehensive care package to HIV-exposed and HIV-infected children (including interventions such as TB screening and isoniazid prophylaxis, safe water and malaria prophylaxis, and psychosocial and nutritional support)?

### **HIV drug resistance (HIVDR) and Molecular Epidemiology**

HIV-infected persons in PEPFAR-supported countries usually receive antiretroviral (ARV) treatment without viral load monitoring. Treatment failure may not be detected until clinical and/or immunologic consequences are apparent, and patients may have developed HIVDR by the time failure is detected, which could reduce response to second-line regimens.

Tracking transmission of HIVDR among recently-infected individuals is critical for informing future efficacy of care and treatment programs. Populations with recent infections that could be studied for prevalence of HIVDR include women from PMTCT programs where testing is performed more than once during their pregnancy, and HIV-exposed infants (<18 months of age) found to be infected. Children infected despite WHO recommended regimens for PMTCT are considered at higher risk for HIVDR.

The WHO global strategy for prevention and assessment of HIVDR was established in 2005 and has been implemented in approximately 70 resource-limited countries. However, determination of ideal regimens for empiric ARV treatment or subsequent PMTCT in persons at higher risk for HIVDR requires implementation research in addition to surveillance activities. Priority questions to be addressed include, but are not limited to the following:

- Is there an association between the presence or pattern of HIVDR and the predicted or actual response to WHO-recommended second-line ART regimens in patients failing first-line therapy?
- What is the pattern of HIVDR in patients with significant gaps in ART (lost to follow-up, gaps in drug pickup)? Is there an association between these HIVDR and subsequent response to reinitiating ART?
- What is the prevalence and pattern of HIVDR among children exposed to the PMTCT regimens recommended in the 2010 WHO guidelines? What is the effect of HIVDR on virologic response to WHO-recommended ART regimens in HIV-infected children <24 months of age?
- What is the prevalence and pattern of HIVDR in pregnant women exposed to PMTCT regimens during prior pregnancies? Is there an association between HIVDR and subsequent PMTCT effectiveness?
- What is the prevalence and pattern of HIVDR among pregnant women with incident infection?
- Incident infections may be associated with transmission of emerging HIV strains. What are the performance characteristics of incidence assays, and what is the sensitivity and specificity of molecular diagnostic test kits (e.g. DNA PCR for EID, viral loads including point of care technology) for detecting emerging HIV strains?

#### **Pediatric HIV Surveillance: Assessing Feasibility of Innovative Strategies**

In 2008, it was estimated that 2.1 million children were living with HIV worldwide, 430,000 were newly HIV-infected, and 280,000 succumbed to an HIV-related death. These figures are estimates only, based on methods and tools developed by the UNAIDS/WHO Global Surveillance Working Group on HIV/AIDS and STI because reliable country-specific surveillance data on pediatric HIV infection have been lacking. If implemented, country-level pediatric surveillance systems may be able to more accurately measure the burden of disease among children, monitor new HIV infections, and measure the impact of PMTCT and ART programs on pediatric HIV. However, important methodologic questions for pediatric HIV surveillance need to be addressed. Priority questions for developing pediatric HIV surveillance are the following:

- What innovative strategies might be feasibly implemented to conduct reliable pediatric HIV surveillance among different age groups and in different epidemic contexts? This

might include strategies that build upon existing health systems, health programs (such as HIV prevention, care, and treatment, immunization, and maternal and child health), and population-based surveys.

- What pediatric surveillance methods would best measure the impact of PMTCT and ART programs on the HIV epidemic, with a special focus on HIV-free survival?
- What surveillance methods would best measure HIV prevalence among children aged 2-15 years, which may be a result of a variety of exposures such as unsafe therapeutic injections, blood transfusion, or sexual intercourse?
- What recruitment and sampling methods would best capture information on children aged 12-18 years of age to assess behavioral risk, burden of disease, and the impact of prevention programs targeting youth?

### **Measuring Mortality: Assessing the Feasibility of Innovative Strategies**

Vital registration systems are nonfunctional in many countries with a high burden of HIV and large HIV programs. Although the management of these systems may fall to Census Offices and General Statistics Offices, the health sector needs mortality data to monitor the burden of disease and the impact of public health programs. Since 2002, HIV prevention, care, and treatment programs have expanded rapidly and HIV morbidity surveillance has evolved substantially. In the absence of functional vital statistics systems, many countries rely on statistical models to generate estimates of HIV-related mortality. Innovative approaches to all-cause and cause-specific mortality measurement are needed and the feasibility, including cost and cost-effectiveness, of these approaches needs to be better understood. The primary area of inquiry is the following:

- What innovative strategies might be feasibly implemented in countries lacking a functional civil registration system to reliably monitor mortality (all cause, cause-specific, age-specific and sex-specific mortality) and to evaluate the impact of HIV, TB, malaria, and integrated maternal and child health programs? This might include direct measurement and/or indirect estimation, sample-based approaches, use of sentinel populations and sites, facility-based approaches, community-based approaches, modeling, etc.

### **Economics and Finance**

PEPFAR is guided by the core principles articulated in the Global Health Initiative, namely the need to assure the sustainability of global public health programs through building robust health systems, fostering partner country capacity and ownership, improving program reach and impact through strategic coordination and integration, and providing accountability to guide cost-effective use of global health resources. Research in economics and finance—including economic evaluation, impact evaluation, and evaluation of innovative financing approaches—is a priority within the effort to grow the evidence base for global HIV programming. The common theme for conducting economic research is to maximize impact of HIV programs through increased efficiency and cost-effectiveness. Implementation science studies that generate information relevant to inform programs and policies will be considered responsive. In addition to the research primarily focused on economics and finance, investigators are encouraged to explicitly include an economic evaluation component into any research proposal, regardless of which priority is addressed, in order to inform questions of the value of health interventions and optimal use of resources. Among the priority questions identified in this area are the following:

- What is the cost-effectiveness of integrating programs across health interventions compared to vertical program models?
- What is the relative efficiency of different service delivery models, clinical guidelines, intervention strategies to optimize health and prevention outcomes?
- How does performance-based financing of healthcare delivery influence health outcomes and what is the impact on provider behavior?
- How do innovative financing methods, such as health insurance schemes or user fees, affect the utilization or efficiency of HIV/AIDS services?
- What are the averted costs and outcomes that result from wide-scale provision of antiretroviral therapy, such as averted costs through reduction of in-patient stays for those under treatment or through reduction in orphanhood?
- What are the effects and cost-effectiveness of conditional grants or other individual incentives on prevention behaviors, ART and PMTCT adherence or other health-seeking behaviors?
- What is the impact of HIV/AIDS services on broader development indicators, such as gross domestic product, poverty rates, household wealth or educational outcomes?
- Does having a supply-chain management (SCM) tracking system improve efficiency in management of drugs and cost savings?

### **Human Resources for Health (HRH)**

The shortage of qualified human resources for health (HRH) in PEPFAR countries is a primary constraint to the expansion of HIV prevention, care and treatment services, which additionally weakens national health systems. For this reason, PEPFAR has significantly invested in key HRH domains that facilitate the production of an educated and competent health workforce. Examples of these investments include expanding pre-service education; improving health workforce recruitment, retention, motivation and performance; establishing human resource information systems; enhancing HRH planning and policies; and strengthening health professional regulatory systems. Because the evidence base is limited as to what works for ensuring and sustaining skilled health care providers in resource-constrained settings, establishing a foundation of implementation science in health workforce interventions is an important PEPFAR priority. In this context, the health workforce comprises clinical providers as well as the public health workforce, such as laboratorians, public health advisors, managers, epidemiologists and community health workers. Research priorities for HRH should inform PEPFAR-supported programs regarding effective strategies to increase workforce retention, improve provider performance, and ensure their appropriate distribution, especially in rural settings. Determining the impact and sustainability of these strategies and ascertaining how to scale up proven HRH interventions will make important contributions to the field. Examples of priority HRH questions of interest to PEPFAR include but are not limited to the following:

- What are optimal models for training and retaining faculty/tutors at pre-service educational institutions?
- What are sustainable models for providing clinical mentorship and/or supervision for health workers?
- To what extent do professional standards--as reflected in national regulatory frameworks or scopes of practice--align with global standards in professions, such as nursing and midwifery?

- What models of public sector recruitment, compensation, and/or career paths improve recruitment and retention of health workers? In this regard, what are the effects of financial and non-financial incentives with regard to retaining health workers in underserved areas or preventing outmigration?
- What are innovative and sustainable approaches for improving the distribution of health care providers in rural and/or underserved areas within PEPFAR countries?
- To what extent is workforce absenteeism impacting service delivery in PEPFAR-supported programs?
- What are optimal models for increasing health worker productivity, performance, and motivation that can be adopted in the public sector health system?
- What is the optimal facility-based skill and staffing mix for improved health outcomes and cost effectiveness?

### **Health Information Systems**

Effective health information systems (HIS) have played an important role in the success of PEPFAR. Under the first phase of PEPFAR, substantial investment was made in information systems that support implementation of various components of HIV care, treatment, and prevention scale-up, including electronic medical record systems (EMRs), laboratory information systems, pharmacy and other logistics management systems, blood safety and other program tracking systems, training and human resource management systems, as well as in basic telecommunications infrastructure and technology. These investments in HIS have been accompanied, to various extents, with adoption of information science methods, as well as strategies for building human capacity in HIS. The rapid roll-out and emergent character of the response under the first phase of PEPFAR resulted in development of information systems that were not always aligned with national health policies or existing information systems. Although countries made substantial progress in developing information systems and investments in information and communication technology (ICT) policies and infrastructure to support these technologies, many still continue to struggle with implementing HIS and are often unable to support those systems that had been installed. Questions of particular interest include the following:

- What is the impact of adoption of information technology/health information systems on ability to monitor health events?
- What is the impact of adoption of information technology/health information on improving health outcomes?
- What are determinants of effective strategies for scaling up/strengthening health information systems?
- What are effective, efficient and appropriate strategies, methods and technologies for integrating information systems across disease programs or other domains?
- How can we leverage progress in HIS-strengthening efforts to stimulate development of population-level monitoring systems, such as improved vital registration systems?

## Section II. Award Information

<b>Funding Instrument</b>	<p>This funding opportunity will use the U01 activity code.</p> <p>Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.</p>
<b>Application Types Allowed</b>	<p>New</p> <p>The NIH <a href="http://grants.nih.gov/grants/glossary.htm">OER Glossary</a> (<a href="http://grants.nih.gov/grants/glossary.htm">http://grants.nih.gov/grants/glossary.htm</a>) and the SF 424 (R&amp;R) Application Guide provide details on these application types.</p>
<b>Funds Available and Anticipated Number of Awards</b>	<p>Approximate Fiscal Year Funding: \$5,000,000 per year for 2 years</p> <p>Approximate Total Project Period Funding: \$10,000,000</p> <p>Anticipated Number of Awards: up to 15</p> <p>To assure geographic diversity, CDC will fund no more than three awards per country. See section V.2 for more information.</p> <p>Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.</p>
<b>Ceiling and Floor of Individual Award Range</b>	<p>Floor of Individual Awards Range: \$200,000 per year</p> <p>Ceiling of Individual Awards Range: \$500,000 per year</p>
<b>Project Period Length</b>	<p>Two Years</p> <p>Throughout the project period, CDC's commitment to continuation of awards will be conditional 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.</p>

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

## Section III. Eligibility Information

### **1. Eligible Applicants**

#### **Eligible Organizations**

PEPFAR local partners in countries with CDC GAP offices and with CDC GAP-supported projects are eligible to apply.

#### ***Justification for limited eligibility:***

The PEPFAR Reauthorization Act of 2008 calls for expanding the integration of timely and relevant operational research within the prevention, care and treatment of HIV/AIDS and identifies as key research collaborators public and private nonprofit institutions and agencies in PEPFAR countries. The Global AIDS Coordinator has emphasized the importance of strengthening research capacity in PEPFAR-supported countries as essential for enabling countries most affected by HIV/AIDS to combat their own epidemics. Local institutions in PEPFAR countries are heavily involved in providing services to HIV-infected persons and their communities, have successfully developed the capacity for monitoring and evaluation of PEPFAR programs, and are now uniquely positioned to strengthen operations research (implementation science) as the next critical component of building their HIV/AIDS programs.

Through the cooperative agreement mechanism, CDC staff will be responsible for collaborating with funded institutions on these projects, so that these cooperative agreements can be effectively supported by CDC. Eligibility is limited to public and nonprofit private institutions and agencies with host-country investigators working in the approximately 40 PEPFAR-supported countries with CDC Global AIDS Program (GAP) offices or CDC GAP-supported projects. Applicants however, are not required to currently or previously have received PEPFAR funding to meet the below definition of a PEPFAR local partner.

1. Per the Office of the Global Coordinator's 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 "IV.3. Submission Dates and Times" for more information on deadlines.

- If the total amount of appendices includes more than 50 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, Cooperative Agreement (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.

## **Required Registrations**

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

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code:  
[http://www.dlis.dla.mil/Forms/Form\\_AC135.asp](http://www.dlis.dla.mil/Forms/Form_AC135.asp)
- [Central Contractor Registration \(CCR\)](#) – must maintain current registration in CCR to be renewed annually.
- [Grants.gov](#)
- [eRA Commons](#)

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

#### **Central Contractor Registration and Universal Identifier Requirements**

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

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. CCR is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR internet site at [www.ccr.gov](http://www.ccr.gov) (<https://www.bpn.gov/ccr/default.aspx>).

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

#### **Foreign Organizations**

Foreign (non-US) organizations must follow policies described in the [HHS Grants Policy Statement](http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html) (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide.

International registrants can confirm DUNS by sending an e-mail to [ccrhelp@dnb.com](mailto:ccrhelp@dnb.com), including Company Name, D-U-N-S Number, and Physical Address, and Country.

Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: [http://www.dlis.dla.mil/Forms/Form\\_AC135.asp](http://www.dlis.dla.mil/Forms/Form_AC135.asp).

### **Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions**

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

### **2. Cost Sharing**

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>). Based on authorization language, this section should only be included in the FOA, if applicable.

### **3. Other**

#### **Additional Information on Eligibility Number of Applications**

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

As defined in the HHS Grants Policy Statement (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit.

**Investigators applying for more than one combination prevention award in collaboration with PEPFAR will only receive funding for projects that are scientifically or geographically distinct.**

## **Section IV. Application and Submission Information**

## **1. Obtain Application Package**

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

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

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, with the exception of all Federal Holidays. 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 is needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at [support@grants.gov](mailto:support@grants.gov). Submissions sent by email, fax, CD's or thumb drives of applications will not be accepted.

## **2. Content and Form of Application Submission**

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded and uploaded as Attachment A from the following link: <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>.

### **Letter of Intent**

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

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Descriptive title of proposed research  
Name, address, and telephone number of the PD(s)/PI(s)  
Names of other key personnel  
Participating institutions  
Number and title of this funding opportunity

The letter of intent should be sent to:

Lata Kumar  
Scientific Review Officer  
CGH Science Office  
Center for Global Health  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE Mailstop D-69)  
Atlanta, GA 30333  
Telephone: 404-639-7618  
Email: [lek7@cdc.gov](mailto:lek7@cdc.gov)

### **Required and Optional Components**

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

*This announcement requires submission of the following information:*

**A Project Abstract** must be completed in the Grants.gov application forms using the SF 424 application package/PHS Form 398. 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 research 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.

### **Research Plan Components/Attachments**

A Research Plan must be submitted with the application forms (see Supplemental Information for this section below), per the SF424/PHS Form 398. The research plan must be uploaded in a PDF file format when submitted via Grants.gov.

All instructions in the SF424 (R&R) Application Guide must be followed. Please include the following items under the Research Strategy Section of the Research Plan:

- Background and Significance
- Research Design and Materials
- Research Capacity (i.e., current capacity, needs and how they will be addressed)
- Timeline (e.g., GANTT Chart)
- Management of Project Funds and Reporting

The Research Strategy component of the Research Plan must be submitted in the following format:

- Front 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 sequentially
- Maximum number of pages: 15 (If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed);

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consist of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). See Part I, Section 5.5 of the SF 424 (R&R) Application Guide ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)) for additional information.

Please attach applicable sections of the following Research Plan components:

1. Introduction to Application
2. Specific Aims
3. Research Strategy
4. Inclusion Enrollment Report
5. Progress Report Publication List

#### Human Subjects Section

6. Protection of Human Subjects
7. Inclusion of Women and Minorities
8. Targeted/Planned Enrollment Table
9. Inclusion of Children

#### Other Research Plan Sections

10. Vertebrate Animals

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

The Research Plan *narrative* is comprised of components 2, 3, and 4 above. Component 4 (Inclusion Enrollment Report) applies only to renewal and revision applications for clinical research. Note that the Research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach.

All instructions in the SF424 (R&R) Application Guide ([http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_Adobe\\_VerB.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.pdf)) must be followed, with the following additional instructions:

***An HIV/AIDS Related Funding Matrix information should be submitted as a separate PDF file with the application package:*** 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

## **Appendix**

Do not use the appendix to circumvent page limits. A maximum of 15 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide. Additional information may be included in the application appendices. **The total amount of appendices must not exceed 50 pages and can only contain information related to the following:**

- Up to five publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Do not include manuscripts submitted for publication. Applicants should refer to instruction guides and specific Funding Opportunity Announcements (FOAs) to determine the appropriate limit on the number of publications that may be submitted for a particular program. Note that not all grant activity codes allow the inclusion of publications.
  - Publications in press: Include only a publication list with a link to the publicly available on-line journal article or the NIH Pub Med Central (PMC) submission identification number. Do not include the entire article.

- Manuscripts accepted for publication but not yet published: The entire article may be submitted electronically as a PDF attachment.
- Manuscripts published but a publicly available online journal link is not available: The entire article may be submitted electronically as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Graphic images of gels, micrographs, etc. provided that the image (may be reduced in size) is also included within the (stated) page limit of Items 2-5 of the Research Plan component. No images may be included in the Appendix that are not also represented within the Research Plan.

- ***Project Budget Justification:***

If included under the SF424 application/PHS Form 398 – Budget Section, the budget justification will not count toward the Appendix page limit. 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
- ***Job descriptions*** of proposed key positions to be created for the activity
- ***Applicant's Corporate Capability Statement;***
- ***Letters of Support*** Letters of support from 1) all partners, including non-governmental agencies and academic institutions; 2) a member of the host-country government;
  - ***If include in the SF 424 application package/PHS Form 398 – Letters of Support Section, the letters of support will not count toward the Appendix page limit.***
- ***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” Section III.

### **Page Limitations**

All page limitations described in this individual FOA must be followed. For this FOA, the Research Strategy component of the Research Plan narrative is limited to 15 pages, and the Appendix section is limited to 50 pages. For the other components of the research plan, page limitations and formatting are per the instructions for SF 424 application/PHS Form. The complete application must be paginated per the SF424/PHS Form 398. Failure to comply with the above requirements will result in a non-responsive application.

Supporting materials for the Research Plan narrative included as appendices may not exceed 15 PDF files with a maximum of 50 pages for all appendices.

### **Format for Attachments**

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

**CDC require all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)).**

**Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process.**

### **3. Submission Dates and Times**

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

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

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov. **Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.**

**Submit your application 2 days prior to the due date to allow for the correction errors; which is March 27, 2012.**

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

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

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

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

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

#### **4. Intergovernmental Review (E.O. 12372)**

This initiative is not subject to intergovernmental review ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)).

#### **5. Funding Restrictions**

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

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

- 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.
- Recipients may only expend funds 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.

- 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.
- Funds for research involving human subjects will be withheld until the appropriate Federal-wide Assurance and Institutional Review Board Approvals are in place
- 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.
- Projects, if directed by CDC staff and involve the collection of information from 10 or more individuals, and are funded by a grant/cooperative agreement, will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

**Commented [A1]:** This is based on the new OMB/PRA guidance lata

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 Country Operational Plan(s) (COPs). 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 **FY2011** grants and cooperative agreements (for as many fiscal years as applicable) in the PEPFAR-supported country \_\_\_\_\_ ("PEPFAR Local Partner"). 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. 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](http://www.usaid.gov/business/business_opportunities/cib/pdf/GlobalHealthMemberlist.pdf)

## **6. Other Submission Requirements and Information**

### **Application Submission**

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

**Applicants must complete all required registrations before the application due date.** Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11144](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144)).

### **Important reminders:**

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

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the

Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.

Applicants are reminded to enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the FWA before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of this Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: [http://grants.nih.gov/grants/ElectronicReceipt/avoiding\\_errors.htm](http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm) or [http://grants.nih.gov/grants/ElectronicReceipt/submit\\_app.htm](http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm)

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

## Section V. Application Review Information

### **1. Criteria**

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

#### **Overall Impact**

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

#### **Scored Review Criteria**

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

#### **Significance**

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

#### **Investigator(s)**

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

#### **Innovation**

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

### **Approach**

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

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

### **Environment**

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

### **Additional Review Criteria**

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

#### **Protections for Human Subjects**

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

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

please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements ([http://www.cdc.gov/od/pgo/funding/grants/additional\\_req.shtm#ar1](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1)).

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

### **Inclusion of Women, Minorities, and Children**

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (<http://www.cdc.gov/OD/foia/policies/inclusio.htm>).

### **Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary

care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150)).

### **Biohazards**

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

### **Additional Review Considerations**

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

#### **Applications from Foreign Organizations**

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

#### **Resource Sharing Plans**

HHS/CDC policy requires that recipients of grant awards make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: <http://www.cdc.gov/od/foia/policies/sharing.htm>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

### **Plan for Sharing Research Data**

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants should describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation they will provide, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not the awardee will place any conditions on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). References to data sharing may also be appropriate in other sections of the application.

All applicants must include a plan for sharing research data in their application. The HHS/CDC data sharing policy is available at <http://www.cdc.gov/od/pgo/funding/ARs.htm> under Additional Requirements 25 Release and Sharing of Data. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

### **Sharing Research Resources**

HHS policy requires that grant award recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (see the HHS Grants Policy Statement [http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc).) Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by the HHS/CDC Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

## **2. Review and Selection Process**

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

As part of the scientific peer review, all applications will:

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

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

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Investigators applying for more than one implementation science award in collaboration with PEPFAR will only receive funding for projects that are scientifically distinct.

### **Funding Preference:**

In making awards, funding decisions will attempt to achieve geographic diversity. To assure this, CDC will fund no more than three awards per country.

Applicants from the countries already receiving 3 awards under RFA GH11-005, published in FY2011, will not be eligible for funding. Those countries are South Africa, Zambia, and Uganda.

Applications that receive the best scores by the review committee will be stratified by country. The top three applicants under each country are more likely to be funded.

## **3. Anticipated Announcement and Award Dates**

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

Information regarding the disposition of applications is available in the HHS Grants Policy Statement (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>).

## Section VI. Award Administration Information

### **1. Award Notices**

Any applications awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>).

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

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs specified in the FOA document.

### **2. Administrative and National Policy Requirements**

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

Additional requirements are available at the following internet address:  
[http://www.cdc.gov/od/pgo/funding/Addtl\\_Reqmnts.htm](http://www.cdc.gov/od/pgo/funding/Addtl_Reqmnts.htm).

#### **Cooperative Agreement Terms and Conditions of Award**

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

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

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

- Overseeing all management, administrative, and scientific/programmatic aspects of the research including all data, resources and operations.
- Providing the necessary personnel and supplies to implement components and analyze the results.
- Collaborating with local senior researches, CDC researchers and community-based organizations or similar community liaison for the duration of the project period on several activities such as the development of the data-collection instruments, specimen - collection protocols, and data-management procedures.
- Working with HHS/CDC scientists to refine protocols to improve the study and other proposal components based on reviewers' comments in the summary statement.
- Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants, as determined by the study protocols and the program requirements.
- Following study participants as determined by the study protocols.
- Establishing procedures to maintain the privacy of the study participants and confidentiality of the research data.
- Agreeing to share data and specimens with CDC scientists, as well as appropriate international partners, such as the World Health Organization.
- In collaboration with HHS/CDC, present at national or international meetings and publish research findings in peer-reviewed scientific journals.
- Participating in conference with HHS/CDC project official(s) and research team; and attend in-person meetings with HHS/CDC co-investigators.
- Collaborating with USG agency scientists subject to U.S. Government rights of access consistent with applicable law and current DHHS, PHS, and CDC regulations, policies, and applicable bilateral agreements.
- Meeting the reporting requirements outlined in the Notice of Grant Award.
- Obtain and maintain the appropriate Institutional Review Board approvals for all institutions or individuals participating in research involving human subjects.
- Sharing all data and other project and programmatic information with CDC and the Ministry of Health upon request.
- Retaining custody of and having primary rights to the data and software developed under this award, subject to U.S. Government rights of access consistent with current DHHS, PHS, and CDC policies.

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:  
HHS/CDC activities:

- Monitor the cooperative agreement.

- Collaborate with recipient to establish priorities for the development and implementation of the recipient activities, both among and within each of the areas, through regular meetings and communication.
- Provide technical assistance to the recipient by linking them with other national and international agencies that might provide additional technical or material assistance.
- Collaborate as needed with funded institutions by providing technical assistance in support of activities implemented under this agreement.
- Collaborate with the funded institutions in the development and setting of goals, objectives, effective and innovative strategies and methodologies.
- Collaborate in development of a research protocol for IRB review by all collaborating institutions that are participating in the research project. Obtain and maintain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
- Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses. Based on this, HHS/CDC will make recommendations aimed at solving problems and at improving the quality and timeliness of the research activities.
- Provide consultation and guidance as needed in support of activities implemented under this agreement.
- Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.
- Additionally, an HHS/CDC agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the NoA.

Areas of Joint Responsibility include: None ; all responsibilities are divided between awardees and CDC staff as described above.

### **3. Reporting**

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

The Web site includes information on each Federal financial assistance award and contract over \$25,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and

6. Names and compensation of highly-compensated officers (as applicable)

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

For the full text of the requirements under the Federal Funding Accountability and Transparency Act of 2006, please review the following website:

[http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_bills&docid=f:s2590enr.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s2590enr.txt.pdf)

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11160](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11160)) annually and financial statements as required in the HHS Grants Policy Statement.

Each funded applicant must provide CDC with an annual Interim Progress Report no less than 90 days before the end of the budget period submitted via [www.grants.gov](http://www.grants.gov). 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 the country where work has been done; and
- k. Additional Requested Information;

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

1. Annual progress report, due 90 days after the end of the budget period.
2. Financial Status Report (SF 269), no more than 90 days after the end of the budget period.
3. Final performance and Financial Status Reports, no more than 90 after the end of the project period.

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

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

## Section VII. Agency Contacts

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

### Application Submission Contacts:

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

Contact Center Phone: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

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

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

Phone: 1-301-402-7469 or 1-866-504-9552

TTY: 1-301-451-5939

Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

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

CDC Technical Information Management Section (TIMS)

Procurement and Grants Office

Telephone 770-488-2700

Email: [PGOTIM@cdc.gov](mailto:PGOTIM@cdc.gov)

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

### Scientific/Research Contact:

William C. Levine, MD, MSc

Associate Director for Science

Division of Global HIV/AIDS, Center for Global Health

U.S. Department of Health and Human Services

Centers for Disease Control and Prevention

1600 Clifton Road, NE (Mailstop E-41)

Atlanta, GA 30333

Telephone: 404-639-6472

Email: [wlevine@cdc.gov](mailto:wlevine@cdc.gov)

### Peer Review Contact:

Lata Kumar, MS, MPH, MBA

Scientific Review Officer

CGH Science Office  
Center for Global Health  
U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE (Mailstop D69)  
Atlanta, GA 30333  
Telephone: 404-639-7618  
Email: [lkumar@cdc.gov](mailto:lkumar@cdc.gov)

**Financial/Grants Management Contact:**

Rene Benyard  
Grants Management Specialist  
Department of Health and Human Services  
CDC Procurement and Grants Office  
2920 Brandywine Road, MS: K-75  
Atlanta, GA 30341  
Telephone: 770-488-2757  
Email: [RBenyard@cdc.gov](mailto:RBenyard@cdc.gov)

## **Section VIII. Other Information**

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

### **Authority and Regulations**

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).