RFA Title:	*Challenge TB*
RFA Number:	RFA-OAA-14-000006
Catalog of Federal Domestic Assistance (CFDA) Number:	98.001
Issuance Date:	Thursday, December 26, 2013
Deadline for Questions:	January 17, 2014 9:00am Washington DC time
Deadline for Receipt of Applications:	February 10, 2014, 9:00am Washington DC time

Subject: Request for Application (RFA) No. RFA-OAA-14-000006: *Challenge TB*

Dear Prospective Applicant:

Pursuant to the authority granted with the Foreign Assistance Act of 1961, as amended, the United States Government (USG), represented by the Agency for International Development (USAID), Bureau for Global Health (GH), Office of Health, Infectious Diseases, and Nutrition (HIDN) is seeking applications from eligible institutions for the implementation of *Challenge TB* described in Section I of this RFA. The Eligibility Criteria is described in Sections I of this Request for Application (RFA).

USAID expects to issue one cooperative agreement under this RFA. The level of funding allocated for this project will not exceed $500-$550 million over a five-year implementation period (2013-2018). A cost share minimum amount of 5% of the cooperative agreement projected value is required by the Prime and/or it's Sub-recipients under this RFA.

USAID's policy, in compliance with 22 CFR 226.81, does not allow profit under assistance instruments. However, all reasonable and allowable expenses, both direct and indirect, which are allocable to the program activities and are in accordance with applicable cost standards shall be reimbursed under the agreement, as prescribed in 22 CFR 226, as well as 2 CFR 230 for non-profit organizations, 2 CFR 220 for educational institutions, 2 CFR 215 for institutions of higher education, hospitals, and other non-profit organizations, and 48 CFR 31 for profit organizations.

This RFA consists of this cover letter and the following:

1. Section I Funding Opportunity Description;
2. Section II Award Information;
3. Section III Eligibility Information;
4. Section IV Application and Submission Information;
5. Section V Application Review Information
6. Section VI Award and Administration

7. Section VII Agency Contacts
8. Section VIII Other Information

The preferred method of distribution of USAID RFA information is via the Internet. This RFA and any future amendments can be downloaded from http://www.grants.gov. Those organizations unable to retrieve the RFA from Grants.gov may request a PDF version by emailing Amy Wire at awire@usaid.gov.

The federal grant process is now web-enabled, allowing for applications to be received on-line on the grants.gov website, http://www.grants.gov. Therefore, all applications must be submitted via the grants.gov website. USAID bears no responsibility for data errors resulting from transmission or conversion processes associated with electronic submissions.

Issuance of this RFA does not constitute an award commitment on the part of the Government, nor does it obligate the Government to pay for costs incurred in the preparation and submission of an application. Applicants who are considered for an award, and have never received US government funding before, will be subject to a pre-award audit to determine fiscal responsibility, ensure adequacy of financial controls, and, if necessary, establish an indirect cost rate.

In addition, USAID cannot award the cooperative agreement anticipated by this RFA until funds have been appropriated, allocated and committed through internal agency procedures. While USAID anticipates that these procedures will be successfully completed, potential Applicants are hereby notified of these requirements and conditions for the award. The Agreement Officer (AO) is the only individual who may legally commit the Government to the expenditure of public funds.

The successful applicant may not incur any costs, chargeable to this program, before receipt of either a fully executed cooperative agreement or a specific, written authorization from the Agreement Officer. Further, the Government reserves the right to reject any or all applications received.

DUE DATE: Applications shall be uploaded to www.grants.gov no later than February 10, 2014, 9:00am Washington DC time. Applications submitted via fax, email, mail service or hand delivery will not be accepted. Applicants who encounter problems with their application submission should email the points of contact, listed below before the submission deadline. Applicants should retain a copy of their application and accompanying enclosures for their records.

Please see Section IV – Application and Submission Information for instructions how to submit the application.

QUESTIONS: Prospective applicants who have questions concerning the contents of this RFA shall submit them via email only, no later than Thursday, **January 17, 2014 9:00am** Washington DC time to Amy Wire at awire@usaid.govand Christie Cooper at ccooper@usaid.gov. Any additional information regarding this RFA will be provided, as necessary, through an amendment that will be posted to www.grants.gov.

In Accordance With (IAW) the instructions provided in Section IV applicants who are deemed by the Technical Evaluation Committee in competitive range may be invited to discuss the technical application orally. Oral discussions will be held in the Washington DC metropolitan area. The specific location and schedule will be coordinated after applications have been received. Applicants should expect the oral discussions to occur in or about March 2014.

Applicants must submit two applications: one technical application and one cost application. Each application must have a cover page that contains the name and address of the applicant, the RFA # (referenced above), and clearly identify if the application is the technical application or the cost application. Applications that omit required submission information as specified in Section IV, or deviate in anyway from the instructions provided in Section IV, will be deemed non-responsive and will not be reviewed by the technical panel.

POINTS OF CONTACT:

Primary Point of Contact:
Amy Wire, M/OAA/GH
Agreement Specialist
awire@usaid.gov

Alternate Point of Contact:
Christie Cooper
ccooper@usaid.gov

Thank you for your consideration of this USAID initiative. We look forward to your organization's participation.

Sincerely,

/s/

Patricia Bradley
Agreement Officer
M/OAA/HSR
Office of Acquisition and Assistance (OAA)

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ABBREVIATIONS AND ACRONYMS

ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immune Deficiency Syndrome
AOR	Agreement Officer's Representative
ART	Anti-Retroviral Therapy
ATS	American Thoracic Society
CA	Cooperative Agreement
CBO	Community-based organization
CDC	US Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CSH	Child Survival and Health Programs Fund
DA	Development Assistance
DALY	Disability Adjusted Life Year
DOTS	Internationally recognized basic TB services package
DST	Drug Susceptibility Testing
ESF	Economic Support Fund
FIND	Foundation for Innovative New Diagnostics
FHI	Family Health International
FSA	FREEDOM Support Act
FY	Fiscal Year
GDF	Global Drug Facility
GDP	Gross Domestic Product
Global Fund	Global Fund to Fight AIDS, TB, and Malaria
GH	Bureau for Global Health
GH/HIDN	Global Health, Office of Health, Infectious Disease and Nutrition
HIV	Human immunodeficiency virus
HRD	Human Resource Development
IDA	International Disaster Assistance
IPT	Isoniazid Preventive Treatment
IQC	Indefinite Quality Contract
IR	Intermediate Result
JATA	Japanese Anti-TB Association
LTBI	Latent TB Infection
M&E	Monitoring and Evaluation
MDG	Millennium Development Goal
MDR-TB	Multi-drug Resistant TB
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	Non-Governmental Organization

NICRA	Negotiated Indirect Cost Agreement
NIH	National Institutes of Health
NTP	National TB Program
OAA	Office of Acquisition and Assistance
OGAC	Office of the Global AIDS Coordinator
OR	Operations Research
OFDA	Office of Foreign Disaster Assistance
OMB	Office of Management and Budget
PATH	Program for Appropriate Technology in Health
PEPFAR	US President's Emergency Plan for AIDS Relief
PHN	Population Health and Nutrition
PIH	Partners in Health
PLHIV	Person Living with HIV
PMDT	Programmatic Management of Drug Resistant TB
PPP	Public Private Partnership
PQM	Promoting the Quality of Medicines
PVO	Private and Voluntary Organizations
RFA	Request for Application
SF	Standard Form
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SO	Strategic Objective
TB	Tuberculosis
TBCTA	Tuberculosis Coalition for Technical Assistance
TEC	Technical Evaluation Committee
TO	Task Order
Union	International Union Against Tuberculosis and Lung Disease
URC	University Research Corporation
USAID	United States Agency for International Development
USG	United States Government
USP	United States Pharmacopeia
VCT	Voluntary Counseling and Testing
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

SECTION I – Funding Opportunity Description

A. INTRODUCTION

The Bureau for Global Health (GH) at USAID is issuing this RFA for a Cooperative Agreement (CA) to build and expand upon previous USAID Tuberculosis (TB) prevention and treatment efforts over the last fifteen years. *Challenge TB* will be one of the main global mechanisms in the next five years for implementing USAID's TB strategy as well as contributing to TB/HIV activities under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), as requested. The new activity funded under this RFA will complement existing and planned projects in the GH Bureau to provide global technical leadership and support to National TB Programs (NTPs) and other in-country partners.

The authorizing legislation for this RFA is Foreign Assistance Act of 1961. Both US and non-US PVOs and NGOs are eligible for award of the Cooperative Agreement (CA) under this RFA. For U.S. organizations, 22 CFR 226, OMB circulars, and the ADS 303maa, Standard Provisions for U.S. Non-governmental Organizations are applicable. For non-U.S. organizations, ADS 303mab, Standard Provisions for Non-U.S. Non-governmental Organizations will apply.

B. PURPOSE

The purpose of this cooperative agreement is to support countries with high burdens of TB, MDR-TB, and TB/HIV achieve their national strategic plan goals, thus contributing to the achievement of the 2015 Millennium Development Goal (MDG) objectives and strive towards the post-2015 global goals. The Recipient will strengthen the TB services to improve prevention, diagnosis, treatment and care, especially for the poorest and most vulnerable populations in high risk settings. The approach to address this major public health problem should utilize locally owned and generated innovations and research, and cutting-edge technical expertise as well as coordinate and collaborate closely with the Global Fund to maximize limited resources. The purpose of this cooperative agreement is to achieve the following three objectives:

Objective 1: Expand Access to Prevention Services

Objective 2: Improve Patient-Centered Quality Care Systems for TB, MDR-TB and TB/HIV

Objective 3: Sustain and Enhance Systems

C. BACKGROUND

Globally, TB prevalence and mortality have decreased significantly when compared to 1990 levels, and the world is on track to reach the 2015 MDG to reduce TB mortality by 50%. Despite these successes, there were an estimated 8.7 million new cases of TB in 2011 and 1.4 million deaths, including 430,000 deaths in people who were HIV-positive.[1] An estimated one third of

[1]Global Tuberculosis Report 2013, World Health Organization (WHO).

new TB cases occurred among women, and about 500,000 women died from TB. Over 500,000 children under the age of 15 were estimated to have fallen ill, and over 70,000 children died.[2]

Of the estimated 8.7 million new cases in 2011, only 5.8 million were actually diagnosed (62%). Although the number of cases detected has significantly increased over the past decade, there are still an unacceptably high number of cases not diagnosed or put on treatment every year. The number of annual TB deaths makes TB one of the greatest infectious disease killers globally – only slightly behind HIV and AIDS.

Throughout the world, an estimated two billion people are infected with *Mycobacterium tuberculosis*. Any time there is a weakening of the immune system, individuals infected with latent TB are vulnerable to progression to active TB disease and may begin to experience symptoms such as chronic cough, fever, weight loss, and fatigue. HIV and AIDS, diabetes, malnutrition, and other illnesses can make a person more vulnerable to TB illness. Additionally TB disproportionately affects high risk populations, such as people living in poverty, those experiencing crowded living/working conditions, poor ventilation, lack of access to clean water and sanitation, prisoners, miners, and those whose health status is already compromised. Developing and transitioning countries make up ninety-five percent of TB cases globally.

Although men are more likely to be infected with TB, women are more likely to develop active TB disease and experience symptoms associated with the illness. TB is one of the leading causes of death among women worldwide. In addition to the burden of mortality, there is some evidence that TB during pregnancy leads to complications for both mothers and infants. Moreover, there are an estimated 10 million children who have lost at least one parent due to TB. The economic burden of TB at household level is significant. In addition to the immediate loss of income and productivity for the household member who is sick, other family members may be temporarily pulled out of work and/or school in order to provide care. In many places, families must pay for daily or weekly transport to a health facility even if TB diagnosis and treatment are available free of charge. At the national level, it is estimated that some countries lose from four to seven percent of Gross Domestic Product (GDP) due to TB. Governments of high burden countries must be convinced to invest more domestic resources in TB care and treatment services to prevent further transmission as well as save lives and money.

As mentioned above, People Living with HIV (PLHIV) have a higher risk for contracting/developing TB. The HIV epidemic continues to drive the spread of TB in countries where both diseases are highly prevalent. In sub-Saharan Africa, almost 40% of all TB patients are also infected with HIV. People with TB/HIV co-infection often have different symptoms and are more difficult to diagnose than people who are not co-infected, using the standard tests used throughout the world. When they are diagnosed with both TB and HIV, they may have to visit more than one clinic to receive care for both illnesses. In 2011, only 48% of HIV-positive TB patients globally were started on antiretroviral treatment.

In other regions, most notably Eastern Europe and Central Asia, drug resistance has grown steadily during the last decade, and globally there are about 630,000 estimated cases of Multi-Drug Resistant TB (MDR-TB). This is largely a result of clinical and programmatic mismanagement of TB, such as drugs being of low quality, providers not prescribing the proper

[2] This is an estimate as it is difficult to measure the burden of TB disease in children, and data is limited.

regimen, and/or patients not receiving support to ensure they take the full six months of treatment. MDR-TB is much more difficult to diagnose and treat compared to drug-sensitive TB, requiring specialized laboratory expertise and infrastructure and an 18 to 24 month regimen of very expensive, toxic medication which may not be readily available to the National Tuberculosis Program (NTP). Of the estimated 630,000 cases of MDR-TB, only 60,000 were diagnosed in 2011. Extensively Drug-Resistant TB (XDR-TB) has been reported by 84 countries, and although it is still quite rare (approximately 9% of all MDR-TB cases), the treatment outcomes are very poor.

C.1. The Global Strategy to Stop TB

Global TB prevention, diagnostic and treatment efforts have been shaped by the World Health Organization's Stop TB Strategy since its launch in 2006. WHO led the international community (NTPs, donors, civil society, technical partners, private sector, and other stakeholders) in the development of the strategy in conjunction with the Stop TB Partnership's Global Plan 2006 – 2015. It was also endorsed at the WHO World Health Assembly by the member states. The strategy laid the foundation for comprehensive and systematic support of TB programs for partners and donors to implement. The Stop TB Strategy built upon the original DOTS strategy (the internationally recognized basic TB services) and includes 6 major components:

1. Pursue high-quality DOTS expansion and enhancement;
2. Address TB/HIV, MDR-TB and the needs of poor and vulnerable populations;
3. Contribute to health systems strengthening based on primary health care;
4. Engage all care providers;
5. Empower people with TB, and communities through partnerships; and
6. Enable and promote research.

Increased investment in the scale-up of the Stop TB Strategy has resulted in significant progress towards global targets. Since 1990, the global TB mortality rate has decreased by 45% and the TB prevalence rate has declined by 37%. TB case detection (all forms) has increased from 40% in 1995 to 66% in 2012. Additionally, successful treatment of smear-positive TB cases has improved from 57% in 1995 to 87% in 2012. Despite these gains, TB is still a global threat. In 2012 there were nearly 3 million undiagnosed cases. Of the estimated 630,000 MDR-TB cases, less than 100,000 of them were detected and identified as eligible for treatment. Although the proportion of TB patients who know their HIV status continues to increase and reached 74% in the African region, access to Antiretroviral Treatment (ART) remains weak – in 2012 less than 60% of HIV-positive TB patients were on ART. Private sector engagement remains challenging as the private sector is large, unregulated and growing in many countries and often provides services not in line with international TB standards of care. The lack of treatment for these people will lead to the further spread of disease and death.

The 2015 MDG includes many objectives, one of which is to reduce TB prevalence and mortality by 50% compared to 1990 rates. The MDGs motivated Ministries of Health (MOH), donors, and technical partners to diagnose new cases and treat them appropriately. Diagnosis has stagnated and prevention/ treatment of MDR-TB are not keeping pace with the epidemic. USAID will be revising its strategy next year to align with the global post-2015 TB goal of a *world free of tuberculosis*. The USG strategy will respond to both current challenges and future priorities, including post-2015 milestones and targets. In order to achieve these goals and targets, USAID

will accelerate implementation of local, evidence-based, and cost-effective interventions designed to prevent the further spread of TB and drug resistant TB, and to prevent deaths.

The "post-2015" view of TB support will be ambitious and will require a dramatic scale up of TB diagnosis and treatment, especially invulnerable and poor populations; it will require advances on universal health coverage and economic development and poverty reduction; substantial investment in research and development to accelerate the availability of new TB tools; and widespread uptake of these new tools as they become available. Below is the vision of what the world will look like post 2015 if all the objectives are met:

Vision: A world free of TB

Goal: End the Global TB Epidemic

Targets for 2035: 95% reduction in TB deaths (compared with 2015) and less than 10 cases per 100,000 population

Milestones for 2025: 75% reduction in TB deaths (compared with 2015) and less than 50 cases per 100,000 population

The USG through USAID is the largest bilateral donor, supporting global TB prevention and care in approximately 26 countries. Over the past seven years, USAID's TB prevention and care programs that have allocated approximately $1,250,000,000 to save lives and prevent the spread of TB and MDR-TB. USAID is implementing TB programs to accelerate detection and treatment of TB for all people, scale-up TB/HIV integration, expand prevention and treatment of MDR-TB, and overall strengthening of health care systems.

USAID led the development of a USG TB strategy (2009-2014) in response to the Lantos-Hyde Reauthorization Act of 2008. The strategy, closely linked to the Stop TB Strategy and GH Initiative principles, includes the following targets to be reached by 2014: 50% reduction in TB prevalence and mortality (relative to 1990); 70%smear-positive TB case detection rate; 85% treatment success rate; successful treatment of 2.6 million new smear-positive TB patients; and diagnosis and treatment of 57,200 new MDR-TB cases.

By 2011, USAID-supported projects have achieved the following milestones:

1. TB mortality and prevalence have decreased by 42% and 40%, respectively between 1990 and 2011;
2. TB case detection (all forms) of 62%;
3. Treatment success rate of 86% ;
4. Successfully treated over 1.5 million smear-positive TB patients; and
5. Diagnosed and initiated treatment of 45,000 people with MDR-TB.

Challenge TB will be one of the main USAID mechanisms to contribute to the goals and targets in select countries, and to implement activities to contribute to the post-2015 goals. Although *Challenge TB* is a successor to, and builds upon previous USAID TB prevention and care efforts

over the last fifteen years, it will have a more intensified focus on country owned and led processes that weave in local, cutting-edge innovations to leapfrog the results forward. *Challenge TB* will be one of the main global mechanisms for country level implementation of USAID's TB strategy as well as contribute to TB/ HIV activities under PEPFAR, as requested. This project is designed to support Ministries of Health, NTPs, and other key stakeholders to spearhead quality and evidence-based solutions to TB challenges in their countries. *Challenge TB* will provide a menu of choices to address the changing landscape and needs in different countries and settings as well as complement existing and planned projects in the Bureau for GH and country-level activities.

USAID is a global technical leader in policy and tool development, and country level strategic guidance. USAID is active in the Stop TB Partnership Coordinating Board and its working groups, and works closely with the Global Fund to Fight AIDS, TB, and Malaria (Global Fund) grants and other global TB partnerships to ensure an efficient and effective approach to achieving success. In addition, our efforts are contributing to research in new and expanded tools and technologies for improved diagnosis, treatment, policy and implementation. At a country level, USAID TB activities are aligned closely with NTP to support their strategic plans and ensure close coordination with Global Fund and other country partners. The programs are embedded within the MOH NTP to ensure country ownership, maximize efforts and avoid duplication of the work of the NTPs and other partners, such as the Global Fund.

USAID's comparative advantage is its ability to implement TB programs at scale; pilot innovative approaches in field settings; monitor, document, and use results; and work directly with MOH to build national and local capacity. USAID uses country implementation experience to inform global policy and guidance. USAID is the only donor working in TB with both field and development experience, and has become a technical leader after nearly 15 years of such experience in the field. USAID also strongly supports and coordinates with TB activities and programs of other USG agencies including the US Centers for Disease Control and Prevention (CDC), the Office of the Global AIDS Coordinator (OGAC), and the National Institutes of Health (NIH), for example.

USAID's TB effort is concentrated in a number of countries (Table 1) to focus financial and human resources of USAID and its partners. The country selection is based on one or more of the following criteria:

1. High burden of TB cases;
2. High burden or prevalence of drug resistant TB;
3. High incidence of TB;
4. High HIV and AIDS prevalence (TB/HIV co-infection);
5. Lagging TB case detection and treatment success rates; and
6. Other factors including political commitment, technical and financial need, and managerial feasibility.

Table 1. USAID TB Priority Countries[3] as of 2013
Afghanistan*, Armenia**, **Bangladesh***, **Burma***, **Cambodia***, **Democratic Republic of Congo***, **Ethiopia***, Georgia*, **India***, **Indonesia***, Kazakhstan*, **Kenya***, Kyrgyzstan*, Malawi, **Mozambique***, **Nigeria***, **Philippines***, **South Africa***, South Sudan, Tajikistan*, **Tanzania***, **Uganda***, Ukraine*, Uzbekistan*, Zambia, **Zimbabwe***

Bold designates TB high burden country
**Designates a MDR-TB high burden country.*

USAID also supports additional countries and regional platforms through Regional support in Europe and Eastern Europe, Latin American, the Caribbean, Africa, and Asia.

In addition, any PEPFAR funding received would be working in an overlapping but different list of countries. Please also refer to the PEPFAR website for a list of their countries that should be addressed for TB/HIV activities in this RFA. http://www.pepfar.gov/countries/index.htm.

C.2. USAID/GH-Supported TB Partners

USAID is a global leader in combating TB. Support to global and country programs started in 1998 with $10 million and has grown to more than $230 million in FY 2012. USAID works with a wide array of partners to achieve TB care and prevention objectives.

USAID field Missions program funds through bilateral or global programs and are mandated to work with the MOH, NTP, and other local organizations at the country level. USAID GH in Washington DC manages a number of TB programs, of which *Challenge TB* will be one.

TB CARE I and TB CARE II cooperative agreements: One of the key mechanisms for supporting USAID's TB care and prevention strategy has been the TB CARE projects. The purpose of TB CARE assistance is two-fold. First, it attempts to improve and expand the capacity of USAID to respond to the global TB epidemic by providing well-coordinated state-of-the-art, context appropriate, technically sound and cost-effective consultation and technical assistance to high-prevalence countries and Missions. A further goal is to build additional global capacity for the provision of technical assistance. Second, TB CARE is intended to complement and expand existing global TB control efforts by working in collaboration with other global TB partners and maximize on-going efforts to accelerate the pace of DOTS expansion to meet global targets.

The TB CARE I coalition consists of the prime organization KNCV Tuberculosis Foundation and six main sub-recipients including the American Thoracic Society (ATS), Family Health International (FHI), Japan Anti-Tuberculosis Association (JATA),Management Sciences for Health (MSH), the Union, WHO, and a number of additional sub-partners at country level. This

[3]Some of the top 22 high-burden countries do not appear in the table of priority countries for the USG. For example, Brazil, China and Thailand have domestic resources available to support TB efforts. These countries may require technical assistance or limited country-level support.

coalition collectively refers to themselves as the Tuberculosis Coalition for Technical Assistance (TBCTA).

The TB CARE II partnership consists of University Research Corporation (URC), Partners in Health (PIH), Jhpiego, and Project HOPE as the main implementing partners. There are additional resource partners that form the TB CARE II partnership.

In addition, all USAID-funded TB CARE I publications and annual reports can be found at http://www.tbcare1.org/. TB CARE II publications and information can be found at http://tbcare2.org/.

Additionally the TB Task Order that was awarded in 2009, is a coalition of partners implemented comprehensive country TB and TB/HIV programs, and implemented regional and core programs in advocacy, communications, and social mobilization; MDR-TB; Global Fund technical assistance; and the introduction of new tools. The Task Order (TO) provides technical and management support to on-going USAID funded tuberculosis program activities at global, regional and country levels, carry out reviews and analyses of TB program activities, and provide USAID offices and missions a mechanism to access expert short and long term technical assistance.

The TB TO 2015 consortium is led by PATH and includes the American Society for Microbiology, Dartmouth College, Eli Lilly MDR-TB Partnership, Fondazione Salvatore Maugeri, Foundation for Innovative New Diagnostics (FIND), Initiatives, Inc., MSH, TB Photovoice, University of California San Francisco, and PIH.

The recipient of this RFA will work closely with MOH, in line with National TB strategic plans, and complement activities supported through other donors including the Global Fund. The partners provide a diverse set of technical competencies from a mix of international consultants and local staff. The in-country programs implemented by TB CARE I and II and the TB Task Order 2015 provide focused, high-quality technical support directly to MOH. USAID's strong field presence and implementation experience through these projects allows for scale up of proven approaches and roll out of innovative technologies. A number of tools, guidelines, and pilot projects have resulted from many of the core activities implemented by these projects, **shaping global best practices and adding to the TB knowledge base.**

In addition to these flagship TB projects, the USAID GH TB team manages a comprehensive portfolio of TB activities and partners including:

(a) **Global Alliance for TB Drug Development**: Established in 2000 as a not-for-profit product development partnership to lead the search for new TB regimens and catalyze global efforts for new TB regimens. USAID contributes to the work of the partnership in late-stage clinical trials of new TB drug regimens.
(b) **Global TB Drug Facility:** USAID provides support to the Global TB Drug Facility (GDF) for country grants for the purchase of TB drugs. In addition, USAID provides technical assistance to the GDF to ensure pharmaceutical management issues are properly addressed as well as provides support to countries for monitoring GDF grants.
(c) **Promoting the Quality of Medicines (PQM):** The PQM project is a USAID cooperative agreement with the United States Pharmacopeia (USP) to provide assistance to countries to help

ensure the quality, safety, and efficacy of medicines essential to USAID priority diseases, particularly malaria, HIV/AIDS, and TB. The project supports expanding the number of drug manufacturers able to provide WHO pre-qualified TB drugs.

(d) **Stop TB Partnership**: USAID is a financial supporter of the Stop TB Secretariat, a member of the Stop TB Coordinating Board, and is represented on all of the Stop TB working groups (DOTS expansion, new TB drug development, MDR TB, TB/HIV, and TB diagnostics). USAID support was instrumental in the development of the Global Plan, and to the establishment of national Stop TB partnerships and preparation of plans for DOTS expansion in most HBCs. USAID supports the Stop TB Secretariat to develop new tools and provide technical assistance for social mobilization and communication.

(e) **Systems for Improved Access to Pharmaceuticals and Services (SIAPS)**: The SIAPS project is a cooperative agreement with MSH that provides technical assistance on drug selection, forecasting, availability, and proper use by both providers and consumers. The project provides support to NTPs in drug management as well as external technical assistance.

(f) **Technology, Research, Education and Technical Assistance for Tuberculosis (TREAT TB)**: A CA with the Union focused on developing and implementing sound TB research through field evaluations of diagnostic tools; clinical trials of priority research questions; and targeted operational research benefitting global, regional, and country TB control efforts.

(g) **WHO Global TB Program**: Grant funding to support global TB policy development and guidance including: TB monitoring and surveillance and impact measurement; surveillance and management of MDR and XDR-TB; innovations for intensifying early and complete TB case detection and effective service delivery; technical capacity building for policy adaptation, implementation and service delivery; and the Global Laboratory Initiative.

D. TECHNICAL APPROACH

USAID strives to reach the global post-2015 goals, targets and milestones described above in Section B.1 and strengthen the USG strategy and technical approach to respond to both current challenges and future priorities. USAID projects will contribute to global TB case detection targets (≥80%) and treatment success targets (≥95%). In order to achieve these goals and targets, USAID will accelerate implementation of proven, cost-effective interventions designed to prevent the further spread of TB and drug resistant TB, and to prevent deaths. *Challenge TB* will be one of the main USAID mechanisms to contribute to these goals and targets in select countries, and to implement activities to contribute to the post-2015 goals.

USAID needs to sustain global and country investments to prevent the transmission of TB and the development of MDR-TB. The TB cases need to be found earlier and quality of treatment needs to be maintained at a very high level. Unfortunately, there are already many countries facing the spread of MDR-TB. The magnitude of the MDR-TB burden continues to outpace the scale-up of interventions. Focused attention is needed on MDR-TB so that the gains made in TB over past decades are not wasted. Quality and appropriate treatment models with palliative care with private sector involvement should be developed and rolled out in countries with the greatest burden of MDR-TB.

TB continues to be one of the greatest killers of PLHIV, and the rate of screening for TB is low. These two factors (high mortality and low screening rates) underscore the need to improve the number of screenings for TB/HIV interventions and services. This program (along with other USAID programs) will increase screening activities in two areas: it will scan PLHIV for TB, and

it will scan TB patients for HIV. Innovative diagnostics to detect co-infected patients is a major component of this cooperative agreement including close collaboration with PEPFAR and other partners to ensure maximum impact. A comprehensive approach to infection control is a critical part of prevention services for all.

It is expected that the recipient will contribute to the global goals of a world free of TB measured by reductions in mortality as well as reach at least 80% of estimated TB cases and successfully treat 90% of those cases; enhance quality services for the prevention, detection and treatment of MDR-TB; and increase early case detection, expand intensified case finding, enhance airborne infection control efforts and expand access to and integrate treatment of TB and HIV in co-infected individuals. The following nine countries will be used as the marker to measure contribution and apply approaches: Bangladesh, Burma, Cambodia, DR Congo, India, Indonesia, Mozambique, Nigeria, and Ukraine.

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D.1 Objectives

The approach to providing global leadership and field implementation must be comprehensive and aligned with the following objectives:

O.1 Expanded Access to Prevention Services
O.1.1 Infection Control
O.1.2 Active Case Finding
O.1.3 Latent TB Infection (LTBI) Strategies

O.2 Improved Patient-Centered Quality Care Systems for TB, MDR-TB and TB/HIV
O.2.1 Universal Access to Appropriate Treatment
O.2.2 Laboratory Network Strengthening
O.2.3 Comprehensive Care Services
O.2.4 Engaging all Care Providers

O.3 Sustained and Enhanced Systems
O.3.1 Political Commitment and Leadership
O.3.2 Comprehensive Partnerships
O.3.3 Demand Driven TBServices
O.3.4 Drug Policy and Management
O.3.5 Data Quality, TB Surveillance, and Monitoring and Evaluation
O.3.6 Human Resources Development (HRD)

The evidence-based approaches to the technical objectives should weave in the five cross-cutting elements below to create a vanguard roadmap for propelling the project forward to meet the goals and objectives. These issues should be addressed globally and as appropriate at the country level in of the support MOH and other key stakeholders. The five *Challenge TB* cross-cutting elements are the following:

(1) Access to services for all people;
(2) Urban Services;
(3) Locally owned and generated innovations and research;
(4) Coordination and Collaboration with Global Fund; and
(5) Cutting-edge Technical expertise.

The recipient will not support Core funded global activities for drug management or operational research. USAID has other mechanisms for implementing the global leadership components of these activities. However, these activities will be supported at the country level through field support as deemed necessary.

Objective 1: Expanded Access to Prevention Services

The recipient will support MOH efforts to expand access to TB prevention including focused contact investigations, promotion of latent TB infection treatment and expanded infection control.

Without interventions to prevent transmission, infection, and disease, the global community will not be able to achieve a significant reduction in the number of TB cases, will not eliminate the burden; disease, and thus not meet the post 2015 goals nor get closer to the aim of eliminating TB. Although resources in countries limit the extent of preventive interventions, the recipient will develop and implement a strategy aimed at the prevention of TB which will include the following:

O.1.1 Expanded infection control in public and private sector facilities;
O.1.2 Active Case Finding; and
O.1.3 Promotion of latent TB infection treatment in targeted populations and communities.

Implementation of this objective will include, but not limited to, the following areas of work:

O.1.1 Infection Control

Preventing the spread of TB and MDR-TB in congregate setting and communities is a major concern to USAID, and a fundamental core requirement of this RFA. The prevention and reduction of the number of infections for high risk populations and settings is critical to achieve the objectives. Although the main evidence-based infection control measures are known, the most cost-effective and efficient manner to implement them in specific countries is still be studied. There are often not enough resources to support all interventions to strengthen infection control throughout the entire health care system.

It is important for infection control activities to follow a careful, structured, and comprehensive approach. Considering the limited resources, the approach should prioritize the most effective interventions, demonstrate the evidence for each activity, and develop synergies with other activities. It is critical for these activities to help measure reductions in transmission at the national and sub-national levels and contribute to the overall project results.

O.1.2 Active Case Finding

As another form of infection control, it is important for a good TB program to systematically and actively investigate TB infection and diseases to identify TB cases before people would normally seek care for symptoms. Effective investigation of TB contacts within NTPs and other services can aid in detecting the presence of the disease. The prioritization of risk groups, settings and delivery strategies will be important to achieve the greatest impact in each country and globally.

There is limited evidence on how different active case finding strategies can contribute to overall national goals. The measurement of this impact and the lessons learned from implementation will be important to inform and adapt country and global policies.

O.1.3 Latent TB Infection (LTBI) Strategies

There are estimated two billion people globally with latent TB. There has been little attention to this issue in high burden countries even though preventative therapy can greatly reduce the risk to develop TB disease. A lack of resources and concerns about the development of drug resistance are likely the biggest barriers to LTBI treatment uptake.

However, it is critical for countries to develop strategies to prioritize risk groups and settings for preventative treatment, especially those with more domestic resources and high transmission within communities. There is a need to provide policy and programmatic support on the appropriate use of LTBI treatment for high risk groups, and develop models for scale-up in appropriate settings and countries.

Objective 2: Improved Patient-Centered Quality Care Services for TB, MDR-TB and TB/HIV

The recipient will support the country's efforts and develop new innovative approaches to improve the quality of treatment and focus on patient-centered approaches to care.

Ensuring universal access to diagnosis and care for all persons suspected of having TB is a pillar of a successful TB program. Comprehensive universal access will include several overlapping components: active case finding, community-based TB interventions, laboratory network strengthening, and working with the private sector and other important populations like prisons. Even though most countries are able to detect the presence of TB through passive case-finding approaches, we will not be able to achieve our goals of reducing burden and death from TB without focused activities to find and treat the most vulnerable patients.

O.2.1 Universal Access to Appropriate Treatment
O.2.2 Laboratory Network Strengthening
O.2.3 Comprehensive Care Services
O.2.4 Engaging all Care Providers

Implementation of this objective will include, but not limited to, the following areas of work:

O.2.1 Universal Access to Appropriate Treatment

Every individual has the right to access quality treatment. Although TB, MDR-TB, TB/HIV treatment is usually mandated by national policies and provided free of charge within the health care system, quality treatment is still not accessible to many groups of people. In addition, the services are not conducive to achieve good treatment outcomes. As countries have more capacity, it is important for programs to develop and utilize locally generated innovations and research to extend the reach of services beyond the health facilities to treat all people with TB, MDR-TB and TB/HIV. In particular, access to treatment needs to be expanded to ensure women are appropriately reached and gender considerations are integrated into all TB programs. In addition to gender, there is a need to focus particularly on addressing the cultural, social,

economic and/or political barriers to access to services for individuals and/or groups at high risk for TB, including children.

O.2.2 Laboratory Network Strengthening

A functional comprehensive laboratory network is a priority for a successful TB program. The network must be able to address the management, organizational, bio-safety, and work quality aspects of the laboratory at all levels. This technical area will focus on the policy, management, supervisory and quality assurance systems for smear microscopy, culture, drug susceptibility testing (DST), GeneXpert, and all other new diagnostics. It is critical for future approaches to lab strengthening are comprehensive and strategic in nature to fully address the gaps in globally, regionally and country level networks. The capacity of laboratories to detect drug resistant TB strains in USAID priority countries is often limited. The development, introduction, and expansion of laboratories to conduct quality culture and DST, and introduce new and more effective diagnostic tools for MDR-TB detection is an urgent and critical issue to be addressed. There needs to be comprehensive and rapid approach to building this capacity at the national and sub-national level to address the current challenges.

O.2.3 Comprehensive Care Services

An essential component of a good national TB program is a functional nation-wide quality and comprehensive patient support and palliative care services for TB, MDR-TB and TB/HIV. National TB Programs need support in the development of patient-centered interventions to remove the barriers and stigmas associated with people completing TB, MDR-TB and TB/HIV treatment as well as develop and implement comprehensive systems for all aspects of care in a variety of settings. This assistance will also include learning from current best practices, developing country specific approaches and enabling local partners to play an active role in the delivery of care packages. Support for systems will include both patient support and palliative care.

O.2.4 Engaging all Care Providers

In many countries the private, quasi-governmental, and non-MOH public sectors play an important role in providing health and TB services. The quality and monitoring of services of all care providers and links to the MOH services must be improved to meet the targets for case detection and successful treatment. Many countries have engaged TB providers through pilot Public-Private Partnership (PPP) projects but very few of them have figured out how to motivate the private sector to address public health issues and the public sector to understand the business models required sustaining quality services in the private sector. The private sector needs to be encouraged to reach in and help achieve the TB goals and objectives. Models of TB, MDR-TB and TB/HIV care packages and services in the private sector need to be locally generated to address the demands and needs of the communities, patients, and providers. To address the gaps, there is a need to develop strategies to scale-up the current best practices and/or create new locally driven models to expand on the provider (e.g. private physicians, pharmacists, hospital staff, work place health staff, prison health practitioners, military health practitioners, etc.) and service range. In addition, these activities should be conducted in collaboration and complement other health PPPs.

Objective 3: Sustained and Enhanced Systems

The recipient shall support the country's efforts to strengthen the health system as it relates to TB, particularly for improving political commitment and leadership for TB, developing and strengthening of TB partnerships, increasing demand for quality services, improving drug policies and management, strengthening the monitoring and evaluation (M&E) systems and building the human resource capacity.

TB services are implemented within the existing health systems. The development of this system is critical for TB care and treatment, particularly certain aspects. There needs to be an enabling policy and regulatory framework as well as financial resources available to demonstrate country ownership and leadership. The engagement of partners from different sectors and interest groups will enrich the country's response to the epidemic as well as ensure accountability collectively. One of the most important stakeholders is the affected communities. This community should be supported to raise awareness and demand services that are user-friendly and patient-centered. Lastly, countries need support with the development of other health services such as drug policy and management, M&E and human resources to achieve their objectives.

O.3.1 Political Commitment and Leadership
O.3.2 Comprehensive Partnerships
O.3.3 Demand Driven TB Services
O.3.4 Drug Policy and Management
O.3.5 Data Quality, TB Surveillance, and Monitoring and Evaluation
O.3.6 Human Resources Development (HRD)

Implementation of this objective will include, but not limited to, the following areas of work:

O.3.1 Political Commitment and Leadership

Political commitment is necessary to catapult countries towards achieving the post-2015 goals. It will be critical for various sectors in the government to commit to investing adequately in TB care and treatment. Innovative policies and financing will be required to address the universal coverage for all people. There will need to be political commitment to ensure people are able to access quality services in the public or private sector without incurring huge out-of-pocket costs. Evidence and best practices need to be developed to inform and assist the governments with multi-sectoral policies and financing mechanisms.

Country ownership requires an NTP with strong leadership and management skills to successfully develop and implement an effective strategic plan. Leaders in TB prevention, diagnosis and treatment are required at all levels of the program, although their roles and responsibilities will vary depending on the structure of the health care system. The leaders need to be able to develop systems for effectively managing, retaining and increasing the human and financial resources to develop a sustainable and enhanced system. These are critical skills not necessarily taught through the formal education system in many of USAID's focus countries, requiring the development of these skills at all levels. Each country's NTP leadership and management capacity needs to be analyzed to identify the gaps and a strategic and comprehensive approach to improving it developed. The approach needs to be interactive and extend far beyond tool development.

O.3.2 Comprehensive Partnerships

A National Partnership is an innovative way to empower key decision makers and stakeholders in TB care and treatment. This engagement will provide different perspectives and voices to the national response as well as improving the access to various competencies of different sectors of society. Each sector has a comparative advantage and can help the overall program perform better and more effectively. A national partnership is a voluntary alliance between organizations that is based on the public, civil society, and private/business sectors to commit to working together towards TB prevention, care and treatment. It is also a mechanism to hold a group of stakeholders mutually accountable for achieving the national strategic plan and the Global Fund grant. There need to be better coordination platforms at the country level for partners to work together to achieve the national TB goals collectively.

O.3.3 Demand Driven TB Services

Communities and affected populations need to be empowered to play an active role in the delivery of TB services. It is very important for the end user, providers, and communities to be involved in the development of the TB service delivery process as well as the development of policies and plans. As their knowledge and awareness increases, the quality of care and treatment will also increase. It is through informed decision-making that communities change their health seeking behaviors. Over time, they will have the capacity to inform policies and interventions that are focused on being user-friendly and patient-centered. In addition, they are one of the most powerful voices in advocating for improving the quality of and access to services. The development and implementation of country level strategies and approaches for engaging these partners to demand better TB care and treatment will be critical for improving the service delivery system for TB patients.

O.3.4 Drug Policy and Management

The procurement and management of quality first line, second line, other ancillary drugs and commodities are essential components of any TB program. However, it is often part of a larger nationwide drug management system that is cumbersome and complicated. Since this is one of the largest costs of a TB program, it is critical to ensure proper use and management of them. Furthermore, the inappropriate treatment or poor quality drugs can generate drug resistance. Countries need support with the development and enhancement of strong policies and regulatory frameworks with systems to monitor their enforcement in all sectors. In addition, there needs to be systems for measuring on a regular basis the quality and quantity of anti-TB drugs in the country. A comprehensive nationwide system should successfully select, forecast, procure, distribute and monitor the necessary drugs required for successful treatment. Close coordination with other partners supporting overall commodity management systems is essential to ensure the inclusion of anti-TB drugs.

O.3.5 Data Quality, TB Surveillance, and Monitoring and Evaluation (M&E)

NTPs need assistance with the development and strengthening of M&E systems (including surveillance and supervision) to improve the quality and completeness of data collected, and that the data is used to inform policy and implementation at all levels. New innovations should be

explored to improve the systems, including electronic recording and reporting, and linkages with other health information systems in the country. In addition, it is critical to ensure there are real-time mechanisms for measuring the quality of the services and interventions to make rapid program improvements. Accurate and available MDR-TB surveillance data are essential for targeting interventions and resources more effectively as well as improving program performance. Country-level drug resistance surveillance and surveys are a critical piece of information necessary for countries to determine their progress towards national goals.

O.3.6 Human Resources Development (HRD)

Without adequate and quality human resources, the health care system and TB program can't function. The NTP needs support to improve the development, quality and retention of human resources dedicated for health. As so many people in the country have been trained already through traditional methods, new and innovative approaches should be developed to ensure effectiveness. In addition, there are many human resource development activities being supported by other health areas. It is important to make sure interventions are well coordinated and integrated within other MOH and donor-supported approaches and activities. The approach will need to enhance the capacity of community and facility level staff to improve the quality of services provided and expand TB case finding across all health areas.

D.2. Cross-cutting Elements

The cross-cutting elements are key issues that reach across the TB technical objectives that can be incorporated in a concise fashion to provide a richer approach to TB prevention, care and treatment. These themes include Access to services for all people, Synergistic Support to MOH and NTPs, Innovation in approach, Sustainability of services, and Technical expertise.

Access to Services for All People
Marginalized and vulnerable populations as well as those most at risk are a special focus for USAID's TB program. Unless TB services are extended to serve these populations, the achievement of global and country level goals will not be possible. In addition, these populations need to be empowered to make informed decisions on their own care and treatment. Some of these groups include women, children, youth, injecting drug users, alcoholics, migrants and displaced persons, and PLHIV.

In particular, the barriers to access services for girls and women are considerable in some countries. While more men contract TB than women, TB is a leading (infectious) cause of death amongst women. Girls and women encounter significant barriers to treatment and every year about 500,000 women die of TB, and over three million women contract the disease. This accounts for about 17 million Disability Adjusted Life Years (DALY) and since TB affects women mainly in their economically and reproductively active years, the impact of the disease is strongly felt by their children and families. The mortality, incidence, and DALY indicators do not reflect this hidden burden of social impact. To reduce the effect of TB on girls and women, considerable effort is still required to remove barriers to accessing TB services.

In addition, TB is a disease of poverty affecting the most marginalized and hard to reach populations. There have been efforts and small-scale models to systematically identify and address these groups in USAID priority countries. However, there is a need to ensure the models

are documented and the best practices are scaled-up. Children are particularly ignored by TB prevention, diagnostic and treatment efforts. According to WHO, at least half a million children contract TB each year, and up to 70,000 children die of TB every year. There were over ten million orphans due to parental TB deaths in 2010. Strategies to diagnose and treat children need to be developed in the USAID-supported countries.

As more than half of the world's population today is under the age of 30, with the vast majority living in the developing world, it is crucial to make sure that this population cohort is taken into consideration when programming. Youth can play an active role in strengthening of services and outreach as well as development of new technologies and innovations. Interventions to engage youth, students, and young professions in developing local solutions will be critical to the sustainability and capacity building of all the objectives.

Urban Services

The global urbanization will have an impact on many countries, especially those with high TB burdens. By 2030, urban areas worldwide will house an additional 1.4 billion people, with the vast majority of this growth occurring in the developing and transitioning countries. TB disproportionately affects those dwelling in urban areas due to the overcrowding and links to poverty. Many TB patients in urban settings are from highly deprived communities that may contribute to a poorer outcome. In countries with large, urban areas, the local challenges to accessing and retaining TB services are even more critical than other areas. Deliberate strategies for assessing the situation, developing and implementing local solutions, and evaluating the interventions for best practices and scale-up needs to be developed to tackle this issue in a systematic and sustainable manner.

Locally Owned and Generated Innovations and Research

The global TB community has lagged in the development and introduction of new approaches, technologies, and research. In order to sustain efforts and truly develop country level capacity, effective approaches for promoting locally generated and innovative solutions to existing challenges are important for meeting country and global goals. In addition, the engagement of new partners and individuals, such as young professionals and university students will strengthen the activities as well as invest in the future generation. As countries progress and develop, any assistance program will need to adapt approaches to the country specific context to develop solutions that are innovative and address the key TB issues including stagnating case detection, low treatment success, high mortality and default rates, private sector engagement, innovative financing mechanisms, etc. There needs to enhanced mechanisms for funding and supporting these groups and ideas.

In addition to innovative implementation approaches, new technologies to improve diagnosis and treatment of tuberculosis, specifically in low resource settings will be necessary to address the challenges. Existing or new country platforms for introduction and scale-up of new technologies need to be strengthened. Such examples of new technologies include Xpert MTB/RIF implementation, new or improved treatment regimens, and mHealth. There is a need for comprehensive technical approaches and M&E frameworks to roll-out and assess the technologies. The best practices and lessons learned from these activities should inform country and global policies to contribute to the achievement of results.

Coordination and Collaboration with the Global Fund
The US Government is the largest donor to the Global Fund (GF) as well as the GF being the largest donor for TB care and treatment. It is strategically important for USAID's bilateral TB program to support, leverage, and optimize these resources. Global Fund grants and USG bilateral TB work plans are designed to provide support to fill strategically important financial, human, and programmatic gaps identified in these plans. This approach ensures country ownership, promotes NTP management capacity, enables coordination of external and national TB resources, and maximizes outcomes.

Over the past two years, there have been many large changes at the GF, resulting in the development of a new funding model. This significantly changes the way grants are awarded and implemented, and countries need to be prepared for these changes to ensure the achievements that have made over the past several years are sustained and improved upon. In response to this change and the need to accelerate TB care activities, USAID has developed a technical assistance model to ensure that GF grants are successfully implemented; to improve coordination between partners; to build country capacity; and to ensure that the greatest challenges in TB prevention and control are met. This is done through a combination of long-term TA, short-term TA, and multi-partner TA where several different partners provide coordinated TA at the country-level to resolve an issue. Long-term TA will mainly be facilitated by USAID in coordination with our implementing partners.

There is a need for closer coordination and collaboration of all USAID-supported technical assistance. The recipient will work closely with USAID to serve as the hub for all GF TB technical assistance supported by the USG. This hub should be located in the project's main management unit, with support from its staff at the country level. A system is required to ensure TA needs are proactively met and on-going follow-up. The work will be done through close coordination with the GF, technical partners, including TBTEAM, the Stop TB Partnership, and other USAID-funded projects, and other donors, included the French 5% Initiative and GIZ/Backup. It will help to ensure high-quality technical assistance is provided at the country level, while ensuring there is no duplication of efforts among the partners.

Cutting-Edge Technical Expertise
It is absolutely critical for USAID-supported countries to have access to the cutting-edge technical knowledge and expertise on the objective and element topics. It is expected any new activities will be able to unleash new ideas and approaches base on strong evidence. It should explore different ways of achieving the objectives by partnering with bold thinkers. USAID needs a mechanism for measuring the quality of the technical expertise and ensuring pioneer thinkers are at the forefront of project implementation. In addition, there needs to be a rigor in transferring this knowledge and expertise to all levels within a country to build their capacity. As mentioned earlier, the locally generated thinking should also be incorporated into the evidence-base.

E. POLICY CONSIDERATIONS

The activity is consistent with the U.S. Government's policies, the Agency's priorities and USAID Mission's Country Development Cooperative Strategy (CDCS) health goals. USAID-supported TB activities will directly contribute to the achievement of an AIDS-free generation, Ending preventable maternal and child deaths, QDDR/USAID Forward, Evaluation Policy,

Gender Equality and Female Empowerment Policy, Youth in Development Policy, Sustainable Urban Services Policy, and Mission CDCSs. The details on the most relevant USAID policies to USAID's TB program are provided below.

Moving Towards an AIDS Free Generation
Many of the USAID TB focus countries have a serious TB-HIV co-epidemic – with upwards of 65 % of new TB cases also infected with HIV: South Africa (65 %), Zambia (64 %), Mozambique (63 %), Malawi (60 %), Zimbabwe (60 %), and Uganda (53 %). In these countries, strategies will focus on integrating TB and HIV activities to reduce the burden of both diseases maximizing PEPFAR resources and the HIV service delivery platform. TB is an important cause of morbidity and mortality among people living with HIV/AIDS (PLHA) and decreasing the burden of TB on those living with HIV is critical to achieving the goals of the AIDS-free generation. National TB Programs need support to expand high quality, DOTS-based interventions, which ultimately decreases the burden of TB on those living with HIV including improvement of infection control in high burden HIV settings and integration of TB and HIV services to ensure that those with co-infection are linked to antiretroviral (ART) services. These interventions ultimately improve access to TB services and decrease the burden of TB among people living with HIV.

Ending Preventable Maternal and Child Deaths
This activity will continue USAID's work in pediatric TB diagnosis and treatment services in high burden settings. Pediatric TB cases have been largely neglected in high burden countries. USAID has been a leader in supporting global technical guidance on pediatric TB. USAID's TB efforts will work towards the objective of ending preventable childhood deaths related to TB by building capacity to diagnose and treat TB among children, which is more complicated than for adults. Generally, women are more likely to receive a delayed TB diagnosis and are at higher risk of death before diagnosis than men. USAID's TB program supports efforts to ensure timely diagnosis and treatment through community based case finding and patient support that will have a positive benefit for women who might otherwise suffer or die from this curable disease. Reaching women earlier will also have a positive impact on TB/HIV related illness and death as well as reducing transmission to their children.

QDDR/USAID FORWARD
The principles housed within the Quadrennial Diplomacy and Development Review (QDDR) and USAID FORWARD will guide *Challenge TB's* overall strategic direction. The QDDR provides a design for increasing the role of American "civilian power" to better advance national interests and to be a better partner to the U.S. military. Leading through civilian power means directing and coordinating the resources of all America's civilian agencies to prevent and resolve conflicts; help countries lift themselves out of poverty into prosperous, stable, and democratic states; and build global coalitions to address global problems. Overall, it examines at development through the lens of increasing democracy and thus, overall stability. USAID FORWARD is an effort to strengthen the Agency by accepting new partnerships, investing in the important role of innovation and focusing on tangible results. This policy emphasizes scaling up innovative solutions. It also encourages local solutions and strong partnerships with entities such as the National TB Program, The Global Fund, and other local non-governmental organizations, to prevent duplication, and gaps, while fostering the best possible outcomes.

Country Development Cooperation Strategies

The design of this mechanism is directly aligned with the principles of a CDCS. Assistance under this mechanism is designed to be tailored to an individual country's needs – whether the country is considered post-conflict, transitional or developing. USAID's TB program is designed to provide appropriate short and long-term technical assistance to partner countries that is complementary to other kinds of health systems strengthening activities outlined within a CDCS. Activities supported under this mechanism will require significant input and oversight by local host country counterparts and USAID Missions.

Implementation and Procurement Reform: As mentioned before, USAID's TB program is designed to support the MOH and National TB Control Programs with high quality expertise and evidence-based approaches to address the main TB challenges in the country. A critical component of this approach is to strengthen the management, planning and implementation of the MOH's NTP to ensure country ownership, maximize efforts and avoid duplication. Another important component will be the strengthening and supporting of local innovations and solutions developed by civil society and private sector capacity to build more sustainable partnerships around TB care and treatment. It is important for USAID and USG resources, including PEPFAR, are maximized and leveraged against domestic resources and other donor funds like those from the Global Fund. Where necessary, Countries will need support in the coordination of these activities to avoid duplication and foster integration and coordination.

Science and Technology: "Innovation in Approach" is one of the guiding principles for USAID's TB program. Innovative approaches and technologies need to be incorporated into overall activities to ensure effective approaches to addressing existing challenges in countries, particularly engaging new partners and young professionals and graduate students. In addition to innovative implementation approaches, there is a need for new technologies that are appropriate to improving diagnosis and treatment of tuberculosis, specifically in low resource settings.

Evaluation Policy
This policy seeks to emphasize the importance of evaluations at USAID, as policy and investment decisions are based on the best available empirical evidence, and use the opportunities yielded by project implementation to produce new knowledge for the larger community. In addition, USAID commits to measuring, evaluating and documenting project accomplishments and shortcomings so that the Agency's multiple stakeholders gain an understanding of the return on investment in development activities. Monitoring and evaluation is a critical component of all of USAID's programs, including the evaluation of the impact of local innovations for scale-up and overall project activities at the country and global levels.

Gender Equality and Female Empowerment Policy
The USAID Gender Equality and Female Empowerment Policy aims to reduce gender disparities in access and control over resources, as well as ensure there is availability to opportunities and services. Particularly when examining gender and TB, most society's men have higher rates of TB than women, especially certain enclaves of men, such as mining communities. However, females face a cultural and social inequality throughout their lives in many parts of the world in the provision of health services. Also, there is a common perception that women's care and prevention of tuberculosis is often of secondary importance to that of men.

Youth in Development Policy

As more than half of the world's population today is under the age of 30, with the vast majority living in the developing world, it is crucial to make sure that this population cohort is taken into consideration when programming. This policy outlines a conceptual approach to youth in development and provides guiding principles and operational practices in support of USAID's efforts to mainstream youth in development, carry out more effective programs, and elevate youth participation. This policy highlights strengthening youth programming and participation, so that youths play an active role and can access economic and social opportunities.

Sustainable Urban Services Policy
By 2030, urban areas worldwide will house an additional 1.4 billion people, with the vast majority of this growth occurring in the developing world. Thus, achieving our development goals is directly tied to how we program and impact these urban areas. This policy provides guidelines to help countries and communities improve the delivery of essential services in urban areas. TB disproportionately affects those dwelling in urban areas due to the overcrowding and links to poverty. Many TB patients in urban settings are from highly deprived communities that may contribute to a poorer outcome.

F. KEY STAKEHOLDERS

There are a number of key stakeholders who are vital for the success of *Challenge TB* and they are:

Offices of Health, Infectious Diseases and Nutrition (HIDN/ID) TB Team, USAID: HIDN/ID/TB Team will oversee and manage the project including provision of technical support from various TB advisors.

USAID Missions: USAID Missions will have the option to buy into the Cooperative Agreement with Field Support, and will guide the development of workplans for country level activities.

Country Ministries of Health, National TB Programs: The new project will operate within the MOH's national strategic TB plan. It will strengthen the TB service delivery system and other services to achieve the goals and objectives. The project will consult with these national stakeholders to identify gaps and priorities on an annual basis to adapt to the evolving needs of the program.

External Experts and Groups: The new project will build on long-standing global health partnerships and relationships cultivated by USAID, including relationships with WHO, Stop TB Partnership, UNAIDS, and the partners involved in the Stop TB Partnership implementation and research working groups. These partners further develop the policy and legal frameworks as well as advance the evidence-base.

Global Fund: The Global Fund is the largest external funder of TB programs in developing countries. This new project will need to work closely with the Fund Portfolio Managers and Principle Recipients to leverage resources as mentioned in the earlier cross-cutting section.

Primary beneficiaries: The primary beneficiaries of the new project are the communities and people in endemic TB countries, particularly the poorest and most vulnerable populations and those living in high risk areas.

New local partners: The new project will promote the development of locally generated and innovative solutions by engaging new local partners and individuals including young professionals and university students.

G. MANAGEMENT REVIEW AND EXTERNAL EVALUATIONS

USAID Management Team (UMT) will conduct annual management reviews, providing a formal examination of issues impacting project implementation, potential and efficiency, as well as the opportunity to reflect on and make recommendations regarding any modifications necessary to improve project management and performance. The UMT will also monitor both financial and technical performance on an ongoing basis and will carry out periodic reviews of specific aspects of performance. Feedback on the Recipient's performance will be collected from key stakeholders, including host-country counterparts and missions, and will be shared with the Recipient to improve performance.

USAID will commission an external performance evaluation to be conducted during the fourth year of the agreement to assess specific aspects of the project. The evaluation will adhere to the principles outlined in USAID's Evaluation Policy. Its methodology and questions will be determined by the UMT in consultation with GH colleagues and evaluation specialists. Data collected by the project under its PMP will feed into this external evaluation.

H. ENVIRONMENTAL CONSIDERATIONS

1. Definitions:

a. **Apparently Successful Applicant(s) means** the Applicant(s) for USAID funding recommended for an award after evaluation, but who has not yet been awarded a grant, cooperative agreement or other assistance award by the Agreement Officer. The Agreement Officer will request that Apparently Successful Applicants submit a Branding Strategy and Marking Plan. Apparently Successful Applicant status confers no right and constitutes no USAID commitment to an award, which the Agreement Officer must still obligate.

b. **Initial Environmental Examination**. An Initial Environmental Examination is the first review of the reasonably foreseeable effects of a proposed action on the environment. Its function is to provide a brief statement of the factual basis for a Threshold Decision as to whether an Environmental Assessment or an Environmental Impact Statement will be required.

c. **Threshold Decision.** A formal Agency decision which determines, based on an Initial Environmental Examination, whether a proposed Agency action is a major action significantly affecting the environment.

d. **Environmental Assessment**. A detailed study of the reasonably foreseeable significant effects, both beneficial and adverse, of a proposed action on the environment of a foreign country or countries.

e. **Environmental Impact Statement.** A detailed study of the reasonably foreseeable environmental impacts, both positive and negative, of a proposed A.I.D. action and its reasonable alternatives on the United States, the global environment or areas outside the jurisdiction of any nation as described in §216.7 of these procedures. It is a specific document having a definite format and content, as provided in NEPA and the CEQ Regulations. The required form and content of an Environmental Impact Statement is further described in §216.7 infra.

2. The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) (http://www.usaid.gov/our_work/environment/compliance/22cfr216.htm) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (http://www.usaid.gov/policy/ADS/200/), which, in part, require that the potential environmental impacts of USAID-financed activities are identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities.

3. As such, no activity funded under this CA will be implemented unless an initial environmental impact assessment and subsequent threshold determination, as defined by 22 CFR 216, and signed by the Bureau Environmental Officer (BEO) has been reached for that activity.

4. *Challenge TB* Initial Environmental Examination (IEE) evaluates the potential impacts of the FPR Programs and has determined that a **Negative Determination with Conditions** is appropriate for the actions described in the document. Other actions not described in the paper, or those activities described in 22 CFR 216.2(d)(1) will require supplemental environmental analysis.

a. The Apparently Successful Applicant will be required to include as part of the initial Implementation Plan, and all subsequent Implementation Plans, all ongoing and planned activities under this CA and the subsequent 22 CFR 216 documentation.

b. A complete environmental mitigation and monitoring plan (EMMP) or a project mitigation and monitoring (M&M) plan shall be prepared by the Recipient as part of the program implementation plan and integrated into each annual implementation plan.
i. This plan shall describe how the Recipient will, in specific terms, implement all IEE and/or EA conditions that apply to proposed project activities within the scope of the award.
ii. The EMMP or M&M Plan shall include monitoring the implementation of the conditions and their effectiveness.
iii. The results of the EMMP will be reported to the AOR and the BEO annually, NLT Oct 1 of each year.

For additional information see Annex E.

END OF SECTION I

SECTION II – Award Information

A. ANTICIPATED AWARD – SCHEDULE

USAID anticipates that one (1) five-year, competitive CA will be awarded in the second quarter of FY 2014and for performance to begin immediately upon award.

Prime Applicants are encouraged to propose partnerships with other eligible organizations (see Section III.1) and/or firms to implement activities under this project. As stated in Section I.6, Program Description – Technical Approach, applicants should be capable of and prepared to support the TB control activities in any of the countries identified in Section I.4.

B. TOTAL ESTIMATED COST AND TYPE OF AWARD

The total estimated cost for this RFA is $500 - $550 million for a period of five years. Contingent upon availability of funds, USAID expects to award one cooperative agreement.

C. USAID MANAGEMENT

An Agreement Officer's Representative (AOR) shall be appointed upon time of award, and serve as the primary contact between USAID and the Recipient. The AOR will be based in GH/HIDN and will assist the project in linking with other GH projects, Mission bilateral and other donors/foundations. In addition, technical input will be provided by Missions for management of activities supported by field support funds.

D. SUBSTANTIAL INVOLVEMENT

USAID shall be substantially involved during the implementation of this CA the following ways:

1. Approval of Recipient's Implementation Plans: Approval of the recipient's annual work plans, reports, research studies/protocols, publications, and all modifications that describe the specific activities to be carried out under the Cooperative Agreement;

2. Approval of Specified Key Personnel: Approval of and any changes to specified key personnel; and

3. Agency and Recipient Collaboration or Joint Participation:

   a. Collaborative involvement in selection of advisory committee members;
   b. Concurrence on selection of sub-award recipients (see 22 CFR226.25 for requirements);
   c. Approval of the recipient's monitoring and evaluation plans;
   d. Agency monitoring to permit specified kinds of direction or redirection because of interrelationship with other projects, as included in the Program Description, negotiated in the budget and made part of the award.

4. Agency Authority to Immediately Halt a Construction Activity
The AO may immediately halt a construction activity if identified specifications are not met.

For specifics and additional detail please refer to USAID policy ADS 303.3.11 – Substantial Involvement in Cooperative Agreements.

E. AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for the procurement of services and commodities for the *Challenge TB* Project, with period of performance 2014-2019, is 937.

END OF SECTION II

SECTION III – Eligibility Information

A. ELIGIBILITY CRITERIA

To be eligible for award of the cooperative agreement under this RFA, an organization must:

1. Be a U.S. or non-U.S. Private Voluntary Organization (PVO) or a U.S. or Non-U.S. Non-Governmental Organization:

   1.1. **PVOs** – are non-governmental organizations that meet the Conditions of Registration as outlined in 22 CFR 203.

   To register with USAID as a PVO, please refer to USAID's website at www.usaid.gov, USAID Keyword: PVO Registration, or http://idea.usaid.gov/ls/pvo for complete information and guidance.

   1.2. **NGO** – are other U.S. non-profit NGOs that do not meet the definition of a PVO, as well as U.S. commercial organizations.

2. Have experience and capacity in performance improvement, policy dialogue, implementation of TB prevention and care activities, and other related technical and managerial areas to achieve the results as described in this RFA;

3. Agree to and have the capacity to work with and hire individuals who have demonstrated experience and technical expertise to plan and implement the Stop TB Strategy throughout the world described in this RFA; and

4. Have the experience and capacity to collaborate with other organizations/groups in undertaking TB prevention and care programming.

B. USAID welcomes applications from organizations which have not previously done business with USAID.USAID encourages applicants with access to high-caliber technical staff, strong management capacity, good organizational skills, and a proven track record in implementing similar programs to undertake and achieve the results outlined in the program description to apply to this RFA

Pursuant to 22 Code of Federal Regulations (CFR) 226.81, it is USAID policy not to award profit under assistance instruments. However, all reasonable, allocable, and allowable expenses, both direct and indirect, related to the application program and in accordance with applicable costs standards 22 CFR 226, as well as 2 CFR 230 for non-profit organizations, 2 CFR 220 for educational institutions, 2 CFR 215 for institutions of higher education, hospitals, and other non-profit organizations, and 48 CFR 31 for profit organizations.

The Recipient must be a responsible entity. The Agreement Officer (AO) may determine a Pre-Award survey is required and if so, would establish a formal survey team to conduct an examination that will determine whether the prospective recipient has the necessary organization,

experience, accounting and operational controls, and technical skills – or ability to obtain them – in order to achieve the objectives of the program. Applications from individuals will not be considered for award.

B. COST SHARE

A minimum cost share of 5% of the projected award value is required for all applications. For this purpose, Applicants should use $500 - $550 million as the estimated value of the award. Such funds should not count existing donations or commitments from sources such as existing pharmaceutical drug donation programs. Funds or in-kind donations may be contributed from the Recipient, other multilateral, bilateral, and foundation donors, local organizations, and private businesses that contribute financially and in-kind to the implementation of activities. If partners are proposed, the cost share may be distributed among partners. The cost share, whether it will be in-kind or dollars, must have a direct impact on this program. For guidance on cost sharing in grants and cooperative agreements, please see 22 CFR 226.23.

Applications that do not meet the minimum cost-share requirement are not eligible for award consideration.

END OF SECTION III

SECTION IV – Application and Submission Information

A. GENERAL INSTRUCTIONS

The preferred method of distribution of USAID assistance information is via the Internet. This RFA contains all necessary information, web links, and materials to submit a complete, full application. Any additional information regarding this RFA will be furnished through amendments and will be communicated through Grants.gov. This RFA and any future amendments can be downloaded from the World Wide Web Address at http://www.grants.gov. For instructions on how to register, see Annex D.

B. SUBMISSION INSTRUCTIONS

1. Applications shall be submitted electronically no later than February 10, 2014, 9:00am Washington, DC Time to www.grants.gov. The application submission deadline cannot be extended. Hard copy applications, whether hand delivered or by postal mail, will not be accepted. The Grants.gov system date and time stamp will be used to determine the applications timeliness. Applicants are advised to be cognizant of the time applications are submitted. Applications submitted after the closing date and time of the RFA will be considered untimely. Untimely applications will not be considered for award. Applicants, who encounter any problems with their www.grants.gov submission, should email the point of contact for this RFA before the application submission deadline, explaining the circumstances.
   Point of Contact: An applicant may obtain any materials needed for the application or otherwise communicate regarding the application requirements with the following points of contact (POC):

   Primary Point of Contact:
   Amy Wire
   Agreement Specialist
   USAID Office of Acquisition & Assistance
   M/OAA/GH, Rm 549-L, SA-44
   1300 Pennsylvania Ave., NW
   Washington, D.C. 20523
   (202) 567-4301
   awire@usaid.gov

   and

   Alternate Point of Contact:
   Christie Cooper
   Agreement Specialist
   USAID Office of Acquisition & Assistance
   M/OAA/GH, Rm 549-C, SA-44
   1300 Pennsylvania Ave., NW
   Washington, D.C. 20523
   Tel: (202) 567-5064

Email: ccooper@usaid.gov

Questions shall be submitted in writing via email to both Points of Contact (POC) listed above, no later than January 17, 2014, 9:00am, Washington DC Time.

2. Issuance of this RFA does not constitute an award commitment on the part of the Government, nor does it commit the Government to pay for costs incurred in the preparation and submission of applications.
3. To facilitate the competitive review of the applications, USAID will only consider applications conforming to the format prescribed in this RFA. The technical and cost applications must be clearly marked with the RFA No, and appropriately labeled as either Technical or Cost Application.

C. REQUIRED CONTENTS OF AN APPLICATION

The following are general instructions for what constitutes a complete, full application. The instructions include the required contents on the application, required format of the application, and the contents of application documents. It is highly recommended that applicants read the entire RFA before submitting an application. Applications should respond directly to the terms, conditions, specifications and clauses of this RFA (including all portions of the Program Description). Applications not conforming to this RFA may be categorized as non-responsive, thereby eliminating them from further consideration.

An application shall consist of a technical application and a cost application. All information shall be presented in the English language and shall be formatted in either Microsoft Word 2010 or Microsoft Excel 2010 with all formulas unlocked.

1. **Technical application**:

.**Technical application**:

1) The technical application is limited to 40 pages. Anything in excess of 40 pages will not be reviewed. Only annexes specifically requested to be included are permitted and will not count toward the 40 page limit. The Agency will not read nor consider information included in an annex that was not specifically requested in the RFA. Only the following items may be included as annexes:

- Key personnel resumes/Curriculum Vitae and references;
- Letters of intention from key personnel;
- Personnel and consultant skills matrix;
- Letters from partners and/or sub-contractors;
- Past performance summary tables; and
- Organizational Chart.

1.1. Additionally, the following pages do not count against the (40) page limit: Cover page, acronym list, dividers, and table of contents.

1.2. The technical application shall be singled-spaced text, Times New Roman 12-point font, 1” margins, on 8.5 inch by 11 inch paper.

1.3. Any graphs, charts, exhibits, tables, executive summary, etc. contained in the body of the technical application shall be numbered and included in the **40** page limit.

1.4. The applicant is requested to include a list of all acronyms used in the application, which provides both the acronym and what it stands for. Applicants are requested to spell out the first use of each acronym in the technical application.

1.5. 1.4. No part of the cost application shall be included in the technical application.

2. <u>Cost application:</u>

2.1. There is no limit on the number of pages for the cost application, however Applicants are encouraged to be as concise as possible.

2.2. The application must be submitted using SF-424 and SF 424A "Application for Federal Assistance." The following information provides instructions for completing forms SF-424 and SF-424A as well as the most current version of forms SF-424 and SF-424A:

Instructions for:
SF-424 http://www.grants.gov/assets/SF424Instructions.pdf
SF424[4] http://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf

Instructions for:
SF-424A http://www.grants.gov/assets/InstructionsSF424A.pdf
SF 424A http://apply07.grants.gov/apply/forms/sample/SF424A-V1.0.pdf

2.3. No part of the technical application shall be included in the cost application.

D. SPECIFIC TECHNICAL APPLICATION INSTRUCTIONS

The technical application in response to this RFA shall address how the applicant intends to carry out the Program Description detailed in Section I of the RFA. It must provide evidence to show that the applicant possesses a clear understanding of the work to be undertaken and the responsibilities of all parties involved. The person signing the application shall initial erasures or other changes. The technical application will be reviewed to ensure that it is compliant with the terms of the RFA and a TEC panel will review and evaluate the technical application to ensure that both applications are IAW all the requirements of the RFA. Applications shall be kept as concise as possible. Detailed information shall be presented only when required by specific RFA instructions.

Note: The Technical Application **shall not exceed 40 pages** excluding annexes requested in this RFA. Any pages in excess of 40 pages will not be evaluated. Any graphs, charts, exhibits, tables, etc. contained in the body of the technical application shall be numbered and included in the 40 page limit. The requirements of the Technical Application are as follows:

[4]Please disregard the expiration date 03/31/2012 as the form is still valid.

1. Executive Summary (Maximum 2 pages)
The applicant must briefly describe how they will meet the RFA requirements, carry out the activity functions, and achieve the anticipated results. The executive summary must briefly describe the technical and managerial resources of the applicant's organization and partners (if appropriate) and how the overall program will be managed.

2. Narrative (recommend 36-38 pages)
The narrative section of the application should contain the elements outlined below:

2.1. Technical Approach
Applicants must address the requirements of the program description and objectives in Section I of this RFA. For this section, Applicants should refer specifically to the Program Description Statement of Goal and Project Objectives that can be found in Section I. The approach in each criteria should identify the TB care and prevention situation, the status of implementation, identify the key issues of implementation and propose a strategic and technical approach for addressing these issues, identify partner organizations for this effort, and tools that would be employed. Specifically the Technical Approach should address how the applicant will accomplish each of the following objectives and sub objectives as well as cross-cutting themes:

O.1 Expanded Access to Prevention Services
O.1.1 Infection Control
O.1.2 Active Case Finding
O.1.3 Latent TB Infection (LTBI) Strategies

O.2 Improved Patient-Centered Quality Care Systems for TB, MDR-TB and TB/HIV
O.2.1 Universal Access to Appropriate Treatment
O.2.2 Laboratory Network Strengthening
O.2.3 Comprehensive Care Services
O.2.4 Engaging all Care Providers

O.3 Sustained and Enhanced Systems
O.3.1 Political Commitment and Leadership
O.3.2 Comprehensive Partnerships
O.3.3 Demand Driven TB Services
O.3.4 Drug Policy and Management
O.3.5 Data Quality, TB Surveillance, and Monitoring and Evaluation
O.3.6 Human Resources Development (HRD)

The cross-cutting elements are the following:

- Access to services for all people;
- Urban Services;
- Locally owned and generated innovations and research;
- Coordination and Collaboration with Global Fund; and
- Cutting-edge Technical expertise.

1) The applicant must provide a comprehensive yet concise summary of their overall strategic and technical approach to reach the project goals, to implement and perform the three objectives and five cross-cutting themes at the global level and in the nine priority countries outlined in Section I of the RFA. There should be synergistic linkages on the approach across the objectives and themes.

2) The applicant must apply their overall strategic and technical approach to each of the nine priority countries outlined in Section I of the RFA within the overall proposal strategy (recommended 2 pages for each country). The approach should be specific in identifying the TB care and prevention situation, the status of implementation, the key issues of implementation and a strategic and technical approach for addressing these issues, identify partner organizations for this effort, and tools that would be employed. In addition, there should be a trade-off analysis on the selection of interventions to demonstrate the most cost-effective approach to achieving the objectives.

3) The applicant must describe how they would develop a strong, cost-effective, evidence-based M&E system with a data quality assurance strategy. The system should link the project interventions with national and project area impact. It will be used throughout the project as a decision making instrument to assist the country to determine the effectiveness and quality of the all interventions and tools, and determine which ones are worthy of scale-up or further implementation. A detailed strategic framework for evaluating performance toward achieving each of the three technical objectives and five cross-cutting elements shall be provided, including expected quantifiable program results, benchmarks and indicators to monitor progress and impact over the life of the project. The applicant should identify how it would develop a system with the government and other partners to ensure the quality of the data used for the project in the most efficient and effective manner.

4) The applicant must apply their overall strategic and technical approach to the proposed activities for global technical leadership within the overall application strategy. The approach should be to identify only those interventions critical to a set of countries that could not be generated from within one country by local partners. The applicant should propose stringent criteria for the selection of activities to receive support with core funds. The interventions should be able to leapfrog countries forward in achieving their objectives.

5) The applicant must provide a description of how to apply country led programs, approaches and partners into the overall strategy. Most of USAID-supported countries are led by empowered National TB Program managers and have other key stakeholders in the country playing important roles. It is critical the support by this project does not crowd out these key actors in the implementation of the project. The project should enable the various partners to lead and implement the program. The applicant should develop an effective approach to achieve throughout the life of the project.

2.2. Staffing and Key Personnel

2.2.1 Key Personnel

As part of the 40-page limit of the technical narrative, applicants shall provide a summary of the scope of experience, skills and expertise of the proposed key personnel listed below:

As annex documents, the applicant shall provide resumes for all four (4) required key personnel. The applicant shall submit a signed letter of intention from all proposed key personnel stating that they understand that they have been proposed and that they intend to make themselves available to serve in the proposed position should the applicant receive the award.

For each of the four Key Personnel, a list of three (3) professional references from within the last five (5) years must be included in the annexes. Reference information must include name, current work company or organization name, address, position within company or organization, telephone number, mobile number and email address. Current and valid contact information MUST be included for each reference. Applicants may want to inform these references that they may be contacted and validate the most suitable contact information.

Each of these four Key Personnel must meet or exceed the qualifications described below. These positions will be expected to provide the overall technical and oversight of the entire project.

Project Director (PD): The PD's responsibilities shall include the overall planning, coordination, and technical direction of the entire project including the work of any sub-recipients as well as oversight of the management of all staff. The PD shall be expected to have regular and transparent communication with the AOR.S/he shall have at least twelve (12) years of experience in each of the following areas related to the priority countries outlined in Section I: 1) designing and implementing TB prevention, diagnosis and treatment programs, 2) participating in the TB technical leadership at the global level, 3) managing similar health projects, and 4) interacting with other donors, technical agencies and host country governments. S/he shall have at least a Masters' degree in public health or an advanced degree in a related health field from an accredited college or university.

Deputy Project Director (DPD): The DPD's responsibilities shall include the oversight of operational procedures and policies, financial controls, and other management functions including management of sub-recipients. In addition, the DPD's skills shall complement and not duplicate the Project Director's skills. S/he shall assist the Project Director in carrying out all areas of the project including fulfilling the Project Director's duties when s/he is absent or unable to perform them. S/he shall have at least ten (10) years of experience in: 1) designing and implementing health programs (with at least 4 of the years in TB), 2) designing and managing operational procedures and policies including the development of systems and monitoring for effective implementation, 3) managing teams and individual staff supervision, and 4) interacting with other donors, technical agencies and host country governments. S/he shall have at least a Masters' degree in public health or an advanced degree in a related field from an accredited college or university.

Monitoring and Evaluation Officer (M&E Officer): The M&E Officer shall have primary responsibility for establishing and maintaining systems to measure, compile, analyze and report project data at all levels and across levels; providing regular project reports to USAID and for developing special reports as needed; producing analysis of program data and identifying methods to use results for program improvement; and building host country capacity to gather and analyze data for program improvement. S/he shall have at least seven (7) years of experience in each of the following areas related to the priority countries outlined in Section I: 1) designing and implementing M&E systems for TB, HIV/AIDS and/or other complex health programs; 2) evaluating quantitative and qualitative health data sets, 3) managing complex data collection

teams/staff and 4) managing the utilization of the data for project and other reporting. S/he shall have at least a Masters' degree in health program evaluation or a related field from an accredited college or university.

Senior Tuberculosis Technical Coordinator: The Senior Tuberculosis Technical Coordinator will ensure the technical integrity and quality of the project as well as assist with the coordination of staff and activities under each technical objective. S/he shall have at least ten (10) years of experience in providing TB technical leadership at the global and at least four (4)of those years comprising of country level experience. S/he should be able serve as the lead in one or more of the TB technical objectives described in Section I. S/he shall have at least a Master's degree in a related health field from an accredited college or university.

2.2.2 Overall Staffing and Other Personnel

As part of the narrative, the applicant shall provide a staffing plan describing how all proposed personnel (key personnel and non-key personnel) offer an appropriate balance of skills, expertise, and demonstrated experience sufficient to achieve the objectives of this project. The staffing pattern shall reflect the minimum number of highly experienced staff sufficient to manage and implement the project. Applicants must provide **in an annex** a personnel and consultant skills matrix of individuals available to provide technical assistance and expected LOE using the template provided in Annex C.

Other Full Time and Short Term Personnel

The applicant shall propose additional personnel or technical teams to carry out the Program described in Section I, based on the applicant's technical approach. It is important for the project to be flexible to meet the evolving technical assistance needs beyond the minimum core staff. The staffing pattern proposed for non-key staff shall explain how additional expertise and skill mix might be obtained while attending to the necessity of cost-containment and avoiding unnecessary staffing. The applicant shall list the key technical areas where staffing/personnel will be needed in relation to the applicant's technical approach.

The applicant shall complete Annex C "Personnel and Consultant Skills Matrix" for each **non-key** full time proposed staff and consultant.

2.3. Management Plan

Applicants shall propose a management plan that addresses the complex set of activities in multiple countries and regions necessary to implement this project.

The management plan must:

1. Describe how the activity would be organized to use the complementary capabilities of all sub-recipients and/or partners most effectively and efficiently,
2. Include the roles and responsibilities of each sub-grantee and/or partner
3. Include lines of authority and communication among the prime and all proposed sub-recipients and/or partners in order to maximize efficiency and best utilize technical expertise/strengths of each partner;
4. Describe the lines of authority and communication of the relationship between headquarters and in-country personnel;
5. Describe policies and management on procurement of goods and services.

6. Describe the strategy for managing the M&E system required in section I that addresses the demand based nature of USAID's Missions utilization of mechanisms. The Applicant shall show how it will effectively manage a complex monitoring system in a timely and efficient manner to meet the needs of all operating units.

2.4 Institutional Capacity

In this section the applicant shall describe the institutional capacity of both the prime applicant and its partners to implement TB programs and activities described in Section I and demonstrate how their combined capabilities will enable successful public health outcomes. Proposed capabilities of the prime and each sub-recipient and/or partner should be demonstrated by presenting outcomes of previous work in specific technical areas. Letters from sub-grantees and/or partners shall reference what expertise they will provide that is relevant to the description in the RFA.

2.5 Past Performance

This section of the application provides information about the Applicant's past performance record in implementing similar programs.

As an Annex, please complete Past Performance Report – Short Form (Annex F) for three (3) past performance references which describe any contracts, grants, or cooperative agreements which the Applicant organization, as well as any sub-recipients or partners, expected to perform more than 10% LOE, has implemented involving similar or related programs over the past three years. Please include the following information: name and address of the organization for which the work was performed; name and current telephone number and email address of responsible representative from the organization for which the work was performed; contract/grant name and number (if any), the period of contract/grant performance, annual amount received for each of the last three years and beginning and end dates; brief description of the project/assistance activity and key project accomplishments/results achieved to date.

It is recommended that the Applicant alert the contacts that their names have been submitted and that they are authorized to provide past performance information when requested.
Please note that USAID reserves the right to obtain past performance information from other sources including those not named in this application.

E. SPECIFIC COST/BUSINESS APPLICATION INSTRUCTIONS

While there is no page limit for this portion, Applicants are encouraged to be as concise as possible, but still provide the necessary details to allow the government to conduct a cost analysis in order to determine that all proposed costs allowable, allocable, reasonable, and realistic.. USAID will require the following detailed information from the Applicant:

The cost application must be completely separate from the technical application. The application must be submitted using SF-424 and SF 424A "Application for Federal Assistance." The form is downloadable on USAID's website at:

Instructions for SF-424 http://www.grants.gov/assets/SF424Instructions.pdf

SF424[5] http://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf
Instructions for SF-424A http://www.grants.gov/assets/InstructionsSF424A.pdf
SF 424A http://apply07.grants.gov/apply/forms/sample/SF424A-V1.0.pdf
Instructions for SF-424B http://www.grants.gov/assets/InstructionsSF424B.pdf
SF 424B http://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf

Failure to accurately complete these forms could result in a non-funded application.
The cost/business application should be for a period of 5 years using the budget format shown in the SF-424A. A cost share minimum of 5% of the Award's projected value is required. For this purpose, Applicants should use $500 to 550 million as the estimated value of the award. Such funds may be mobilized from the Recipient; other multilateral, bilateral, and foundation donors; host governments; and local organizations, communities and private businesses that contribute financially and in-kind to implementation of activities at the country level. However, cost share contributions must meet the requirements stipulated in 22 CFR 226.23 and funding that is already being provided will not be considered an appropriate cost-share.

If the Applicant has established a consortium or another legal relationship among its partners, the Cost/Business application must include a copy of the document establishing the parameters of the legal relationship between the parties. The agreement should include a full discussion of the relationship between the Applicants including identification of the Applicant with which USAID will treat for purposes of Agreement administration, identity of the Applicant which will have accounting responsibility, how Agreement effort will be allocated and the express agreement of the principals thereto to be held jointly and severally liable for the acts or omissions of the other.

To support the proposed costs, please provide **detailed budget notes/narrative for all costs that explain how the costs were derived**. The following provides guidance on what is needed:

1. The breakdown of all costs associated with the program.
2. The breakdown of all costs according to each partner organization involved in the program.
3. The costs associated with external, expatriate technical assistance and those associated with local in-country technical assistance.
4. The breakdown of any financial and in-kind contributions of all organizations involved in implementing this program.
5. Potential contributions of non-USAID or private commercial donors to this program.
6. Procurement plan for commodities, goods and services (if applicable).

The cost application should contain the following budget categories:

1. **Salary and Wages**: Direct salaries and wages should be proposed in accordance with the Applicant's personnel policies;

2. **Fringe Benefits**: If the Applicant has a fringe benefit rate that has been approved by an agency of the U.S. Government, such rate should be used and evidence of its approval should be provided. If a fringe benefit rate has not been so approved, the application should propose a rate and explain how the rate was determined. If the latter is used, the

[5]Please disregard the expirationdate 03/31/2012 as the form is still valid.

narrative should include a detailed breakdown comprised of all items of fringe benefits (e.g., unemployment insurance, workers compensation, health and life insurance, retirement, FICA, etc.) and the costs of each, expressed in dollars and as a percentage of salaries;

3. **Travel and Transportation**: The application should indicate the number of trips, domestic, regional, and international, and the estimated costs. Specify the origin and destination for proposed trips, duration of travel, and number of individuals traveling. Per Diem should be based on the Applicant's normal travel policies;

4. **Equipment**: Estimated types of equipment (i.e., model #, cost per unit, quantity);

5. **Supplies**: Supply items related to this activity (e.g., specimen collection, sample transport, administrative);

6. **Contractual:** Any goods and services being procured through a contract mechanism;

7. **Other Direct Costs:** This includes communications, report preparation costs, passports, visas, medical exams and inoculations, insurance (other than insurance included in the Applicant's fringe benefits), equipment, office rent, etc. The narrative should provide a breakdown and support for all other direct costs;

8. **Indirect Costs:** The Applicant should support the proposed indirect cost rate with a letter from a cognizant U.S. Government audit agency, a Negotiated Indirect Cost Agreement (NICRA), or with sufficient information for USAID to determine the reasonableness of the rates (For example, a breakdown of labor bases and overhead pools, the method of determining the rate, etc.).
   New Recipients: Applicants that have never received a grant, cooperative agreement or contract from the U.S. Government are required to submit a copy of their accounting manual and procurement/management handbook relating to personnel and travel policies.

F. UNNECESSARILY ELABORATE APPLICATIONS

Unnecessarily elaborate brochures or other presentations beyond those sufficient to present a complete and effective application in response to this RFA are not desired and may be construed as an indication of the Applicant's lack of cost consciousness. Elaborate artwork, expensive paper and bindings, and expensive visual and other presentation aids are neither necessary nor wanted.

G. COOPERATIVE AGREEMENT AWARD

a. The Government may, without discussions or negotiations, award an agreement resulting from this RFA to the responsible Applicant whose application conforming to this RFA offers the best value. Therefore, the initial application should contain the Applicant's best terms from a cost and technical standpoint. The Government may reject any or all applications, accept other than the lowest cost application, and waive informalities and minor irregularities in applications received.

b. Although technical evaluation factors are significantly more important than cost factors, the closer the technical evaluations of the various applications are to one another, the more important cost considerations become. The Agreement Officer may determine what a highly ranked application based on the technical evaluation factors would mean in terms of performance and what it would cost the Government to take advantage of it in determining the best overall value to the Government.

H. AUTHORITY TO OBLIGATE THE GOVERNMENT

The Agreement Officer is the only individual who may legally commit the Government to the expenditure of public funds. No costs chargeable to the proposed agreement may be incurred before receipt of either an agreement signed by the Agreement Officer or a specific, written authorization from the Agreement Officer.

I. CERTIFICATIONS AND REPRESENTATIONS

All Certifications and Representations found under Appendix D must be completed and submitted with the cost application.

END OF SECTION IV

SECTION V – Application Review Information

A. OVERVIEW

Each technical application submitted in response to this solicitation will be evaluated in relation to the evaluation factors set forth in this request for application and which have been tailored to the requirements of this application.

The Government anticipates the award of one cooperative agreement as a result of this solicitation and intends to evaluate applications and conduct discussions and/or negotiations with applicants to determine the application most advantageous to the U.S. Government, technical, cost and other factors considered.

However, USAID reserves the right, without discussions and/or negotiations, to award a cooperative agreement to the most responsible applicant whose application conforms to the requirements of this solicitation and offers the best value to the Government. Therefore, applicants' initial application should contain the best terms from a technical and cost standpoint.

Further, USAID reserves the right not to make any award at all, and will not pay for any application preparation costs.

Award will be based on the ranking of applications according to the technical selection criteria identified below.

B. ACCEPTABILITY OF PROPOSED NON-PRICE TERMS AND CONDITIONS

An application is acceptable when it manifests the Applicant's assent, without exception, to the terms and conditions of the RFA, including Annexes. If an Applicant takes exception to any of the terms and conditions of the RFA, then USAID will consider its offer to be unacceptable. The USAID reserves the right to change the terms and conditions of the RFA by amendment at any time prior to the Applicant selection decision.

The criteria presented below have been tailored to the requirements of this RFA. Applicants should note that these criteria serve to:
(a) identify the significant areas that Applicants should address in their applications and
(b) serve as the standard against which all applications will be evaluated.
To facilitate the review of applications, Applicants should organize the narrative sections of their applications in the same order as the selection criteria.

The technical applications will be evaluated in accordance with the Technical Evaluation Criteria set forth below. Thereafter, the cost application of all Applicants submitting a technically acceptable application will be reviewed and costs will be evaluated for general reasonableness, allowability, and allocability.

Cost sharing is an important element of the USAID-Recipient relationship and the cost application should clearly demonstrate Applicant’s plan for providing 5% cost share. The

proposed contributions should meet the standards set in 22 CFR 226.23 for U.S. organizations or the Standard Provision "Cost Share" for non-U.S. organizations.

C. TECHNICAL EVALUATION CRITERIA (TOTAL 100 PERCENT)

The technical evaluation criteria presented below identify the relative importance of each criterion. These criteria are intended to signify the most important matters that Applicants should address in their application, as well as set standards against which all applications will be evaluated. To facilitate the review of applications, applicants should organize the narrative portions of their application with reference to the format guidelines found in Section IV, Application and Submission Information.

USAID intends to award one cooperative agreement to the Applicant whose application best meets the program description and represents the ***greatest value*** to the U.S. Government. Technical applications for the *Challenge TB* project will be evaluated and scored based on the following:

1. Technical Approach: 45 percentage
2. Personnel: 30 percentage
3. Management Plan 12 percentage
4. Institutional Capacity 8 percentage
5. Past Performance: 5 percentage

Technical Application Evaluation

The technical applications will be evaluated on the technical selection criteria provided in Section B. Sub-criteria listed under each section will be equally weighted, unless otherwise noted. To facilitate the review of applications, applicants should organize the narrative portions of their application in the same order as the broad selection criteria and should refer to the detailed instructions found in Section B, Technical Application Selection Criteria. These criteria identify the significant areas that applicants should address in their applications and serve as the standard against which all applications will be evaluated.

A. Technical Application Selection Criteria

The Technical application will be evaluated on the basis of the following factors: technical approach; personnel; management; institutional capacity, and past performance. Applications shall present information on each of these factors. The technical application will be evaluated based on the five criteria, which are weighted according to the percentage assigned to each section.

1. **Technical Approach (Total 45 percent)** The criteria is listed in descending order of importance**.**
    a. The extent to which the applicant's technical approach demonstrates a realistic and feasible plan to achieve the goals and objectives as well as demonstrates analytical depth, effectiveness of intervention, and creativity in delivery.

b. The degree to which the applicant's overall technical approach in each country demonstrates analytical depth, effectiveness and focus of interventions, and creativity in the implementation approach.

c. The extent to which the applicant's M&E strategic framework provides a complete and feasible plan for monitoring progress, collecting data, and disseminating lessons learned and best practices; provides a robust data quality assurance plan; and offers the type and level of proposed results, indicators and targets that are challenging and appropriate.

d. The extent to which the applicant's technical approach to global technical leadership is focused on the most relevant issues and demonstrates effectiveness of interventions.

e. The extent to which the applicant's technical approach demonstrates clarity and analytical depth in support of country-led programming, as well as increased support for local implementing partners.

2. **Personnel (Total 30 percent)** The criteria is listed in descending order of importance**.**

a. The extent to which all key personnel meet or exceed the minimum requirements set forth in Section IV.2.2and reflects the ability to execute the project requirements.

b. The extent to which the proposed overall staffing plan is efficient as well as proposed other personnel possess the full range of experience, skill and expertise in the technical labor areas outlined in the Personnel Matrix (see Annex B).

3. **Management Plan (Total 12 percent)**

a. The degree to which the application describes effective management and administrative arrangements for implementation of the program including clear lines of authority between the prime and its partners and a clear plan to an efficient and effective operations to ensure rapid start up and timely and complete implementation.

b. The degree to which the proposed management plan describes effective strategies to contain costs, including publication and media costs; how financial disbursement to in-country partners will be managed;; where approval authority is located for expenditures of Mission funds and of core funds; and how the applicant will assure timely and accurate financial reporting of multiple funding streams.

c. The degree to which applicant's plan for developing, maintaining, and implementing the M&E system over the life of the project contributes to the efficient and effective management of the project overall.

Institutional Capacity (Total 8 percent)

a. Degree to which the prime and all proposed sub-recipients/partners possess the depth and breadth of institutional capacity in order to implement the *Challenge TB* outlined in Section I.

4. **Past Performance (Total 5 percent)**

a. USAID will evaluate the extent to which the applicant's past performance information obtained demonstrates successful past performance implementing previous work similar in scope to this program. USAID reserves the right to contact any other sources other than the three (3) references offered by an applicant.

Summary Technical Rating:

Technical Approach	45 percent
Personnel	30 percent
Management	12 percent
Institutional Capacity	8 percent
Past Performance	5 percent
Total	**100 percent**

C.6. Cost Effectiveness and Cost Realism

The Applicant's Cost Application (CA) will be evaluated but not scored. However, the results from its analyses have ranking implications. The overall proposed costs are expected to be allowable, allocable to the project, fair and reasonable, and cost effective. All CAs are subject to a cost realism analysis. Information gathered from such considerations may clarify the evaluator's understanding of various application details and lend itself to adjustment of scores/rankings. In the event that Technical Applications are scored substantially the same, cost would become the determining factor for award.

END OF SECTION V

SECTION VI – Award and Administration Information

A. Authority to Obligate the Government

The AO is the only individual who may legally commit the Government to the expenditure of public funds.

B. Reporting Requirements

The recipient will adhere to all reporting requirements listed below. As required under Substantial Involvement, all reports shall be submitted by the due date to the AOR who will be designated by the Bureau for Global Health. The recipient will consult the AOR on the format and expected content of reports prior to submission. In addition to the reports below, the AOR may request additional information to contribute to the internal USAID management reviews.

1. Financial Reporting

Financial reporting requirements will be in accordance with 22 CFR 226 and ADS 303.3.21. Effective January 1, 2010, all financial reports must be submitted using the new Standard Form (SF) 425, and the form and the instructions are available on Office of Management and Budget (OMB)'s website, at http://www.whitehouse.gov/omb/grants_forms/.

2. Performance Reporting

In addition to analyzing the financial situation, there are several performance and technical reporting requirements that are addressed in the annual work plan, as well as the quarterly, annual and final reports. These reports are linked to the performance of the technical report.

a. Annual Work Plan
Within 60 days of signing the CA, the Recipient will be required to submit a work plan requirements listed below. The work plan for subsequent years will be due to the AOR for approval 30 days prior to the start of the new fiscal year. The work plan serves several purposes including a guide to program implementation, a demonstration of links between activities, key technical areas, overarching elements and intended results, a basis for budget estimates and the foundation for the M&E plan for the activities under this CA. These annual work plans may be revised on an occasional basis, as needed, to reflect changes on the ground and with the concurrence of the AOR. The work plan, at a minimum, shall include:

- Brief situation analysis that details how the program contributes to national, regional, or global strategic plans and poverty reduction strategies in the context of what other donors and implementing partners and host-country governments are contributing;
- Program Goals;

- Milestones towards achieving those results;
- Activities to be accomplished that year related specifically toward achievement of milestones;
- Level of effort required in terms of key staff and support staff time and financial resources; and,
- Partner involvement and contributions to achieving the results.

Timeline: Work plans should be organized to clearly link activities to the goals and objectives. The work plan is negotiated with the AOR in consultation with program managers. The plan will outline key activities for the year including country-specific work. Work plan budgets should delineate an overall budget, budget by country, and budget per activity.

All activities that cannot be completed within one year; i.e. one work planning cycle, will be proposed with multi-year budgets and timelines to reflect anticipated completion dates. In addition, the work plan should include a performance management plan. This plan will be negotiated and approved as part of the work plan.

In addition, the work plan shall include a M&E plan. This plan will be negotiated and approved as part of the work plan. The recipient is expected to produce and disseminate only those key publications that directly contribute to achieving results. In general, these will include articles published in peer reviewed journals and major theoretical and technical advances in the field as a result of the project, both as events and publications. All publications based on *Challenge TB*-supported work require prior AOR review and approval prior to publication and dissemination. Events based in the field will be given priority over U.S. or European-based events.

b. Quarterly Performance Monitoring Reports
The recipient will submit three quarterly technical and financial analysis reports per year to each USAID operating unit and AOR on their respective activities within 30 calendar days following the end of the reporting period. In addition, a compilation and analysis of these reports on all project activities shall be submitted to the AOTR within 45 calendar days following the end of the reporting period. The three reports are for the first, second and third quarters. See below the information on Annual Reports for the fourth quarter of each year. The quarterly reports shall briefly document accomplishments toward the program objectives and activities. Process level indicators shall be reported on a quarterly basis and all other indicators shall be reported annually, as agreed upon with the AOR. The reports shall include the following:

- Description of activities conducted in the last quarter and analysis of their collective progress towards objectives;
- Description of the obstacles and their effect of implementing activities and achieving objectives, if appropriate, and remedies or actions undertaken or planned to address these obstacles. Any planned activities not conducted in the quarter need specific explanation;

- Analysis and explanation of costs including any pipeline or unexpected expenditures; and,
- Outline the next steps, any changes in the timeline or plan or activities for the next reporting period.

Notification (to the AOR via email) must be given in the case of problems, delays or adverse conditions which materially impair the ability to meet the reporting deadlines. These notifications shall include a statement of the action taken or contemplated and any assistance needed to resolve the situation.

c. Annual Report

Throughout the life of the CA, the recipient shall be required to submit one annual technical and financial analysis report to each USAID operating unit (each funding source) and AOR on their respective activities within 30 days following the end of the reporting period. In addition, a compilation and analysis of these reports on all project activities shall be submitted to the AOR within 45 days following the end of the reporting period. The end of the reporting period performance monitoring report shall be a summation and analysis of the results and progress against the annual work plan. All agreed upon outcomes and impact level indicators shall be included in the report. In addition, the reports shall include the following:

- Description of activities conducted in the past year and analysis of their collective progress towards objectives and quantifiable output of the programs including accomplishments, lessons learned, intermediate results and milestones;
- Description of the obstacles and their effect of implementing activities and achieving objectives, if appropriate, and remedies or actions undertaken or planned to address these obstacles. Any planned activities not conducted in the past year need specific explanation;
- Analysis and explanation of costs in the past year including any pipeline or unexpected expenditures. Any reprogramming of funds shall be indicated in the report; and,
- Outline the next steps, any changes in the timeline or plan or activities for the next year.

d. Final Report

As USAID requires, 90 calendar days after the completion date of this Agreement, the Recipient shall submit a final report which includes: an executive summary of the Recipient's accomplishments in achieving results and conclusions about areas in need of future assistance; an overall description of the Recipient's activities and attainment of results by country or region, and assessment of progress made toward accomplishing the Objective and Expected Results; significance of these activities; comments and recommendations; and a fiscal report that describes how the Recipient's funds were used. Reference 22 CFR 226.51.

The Recipient shall submit an original and one copy of the final report to the AOTR and one copy to the USAID Development Experience Clearinghouse (DEC): E-mail (the preferred means of submission) is: docsubmit@dec.cdie.org. The mailing

address via U.S. Postal Service is: Development Experience Clearinghouse, 8403 Colesville Road, Suite 210, Silver Spring, MD 20910.

3. Management Review and External Evaluations

The annual work plan shall form the basis for an annual management review by USAID and program staff to review program directions, achievement of the prior year implementation plan objectives, and major management and implementation issues, and to make recommendations for any changes as appropriate. During the third year of the project, USAID may conduct an external mid-term evaluation. In year five USAID may conduct a final evaluation to review overall progress.

C. AWARD AND ADMINISTRATION INFORMATION,

The successful applicant can expect to receive a notice of award signed by the AO. USAID will provide notice of the award electronically to the point of contact stated on the application cover page.

D. STANDARD PROVISIONS

The Applicant will be required to adhere to and govern itself under the Standard Provisions for U.S. NGO or Non-U.S. NGOs as applicable. Links to these Standard Provisions can be found under Section VIII of this RFA.

E. BRANDING AND MARKING REQUIREMENTS

BRANDING STRATEGY - ASSISTANCE (June 2012)

a. Applicant recommended for an assistance award must submit and negotiate a "Branding Strategy," describing how the program, project, or activity is named and positioned, and how it is promoted and communicated to beneficiaries and host country citizens.

b. The request for a Branding Strategy, by the Agreement Officer from the applicant, confers no rights to the applicant and constitutes no USAID commitment to an award.

c. Failure to submit and negotiate a Branding Strategy within the time frame specified by the Agreement Officer will make the applicant ineligible for an award.

d. The applicant must include all estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth, in the budget portion of the application. These costs are subject to the revision and negotiation with the Agreement Officer and will be incorporated into the Total Estimated Amount of the grant, cooperative agreement or other assistance instrument

e. The Branding Strategy must include, at a minimum, all of the following:

(1) All estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth.

(2) The intended name of the program, project, or activity.

(i) USAID prefers to have the "USAID Identity," comprised of the USAID logo and brandmark, with the tagline "from the American people" as found on the USAID Web site at transition.usaid.gov/branding, included as part of the program or project name.

(ii) USAID prefers local language translations of the phrase "made possible by (or with) the generous support of the American People" next to the USAID Identity when acknowledging contributions.

(iii) It is acceptable to cobrand the title with the USAID Identity and the applicant's identity.

(iv) If branding in the above manner is inappropriate or not possible, the applicant must explain how USAID's involvement will be showcased during publicity for the program or project.

(v) USAID prefers to fund projects that do not have a separate logo or identity that competes with the USAID Identity. If there is a plan to develop a separate logo to consistently identify this program, the applicant must attach a copy of the proposed logos.

(3) The intended primary and secondary audiences for this project or program, including direct beneficiaries and any special target segments.

(4) Planned communication or program materials used to explain or market the program to beneficiaries.

(i) Describe the main program message.

(ii) Provide plans for training materials, posters, pamphlets, public service announcement, billboards, Web sites, and so forth, as appropriate.

(iii) Provide any plans to announce and promote publicly this program or project to host country citizens, such as media releases, press conferences, public events, and so forth. Applicant must incorporate the USAID Identity and the message, "USAID is from the American People."

(iv) Provide any additional ideas to increase awareness that the American people support this project or program.

(5) Information on any direct involvement from host-country government or ministry, including any planned acknowledgement of the host-country government.

(6) Any other groups whose logo or identity the applicant will use on program materials and related materials. Indicate if they are a donor or why they will be visibly acknowledged, and if they will receive the same prominence as USAID.

a. The Agreement Officer will consider the Branding Strategy's adequacy in the award criteria. The Branding Strategy will be reviewed to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

b. If the applicant receives an assistance award, the Branding Strategy will be included in and made part of the resulting grant or cooperative agreement.

MARKING PLAN – ASSISTANCE (June 2012)

a. Applicants recommended for an assistance award must submit and negotiate a "Marking Plan," detailing the public communications, commodities, and program materials, and other items that will visibly bear the "USAID Identity," which comprises of the USAID logo and brandmark, with the tagline "from the American people." The USAID Identity is the official marking for the Agency, and is found on the USAID Web site at http://transition.usaid.gov/branding.

b. The request for a Marking Plan, by the Agreement Officer from the applicant, confers no rights to the applicant and constitutes no USAID commitment to an award.

c. Failure to submit and negotiate a Marking Plan within the time frame specified by the Agreement Officer will make the applicant ineligible for an award.

d. The applicant must include all estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth, in the budget portion of the application. These costs are subject to the revision and negotiation with the Agreement Officer and will be incorporated into the Total Estimated Amount of the grant, cooperative agreement or other assistance instrument.

e. The Marking Plan must include all of the following:
(1) A description of the public communications, commodities, and program materials that the applicant plans to produce and which will bear the USAID Identity as part of the award, including:

a. Program, project, or activity sites funded by USAID, including visible infrastructure projects or other sites physical in nature;
b. Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
c. Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
d. It is acceptable to cobrand the title with the USAID Identity and the applicant's identity.

(2) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.

(3) A table of the program deliverables with the following details:
(i) The program deliverables that the applicant plans to mark with the USAID Identity;

(ii) The type of marking and what materials the applicant will use to mark the program deliverables;

(iii) When in the performance period the applicant will mark the program deliverables, and where the applicant will place the marking;

(iv) What program deliverables the applicant does not plan to mark with the USAID Identity , and

(v) The rationale for not marking program deliverables.

(4) Any requests for an exemption from USAID marking requirements, and an explanation of why the exemption would apply. The applicant may request an exemption if USAID marking requirements would:

(i) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials. The applicant must identify the USAID Strategic Objective, Interim Result, or program goal furthered by an appearance of neutrality, or state why an aspect of the award is presumptively neutral. Identify by category or deliverable item, examples of material for which an exemption is sought.

(ii) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent. The applicant must explain why each particular deliverable must be seen as credible.

(iii) Undercut host-country government "ownership" of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications. The applicant must explain why each particular item or product is better positioned as host-country government item or product.

(iv) Impair the functionality of an item. The applicant must explain how marking the item or commodity would impair its functionality.

(v) Incur substantial costs or be impractical. The applicant must explain why marking would not be cost beneficial or practical.

(vi) Offend local cultural or social norms, or be considered inappropriate. The applicant must identify the relevant norm, and explain why marking would violate that norm or otherwise be inappropriate.

(vii) Conflict with international law. The applicant must identify the applicable international law violated by the marking.

f. The Agreement Officer will consider the Marking Plan's adequacy and reasonableness in the award criteria, and will approve and disapprove any exemption requests. The Marking Plan will be reviewed to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

g. If the applicant receives an assistance award, the Marking Plan, including any approved exemptions, will be included in and made part of the resulting grant or cooperative agreement, and will apply for the term of the award unless provided otherwise.

END OF SECTION VI

SECTION VII – Agency contacts

The applicant may contact the following USAID personnel in writing regarding this RFA:

Primary Point of Contact
Amy Wire
Agreement Specialist
USAID Office of Acquisition & Assistance
M/OAA/GH, Rm 549-M, SA-44
1300 Pennsylvania Ave., NW
Washington, D.C. 20523
Tel: (202) 567-4301
Email:awire@usaid.gov

and

Alternate Point of Contact:
Christie Cooper
Agreement Specialist
USAID Office of Acquisition & Assistance
M/OAA/GH, Rm 549-G, SA-44
1300 Pennsylvania Ave., NW
Washington, D.C. 20523
Tel: (202) 567-5064
Email: ccooper@usaid.gov

END OF SECTION VII

SECTION VIII – Other information

A. USAID RIGHTS AND FUNDING

The Government may (a) reject any or all applications; (b) accept other than the lowest cost application, and (c) waive informalities and minor irregularities in the applications received.

Issuance of this RFA does not constitute an award commitment on the part of the Government, nor does it commit the Government to pay for costs incurred in the preparation and/or submission of an application. Applicants who come under consideration for an award that have never received USAID funding will be subject to a pre-award audit to determine fiscal responsibility, ensure adequacy of financial controls, and establish an indirect cost rate (if applicable).

B. APPLICABLE REGULATIONS & REFERENCES

- Mandatory Standard Provisions for U.S., Nongovernmental Recipients **http://www.usaid.gov/pubs/ads/300/303maa.pdf**

- Mandatory Standard Provisions for Non-U.S. Nongovernmental Recipients:**http://www.usaid.gov/policy/ads/300/303mab.pdf**

- 22 CFR 226
http://www.access.gpo.gov/nara/cfr/waisidx_02/22cfr226_02.html

- OMB Circular A-122
http://www.whitehouse.gov/omb/circulars/a122/a122.html

- OMB Circular A-110
http://www.whitehouse.gov/omb/circulars/a110/a110.html

- SF-424 Downloads
http://www.grants.gov/agencies/aapproved_standard_forms.jsp

END OF SECTION VIII

ANNEXES

ANNEX A - PERSONNEL MATRIX
ANNEX B - PAST PERFORMANCE SHORT FORM
ANNEX C - GRANTS.GOV REGISTRATION PROCESS
ANNEX D - CERTIFICATIONS, ASSURANCES, AND OTHER STATEMENTS OF THE RECIPIENT (JUNE 2012)
ANNEX E - INITIAL ENVIRONMENTAL EXAMINATION

ANNEX A - PERSONNEL MATRIX

Name of Personnel	Title (for full time personnel only)	Name of current employer/organization	Expected Level of Effort on the project	Education[1]	Language[2]	Years of Experience[3]	Years of experience working in Developing Country[4]	Years of experience living in Developing country [5]	List USAID TB and PEPFAR Country Experience (see list of countries in Program Description)	1) TB Leadership and Management*	2) Laboratory networks*	3) TB treatment/Case Management*	4) Infection Control*	5) TB Commodity Management*	6) TB Monitoring, Evaluation and Surveillance*	7) Programmatic Management of Drug Resistant TB*	8) TB Drug Resistance Surveillance/surveys*	9) TB/HIV diagnosis, care and treatment*	10) Health Systems Strengthening*	11) TB Advocacy and Political Commitment*	12) Human Resource Development*	13) Engaging all TB care providers (PPP)*	14) Community mobilization*	15) Poverty Reduction/Vulnerable Populations*	16) Gender Issues*	17) Operations Research*	18) Global Fund Operations*	19) Project Financial Management*	20) Project Operational Management*
John Doe		ABC Org.	80%	PhD, MD, MPH	E, F	5	3	1	Bangladesh, Dem Rep Congo, Kenya, Guyana	1		3		3				4	2									
Jane Doe		XYZ Associates	25%	MPH	E, S, O (Tagalog)	8	2	1	Philippines, Dominican Republic	1					3	5												

1. B = Bachelor's; M = Master's; MPH = Masters in Public Health; PhD = Doctoral; MD = Medical Doctor
2. E = English; F = French; P = Portuguese; R = Russian; S = Spanish; O = Other

END OF ANNEX A

ANNEX B – PAST PERFORMANCE INFORMATION

PAST PERFORMANCE REPORT – SHORT FORM
PART I: Award Information (**to be completed by Applicant**)
1. Name of Awarding Entity
2. Award Number:
3. Award Type:
4. Award Value (TEC): (if sub agreement, sub agreement value)
5. Problems: (if problems encountered on this award, explain corrective action taken):
6. Contacts: (Name, Telephone Number and email addresses)
6a. Contract/Agreement Officer:
6b. Contract/Agreement Officer's Technical Representative (COTR/AOTR):
6c. Other:
7. Recipient:
8. Title/Brief Description of Program or Work provided and relevancy to the TB CARE RFA:
9. Information Provided in Response to RFA/RFP:
PART II: Performance Assessment (**to be completed by Agency**)
1. Quality of product or service, including consistency in meeting goals and targets, and cooperation and effectiveness of the Prime in fixing problems. Comment:
2. Cost control, including forecasting costs as well as accuracy in financial reporting. Comment:
3. Timeliness of performance, including adherence to contract schedules and other time-sensitive project conditions, and effectiveness of home and field office management to make prompt decisions and ensure efficient operation of tasks. Comment:
4. Customer satisfaction, including satisfactory business relationship to clients, initiation and management of several complex activities simultaneously, coordination among sub recipients and developing country partners, prompt and satisfactory correction of problems, and cooperative attitude in fixing problems. Comment:
5. Effectiveness of key personnel including: effectiveness and appropriateness of personnel for the job; and prompt and satisfactory changes in personnel when problem with clients where identified. Comment:
6. State significant achievement and/or significant problems as applicable. Comment:

Note: The actual dollar amount of subagreement, if any, (awarded to the Prime or Sub awardee) must be listed in Block 4 instead of the Total Estimated Amount of the overall Agreement. In addition, a Prime may submit attachments to this past performance table if the spaces provided are inadequate; the evaluation factor(s) for Performance Assessment must be listed on the attachment(s).

END OF ANNEX B

ANNEX C – Grants.gov Registration Process

Before submitting an application under this RFA, it is highly recommended that applicants read the entire Section IV, Application and Submission Information in this RFA. Reviewing these sections thoroughly will assist an applicant in submitting a complete, full application.

Register Online at Grants.gov

New Applicants Applying to Grants.gov:

It is **strongly encouraged** that new organizations immediately begin the 5-step Grants.gov registration process (listed below), while simultaneously completing the Application Package. The registration process may take up to two weeks to complete. USAID understands that delays in the registration process may be beyond your control. If an organization has begun the registration process but experiences delays that make it difficult for to meet the application deadline, contact the RFA POC(s) who will work with you to find a solution. If an organization is having difficulties, contact the Agency POC(s) listed in the RFA as soon as possible.

Register as an organization on Grants.gov if you are not already registered. All organizations must register. See below for a brief overview of the registration steps. Grants.gov is also available to lead you through the process.

STEP 1: Obtain a Data Universal Number (DUNS)

The Data Universal Number System **(DUNS)** number is a unique nine-character number that identifies your organization. It is a tool of the federal government to track how federal money is distributed. Most large organizations, libraries, colleges and research universities already have DUNS numbers. Ask your grant administrator or chief financial officer to provide your organization's DUNS number or search online by using the DUNS search.

If your organization does *not* have an existing DUNS number, you will need to request one. You can request a DUNS Number here.

STEP 2: Register Your Organization with the System for Awards Management (SAM)

You must also register with SAM. SAM is the primary registrant database for the U.S. Federal Government. SAM collects, validates, stores and disseminates data about the federal government's trading partners in support of the contract award, grants and the electronic payment processes.

STEP 3: Username and Password

If your organization's E-Business Point of Contact (E-Biz POC) has assigned you AOR rights, you are authorized to submit grant applications on behalf of your organization. AORs must create a username and password to serve as their "electronic signature" when submitting an

application on behalf of their organization. To register as an AOR and create a username and password, go to: https://apply07.grants.gov/apply/OrcRegister

STEP 4: AOR Authorization

Your E-Biz POC must then login to Grants.gov (using the organization's DUNS number for the username and the "MPIN" password obtained in Step 2) and approve the AOR, thereby giving permission to submit applications. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email that includes the requesting AOR's name, e-mail address and phone number. In some cases the E-Biz POC can also be the AOR for an organization. If the E-Biz POC wishes to submit applications on behalf of their organization, he or she must also complete a separate AOR profile with username and password (Step 3 of the registration process) using a different email than the one used for their E-Biz POC registration.

STEP 5: Track AOR Status
To verify that your organization's E-Biz POC has approved you as an AOR, please track your status. You cannot apply for grants without E-Biz POC approval.

For questions, please consult:
- Organization Registration User Guide
- Organization Registration Checklist
- Grants.gov Contact Center: 1-800-518-4726 or support@grants.gov. Hours of Operation: 24 hours a day, 7 days a week.

If you are concerned that you will not finish your CCR registration in time to meet the overall application deadline, contact the RFA POC(s) listed in Section VII who will work with you to find a solution. If an organization is having difficulties, contact the Agency POC(s) listed in the RFA in Section VII as soon as possible.

END OF ANNEX C

ANNEX D Certifications, Assurances and Other Statements of the Recipient
CERTIFICATIONS, ASSURANCES, AND OTHER STATEMENTS OF THE RECIPIENT (JUNE 2012)

NOTE: When these Certifications, Assurances, and Other Statements of Recipient are used for cooperative agreements, the term "Grant" means "Cooperative Agreement."

There are five parts to this section to include the following:

Part I	Certifications and Assurances
Part II	Key Individual Certification Narcotics Offenses and Drug Trafficking
Part III	Participant Certification Narcotics Offenses and Drug Trafficking
Part IV	Survey on Ensuring Equal Employment Opportunity for Applicants
Part V	Other Statements of Recipients

Certifications, Assurances, and Other Statements of the Recipient are to be submitted by the closing date of this RFA. The applicant shall review, comply and fill out all five applicable parts of this section to be considered for award. Any parts or subsections that do not apply to the applicant shall be indicated with “n/a” and a brief explanation of why it does not apply.

PART I - CERTIFICATIONS AND ASSURANCES

1. ASSURANCE OF COMPLIANCE WITH LAWS AND REGULATIONS GOVERNING NON-DISCRIMINATION IN FEDERALLY ASSISTED PROGRAMS

Note: This certification applies to Non-U.S. organizations if any part of the program will be undertaken in the United States.

(a) The recipient hereby assures that no person in the United States will, on the bases set forth below, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under, any program or activity receiving financial assistance from USAID, and that with respect to the Cooperative Agreement for which application is being made, it will comply with the requirements of:

(1) Title VI of the Civil Rights Act of 1964 (Pub. L. 88-352, 42 U.S.C. 2000-d), which prohibits discrimination on the basis of race, color or national origin, in programs and activities receiving Federal financial assistance;

(2) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), which prohibits discrimination on the basis of handicap in programs and activities receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as amended (Pub. L. 95-478), which prohibits discrimination based on age in the delivery of services and benefits supported with Federal funds;

(4) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, et seq.), which prohibits discrimination on the basis of sex in education programs and activities receiving

Federal financial assistance (whether or not the programs or activities are offered or sponsored by an educational institution); and

(5) USAID regulations implementing the above nondiscrimination laws, set forth in Chapter II of Title 22 of the Code of Federal Regulations.

(b) If the recipient is an institution of higher education, the Assurances given herein extend to admission practices and to all other practices relating to the treatment of students or clients of the institution, or relating to the opportunity to participate in the provision of services or other benefits to such individuals, and must be applicable to the entire institution unless the recipient establishes to the satisfaction of the USAID Administrator that the institution's practices in designated parts or programs of the institution will in no way affect its practices in the program of the institution for which financial assistance is sought, or the beneficiaries of, or participants in, such programs.

2. CERTIFICATION REGARDING LOBBYING

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal Cooperative Agreement, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned must complete and submit Standard Form-LLL, “Disclosure of Lobbying Activities,” in accordance with its instructions.

(3) The undersigned must require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients must certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, United States Code. Any person who fails to file the required certification will be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance

"The undersigned states, to the best of his or her knowledge and belief, that: If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned must complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions. Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement will be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

3. PROHIBITION ON ASSISTANCE TO DRUG TRAFFICKERS FOR COVERED COUNTRIES AND INDIVIDUALS (ADS 206)

USAID reserves the right to terminate this Agreement, to demand a refund or take other appropriate measures if the Grantee is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140. The undersigned must review USAID ADS 206 to determine if any certifications are required for Key Individuals or Covered Participants.

If there are COVERED PARTICIPANTS: USAID reserves the right to terminate assistance to or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.

4. CERTIFICATION REGARDING TERRORIST FINANCING IMPLEMENTING EXECUTIVE ORDER 13224

By signing and submitting this application, the prospective recipient provides the certification set out below:

1. The Recipient, to the best of its current knowledge, did not provide, within the previous ten years, and will take all reasonable steps to ensure that it does not and will not knowingly provide, material support or resources to any individual or entity that commits, attempts to commit, advocates, facilitates, or participates in terrorist acts, or has committed, attempted to commit, facilitated, or participated in terrorist acts, as that term is defined in paragraph 3.

2. The following steps may enable the Recipient to comply with its obligations under paragraph 1:

a. Before providing any material support or resources to an individual or entity, the Recipient will verify that the individual or entity does not (i) appear on the master list of Specially Designated Nationals and Blocked Persons, which is maintained by the U.S. Treasury's Office of Foreign Assets Control (OFAC), or (ii) is not included in any supplementary information concerning prohibited individuals or entities that may be provided by USAID to the Recipient.

b. Before providing any material support or resources to an individual or entity, the Recipient also will verify that the individual or entity has not been designated by the United Nations Security (UNSC) sanctions committee established under UNSC Resolution 1267 (1999) (the "1267 Committee") [individuals and entities linked to the Taliban, Usama bin Laden, or the Al-Qaida Organization]. To determine whether there has been a published designation of an individual or entity by the 1267 Committee, the Recipient should refer to the consolidated list available online at the Committee's Web site: http://www.un.org/Docs/sc/committees/1267/1267ListEng.htm.

c. Before providing any material support or resources to an individual or entity, the Recipient will consider all information about that individual or entity of which it is aware and all public information that is reasonably available to it or of which it should be aware.

d. The Recipient also will implement reasonable monitoring and oversight procedures to safeguard against assistance being diverted to support terrorist activity.

3. For purposes of this Certification -

a. "Material support and resources" means currency or monetary instruments or financial securities, financial services, lodging, training, expert advice or assistance, safehouses, false documentation or identification, communications equipment, facilities, weapons, lethal substances, explosives, personnel, transportation, and other physical assets, except medicine or religious materials."

b. "Terrorist act" means -

(i) an act prohibited pursuant to one of the 12 United Nations Conventions and Protocols related to terrorism (see UN terrorism conventions Internet site: http://untreaty.un.org/English/Terrorism.asp); or

(ii) an act of premeditated, politically motivated violence perpetrated against noncombatant targets by subnational groups or clandestine agents; or

(iii) any other act intended to cause death or serious bodily injury to a civilian, or to any other person not taking an active part in hostilities in a situation of armed conflict, when the purpose of such act, by its nature or context, is to intimidate a population, or to compel a government or an international organization to do or to abstain from doing any act.

c. "Entity" means a partnership, association, corporation, or other organization, group or subgroup.

d. References in this Certification to the provision of material support and resources must not be deemed to include the furnishing of USAID funds or USAID-financed commodities to the ultimate beneficiaries of USAID assistance, such as recipients of food, medical care, micro-enterprise loans, shelter, etc., unless the Recipient has reason to believe that one or more of these beneficiaries commits, attempts to commit, advocates, facilitates, or participates in terrorist acts, or has committed, attempted to commit, facilitated or participated in terrorist acts.

e. The Recipient's obligations under paragraph 1 are not applicable to the procurement of goods and/or services by the Recipient that are acquired in the ordinary course of business through contract or purchase, e.g., utilities, rents, office supplies, gasoline, etc., unless the Recipient has reason to believe that a vendor or supplier of such goods and services commits, attempts to commit, advocates, facilitates, or participates in terrorist acts, or has committed, attempted to commit, facilitated or participated in terrorist acts.

This Certification is an express term and condition of any agreement issued as a result of this application, and any violation of it will be grounds for unilateral termination of the agreement by USAID prior to the end of its term.

5. CERTIFICATION OF RECIPIENT

By signing below the recipient provides certifications and assurances for (1) the Assurance of Compliance with Laws and Regulations Governing Non-Discrimination in Federally Assisted Programs, (2) the Certification Regarding Lobbying, (3) the Prohibition on Assistance to Drug Traffickers for Covered Countries and Individuals (ADS 206) and (4) the Certification Regarding Terrorist Financing Implementing Executive Order 13224 above.

These certifications and assurances are given in consideration of and for the purpose of obtaining any and all Federal grants, loans, contracts, property, discounts, or other Federal financial assistance extended after the date hereof to the recipient by the Agency, including installment payments after such date on account of applications for Federal financial assistance which was approved before such date. The recipient recognizes and agrees that such Federal financial assistance will be extended in reliance on the representations and agreements made in these assurances, and that the United States will have the right to seek judicial enforcement of these assurances. These assurances are binding on the recipient, its successors, transferees, and assignees, and the person or persons whose signatures appear below are authorized to sign these assurances on behalf of the recipient.

Request for Application or
Annual Program Statement No. _____

Application No. _____

Date of Application _____

Name of Recipient _____

Typed Name and Title _____

Signature _____

Date _____

PART II - KEY INDIVIDUAL CERTIFICATION NARCOTICS OFFENSES AND DRUG TRAFFICKING

I hereby certify that within the last ten years:

1. I have not been convicted of a violation of, or a conspiracy to violate, any law or regulation of the United States or any other country concerning narcotic or psychotropic drugs or other controlled substances.

2. I am not and have not been an illicit trafficker in any such drug or controlled substance.

3. I am not and have not been a knowing assistor, abettor, conspirator, or colluder with others in the illicit trafficking in any such drug or substance.

Signature: _____

Date: _____

Name: _____

Title/Position: _____

Organization: _____

Address: _____

_____

Date of Birth: _____

NOTICE:

1. You are required to sign this Certification under the provisions of 22 CFR Part 140, Prohibition on Assistance to Drug Traffickers. These regulations were issued by the Department of State and require that certain key individuals of organizations must sign this Certification.

2. If you make a false Certification you are subject to U.S. criminal prosecution under 18 U.S.C. 1001.

PART III - PARTICIPANT CERTIFICATION NARCOTICS OFFENSES AND DRUG TRAFFICKING

1. I hereby certify that within the last ten years:

a. I have not been convicted of a violation of, or a conspiracy to violate, any law or regulation of the United States or any other country concerning narcotic or psychotropic drugs or other controlled substances.

b. I am not and have not been an illicit trafficker in any such drug or controlled substance.

c. I am not or have not been a knowing assistor, abettor, conspirator, or colluder with others in the illicit trafficking in any such drug or substance.

2. I understand that USAID may terminate my training if it is determined that I engaged in the above conduct during the last ten years or during my USAID training.

Signature: _____

Name: _____

Date: _____

Address: _____

_____

Date of Birth: _____

NOTICE:

1. You are required to sign this Certification under the provisions of 22 CFR Part 140, Prohibition on Assistance to Drug Traffickers. These regulations were issued by the Department of State and require that certain participants must sign this Certification.

2. If you make a false Certification you are subject to U.S. criminal prosecution under 18 U.S.C. 1001.

PART IV - SURVEY ON ENSURING EQUAL OPPORTUNITY FOR APPLICANTS

Please note that per USAID policy, all RFA's must include the referenced Survey on Ensuring Equal Opportunity for Applicants in the RFA package. While inclusion of the survey by Agreement Officers in RFA packages is required, the Applicant's completion of the survey is voluntary, and it is not a requirement of the RFA. The absence of a completed survey in an application is not a basis upon which the application will be determined incomplete or non-responsive. Applicants who volunteer to complete and submit the survey under a competitive or non-competitive action are instructed within the text of the survey to submit it as part of the application process.

This survey can be found at this website: http://www.usaid.gov/forms/surveyeo.doc

PART V - OTHER STATEMENTS OF RECIPIENT

1. AUTHORIZED INDIVIDUALS

The recipient represents that the following persons are authorized to negotiate on its behalf with the Government and to bind the recipient in connection with this application or grant:

Name Title Telephone No. Facsimile No.

_____

_____

_____

2. TAXPAYER IDENTIFICATION NUMBER (TIN)

If the recipient is a U.S. organization, or a foreign organization which has income effectively connected with the conduct of activities in the U.S. or has an office or a place of business or a fiscal paying agent in the U.S., please indicate the recipient's TIN:

TIN: _____

3. DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER

(a) Applicability. This applies to the procurement of goods and services planned by the recipient (i.e., contracts, purchase orders, etc.) from a supplier of goods or services for the direct use or benefit of the recipient in conducting the program supported by the grant, and not to assistance provided by the recipient (i.e., a subgrant or subagreement) to a subgrantee or subrecipient in support of the subgrantee's or subrecipient's program. Provision by the recipient of the requested information does not, in and of itself, constitute USAID approval.

(b) Amount of Procurement. Please indicate the total estimated dollar amount of goods and services which the recipient plans to purchase under the grant:

$_____

(c) Nonexpendable Property. If the recipient plans to purchase nonexpendable equipment which would require the approval of the Agreement Officer, indicate below (using a continuation page, as necessary) the types, quantities of each, and estimated unit costs. Nonexpendable equipment for which the Agreement Officer's approval to purchase is required is any article of nonexpendable tangible personal property charged directly to the grant, having a useful life of more than one year and an acquisition cost of $5,000 or more per unit.

TYPE/DESCRIPTION (Generic) _____
QUANTITY _____
ESTIMATED UNIT COST _____

(d) Source If the recipient plans to purchase any goods/commodities which are not in accordance with the Standard Provision "USAID Eligibility Rules for Procurement of Commodities and Services," indicate below (using a continuation page, as necessary) the types and quantities of each, estimated unit costs of each, and probable source. "Source" means the

country from which a commodity is shipped to the cooperating country or the cooperating country itself if the commodity is located in the cooperating country at the time of purchase. However, where a commodity is shipped from a free port or bonded warehouse in the form in which received, "source" means the country from which the commodity was shipped to the free port or bonded warehouse. Additionally, "available for purchase" includes "offered for sale at the time of purchase" if the commodity is listed in a vendor's catalog or other statement of inventory, kept as part of the vendor's customary business practices and regularly offered for sale, even if the commodities are not physically on the vendors' shelves or even in the source country at the time of the order. In such cases, the recipient must document that the commodity was listed in the vendor's catalog or other statement of inventory; that the vendor has a regular and customary business practice of selling the commodity through "just in time" or other similar inventory practices; and the recipient did not engage the vendor to list the commodity in its catalog or other statement of inventory just to fulfill the recipient's request for the commodity.

TYPE/DESCRIPTION _____
QUANTITY _____
ESTIMATED GOODS _____
PROBABLE GOODS _____
PROBABLE (Generic) _____
UNIT COST _____
SOURCE _____

(e) Restricted Goods. If the recipient plans to purchase any restricted goods, indicate below (using a continuation page, as necessary) the types and quantities of each, estimated unit costs of each, intended use, and probable source. Restricted goods are Agricultural Commodities, Motor Vehicles, Pharmaceuticals, Pesticides, Used Equipment, U.S. Government-Owned Excess Property, and Fertilizer.

TYPE/DESCRIPTION _____
QUANTITY _____
ESTIMATED _____
PROBABLE _____
INTENDED USE (Generic) _____
UNIT COST _____
SOURCE _____

(f) Supplier Nationality. If the recipient plans to purchase any goods or services from suppliers of goods and services whose nationality is not in accordance with the Standard Provision "USAID Eligibility Rules for Procurement of Commodities and Services," indicate below (using a continuation page, as necessary) the types and quantities of each good or service, estimated costs of each, probable nationality of each non-U.S. supplier of each good or service, and the rationale for purchasing from a non-U.S. supplier.

TYPE/DESCRIPTION _____
QUANTITY _____
ESTIMATED _____
PROBABLE SUPPLIER _____
NATIONALITY _____

RATIONALE (Generic) _____
UNIT COST (Non-US Only) _____
FOR NON-US _____

6. PAST PERFORMANCE REFERENCES

Please provide past performance information requested in the RFA.

7. TYPE OF ORGANIZATION

The recipient, by checking the applicable box, represents that -

(a) If the recipient is a U.S. entity, it operates as [ ] a corporation incorporated under the laws of the State of, [ ] an individual, [ ] a partnership, [ ] a nongovernmental nonprofit organization, [ ] a state or local governmental organization, [ ] a private college or university, [ ] a public college or university,
[ ] an international organization, or [ ] a joint venture; or

(b) If the recipient is a non-U.S. entity, it operates as [ ] a corporation organized under the laws of _____ (country), [ ] an individual, [ ] a partnership, [ ] a nongovernmental nonprofit organization, [ ] a nongovernmental educational institution, [ ] a governmental organization, [ ] an international organization, or [ ] a joint venture.

8. ESTIMATED COSTS OF COMMUNICATIONS PRODUCTS

The following are the estimate(s) of the cost of each separate communications product (i.e., any printed material [other than non-color photocopy material], photographic services, or video production services) which is anticipated under the grant. Each estimate must include all the costs associated with preparation and execution of the product. Use a continuation page as necessary.

END OF ANNEX D

ANNEXE – INITIAL ENVIRONMENTAL EXAMINATION (IEE)

SUMMARY OF PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)
For
"Accelerating Tuberculosis Technical Assistance and Country Support" TB (ATTACk TB)
Cooperative Agreement

PROGRAM/ACTIVITY DATA

IEE Number: ~~XXX~~ GH-13-27
Program/Project Number: XXX
Country: Global
Functional Objective: Investing in People
Program Area: Health
Program Elements: Tuberculosis
Funding Period: FY 2014 – FY 2018
Life of Activity Funding: $550 million
Life of PIEE: Five years from date of signing or at the time of any change/amendment to the Program.

PIEE Amendment: Yes_____ No_ __ If yes, date of original IEE: _____

PIEE Prepared by: Amy Piatek, GH/HIDN/ID

Current date: March 29, 2013

ENVIRONMENTAL ACTION RECOMMENDED

Categorical Exclusion: _____
Negative Determination: _____
Negative Determination w/ Conditions: ____X___
Positive Determination: _____

SUMMARY OF FINDINGS

The purpose of this document is to review the overall activities and the potential environmental impact that will be undertaken by the "ATTACk TB" program. The "ATTACk TB" Programmatic Initial Environmental Examination (PIEE) evaluates the potential impacts of the CBP activities and has determined that a **Negative Determination with Conditions** is appropriate for the actions described in the document. Other actions not described in the paper, including small scale construction or the procurement or use of pesticides (including larviciding, indoor residual spraying, fogging, and pesticide impregnated materials etc.) will require supplemental environmental analysis.

THRESHOLD ENVIRONMENTAL DETERMINATIONS

The overall environmental determination for the "ATTACk TB" is a **Negative Determination, with conditions**.

Pursuant to 22 CFR216.3(a)(2)(iii), a **Negative Determination with Conditions** is recommended for any "ATTACk TB" activities that have potential for negative impact on the environment in the following categories, as presented in Annex A in of this document:

1) Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies and reagents.
2) Actions that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency obstetric care techniques, administration of injectables, HIV or TB testing, disease diagnosis and treatment, etc)
3) Small-scale water and water quality assurance activities
4) Small-scale rehabilitation of health or educational facilities

SUMMARY OF MONITORING AND REPORTING MEASURES

1. **Agreement Officer Responsibilities**: USAID procurement should include consideration of the implementing partner's ability to perform the mandatory environmental compliance requirements as envisioned under the "ATTACk TB" program. The Agreements Officer (AO) shall include required environmental compliance and reporting language into each implementation instrument, and ensure that appropriate resources (budget), qualified staff, equipment, and reporting procedures are dedicated to this portion of the project.

2. **AOR Responsibilities:** The AOR and/or on-site manager or their representative of the Program/Project will undertake field visits, as possible, and consultations with implementing partners to jointly assess the environmental impacts of ongoing activities, and associated mitigation and monitoring conditions
    a. The AOR, in consultation with the mission activity managers and implementing partners, Mission Environmental Officers (MEO), Regional Environmental Officers (REO), and/or Bureau Environmental Officers as appropriate, will actively monitor and evaluate whether environmental consequences unforeseen under activities covered by this PIEE arise during implementation, and modify or end activities as appropriate. If additional activities are added at the primary award level that are not described in this document, an amended PIEE must be prepared.

3. **Supplemental Initial Environmental Examinations**: In the event that any new proposed activity differs substantially from the type or nature of activities described here, or requires different or additional mitigation measures beyond those described, an amendment to this PIEE will be prepared and the SIEE will reference the amended PIEE.

4. **Environmental Mitigation and Monitoring Plans**: It is expected that subsequent funds will either be core or field support funds awarded at the bi-lateral or the core level. For each major core and country activity under this program, an Environmental Mitigation and Monitoring Plan (EMMP) will be completed by the implementing partner and submitted to the AOR, the Global Health Bureau Environmental Officer (BEO), and the Mission Environmental Officer or the Regional Environmental Officer for their approval.
    a. The EMMP must be completed prior to the start of activities,

b. Implementing partners will provide an Environmental Mitigation and Monitoring Plan (EMMP) for each for the primary award and a country specific EMMP.
c. This EMMP will be a detailed implementation plan for the conditions prescribed in this document.
d. The EMMP will be reviewed and approved by the GH BEO prior to the commencement of activities. The mitigation measures and monitoring criteria found in the EMMP should be incorporated into pertinent Performance Monitoring Plans and Annual Workplans.
e. The implementing partners' Project Work Plan will identify those activities outlined in this PIEE that have potential impacts to the environment and discuss plans for environmental management, mitigation approaches, and monitoring measures. Implementing partners will be required to include Environmental Compliance Monitoring in their project work plan and monitoring and evaluation plan
f. An evaluation of the implementation of the EMMP must be part of the mid, and end of project evaluations.
g. Operating Units will ensure that implementing partners have sufficient capacity to complete to implement mitigation and monitoring measures
h. The EMMP must be stored in project files

5. **Environmental Mitigation And Monitoring Report**: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.
   a. The environmental monitoring report should be submitted to the AOR by November 1 of each year.
   b. The EMMR will record the environmental mitigation and monitoring measures outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.
   c. Based on the process outlined in the Project Work Plan, the implementing partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.
   d. The EMMR must be stored in project files

6. **Sub-Agreements or Funds Transfers**: Any sub-agreements or fund transfers from the implementing partners to other organizations must incorporate provisions stipulating:
   a. Any sub agreement or funds transfer must include provisions that stipulate the implementation of conditions outlined in the SIEE for country level programs or an IEE for non-country level programs.
   b. the completion of an annual environmental mitigation and monitoring plan (EMMP) and report (EMMR) , and submission to the implementing partner.
   c. Any activity to be undertaken will be within the scope of the environmental determinations and recommendations of this PIEE. This includes assurance that any mitigating measures required for those activities be followed.

7. Implementation will in all cases adhere to applicable host country environmental laws and policies.

APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED:

Recommended By: _____ 4/12/13
Amy Piatek/AOR — Date

Approved By: _____ 4/12/13
Elizabeth Fox — Date
HIDN Front Office Director

Concurrence: _____ 4/9/13
Teresa Bernhard — Date
Global Health Bureau Environmental Officer

Approved: X

Disapproved: _____

Filename: P:\TB Team\ATTACk TB\ ATTACk TB_IEE_final.doc

PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)

"ATTACK TB" COOPERATIVE AGREEMENT

TABLE OF CONTENTS

ACRONYM LIST

AIDS	Acquired Immune Deficiency Syndrome
AO	Agreement Officer
AOTR	Agreement Officer's Technical Representative
BEO	Bureau Environmental Officer
CO	Contract/Grants Officer
EMMR	Environmental Mitigation and Monitoring Report
FAR	Federal Acquisition Regulation
FY	Fiscal Year
GH	Bureau for Global Health
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HMIS	Health Management Information Systems
HRH	Human Resources for Health
LOE	Level of Effort
MCH	Maternal Child Health
M&E	Monitoring and Evaluation
MEO	Mission Environmental Officer
MNCH	Maternal, Newborn, and Child Health
MOH	Ministry of Health
NGO	Non governmental Organization
OP	Operating Plan
OAA	Office of Acquisition and Assistance
PIEE	Programmatic Initial Environmental Examination
PMI	Presidential Malaria Initiative
PR	Program Results
PRH	Population, Reproductive Health
REO	Regional Environmental Officer
RFA	Request for Application
SIEE	Supplemental Initial Environmental Examination
SLMG	Sustainable Leadership, Management, and Governance
TB	Tuberculosis
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)
"Accelerating Tuberculosis Technical Assistance and Country Support" TB (ATTACk TB) Cooperative Agreement

PROGRAM/ACTIVITY DATA

IEE Number	**XXX**
Program/Project Number:	XXX
Country:	**Global**
Functional Objective:	**Investing in People**
Program Area:	**Health**
Program Elements:	**Tuberculosis**
Funding Period:	**FY 2014 – FY 2018**
Life of Activity Funding:	**$550 million**

SECTION 1: Background and Activity/Program Description

Purpose and Scope of PIEE

The purpose of this document is to review the overall activities undertaken by the "Accelerating Tuberculosis Technical Assistance and Country Support" TB (ATTACk TB) Cooperative Agreement and provide threshold determinations of environmental impact and conditions for mitigation.

Section 1 of this document covers the categories of activities undertaken by the program: Section 2 is background information on the geographical coverage; Section 3 provides an evaluation of the potential environmental impacts of the Program activities; Section 4 provides the threshold environmental determination for the Program activities; and describes mitigation measures required for implementation.

Overview of the "ATTACk TB" Project

Overview of USAID/GH Tuberculosis Program

The US Government (USG), led by USAID, developed a TB strategy (2009-2014) in response to the Lantos-Hyde Reauthorization Act of 2008. The Strategy, closely linked to the Stop TB Strategy and Global Health Initiative (GHI) principles, includes a number of targets to be reached by 2014: 50 percent reduction in TB prevalence and mortality (relative to 1990); 70 percent case detection rate; 85 percent treatment success rate; successful treatment of 2.6 million new smear positive TB patients; and diagnosis and treatment of 57,200 new MDR-TB cases.

In order to achieve these goals and targets, USAID will accelerate implementation of proven, cost-effective interventions designed to prevent the further spread of TB and drug-resistant TB, and to prevent deaths. USAID is committed to the following:

- Accelerate implementation of improved basic TB services and MDR-TB services to increase the number of patients receiving early and effective treatment; and

- Contribute to improvements in the health system as an integral part of achieving gains in TB control.

Description of Activities under ATTACk TB

The international community is committed to significantly reducing the burden of TB globally and preventing as many deaths from TB as possible. This will be accomplished by rapidly detecting all TB cases, especially in vulnerable populations, and ensuring prompt and appropriate treatment. USAID's proposed new TB project will contribute to these goals and targets by focusing on a number of key areas to support the prevention, care and treatment of TB in our highest priority countries. The project activities will include the following:

- Expanded access to care. Ensuring universal access to diagnosis and care for all persons suspected of having TB is a pillar of a successful TB program. Comprehensive universal access will include several overlapping components: active case finding, community-based TB interventions, laboratory network strengthening, and working with the private sector and prison populations. Even though most countries are able to detect the majority of their patients through passive case finding approaches, we will not be able to achieve our goals of reducing burden and death from TB without focused activities to find and treat the most vulnerable patients.

  Illustrative activities under this component may include the following:
  - Strengthening laboratory diagnosis of TB by developing national lab strategic plans, procurement of lab equipment and supplies, training of staff, external quality assurance.
  - Utilizing community volunteers and other members to find persons suspected of having TB and helping them adhere to treatment once diagnosed.
  - Sensitizing private sector about correct TB policies and procedures, and establishing links between private sector and national TB programs.

- Increased demand from communities for quality services. Communities need to be informed about TB and demand quality, accessible diagnostic and treatment services for all populations. We need to strengthen National TB Control Programs by building more demand from other sources at the country level through strategic partnerships. National Stop TB Partnerships, including communities, civil society, private sector and donors, should be developed to help increase demand for quality services.

  Illustrative activities under this component may include the following:
  - Developing and implementing behavior change strategies to ensure that people with symptoms of TB are accessing proper health care.
  - Strengthening capacity of civil society and other organizations to engage with the national program and MoH to ensure quality TB services.
  - Developing strong partnerships at the national and sub-national level with regular meetings and defined scopes of work

- Enhanced services for the prevention, detection and treatment of MDR-TB. The magnitude of the MDR-TB burden continues to outpace the scale-up of interventions. Focused attention

is needed on MDR-TB so that the gains made in TB over past decades are not wasted. Now is the time to ensure that quality and appropriate treatment models with palliative care and private sector involvement are developed and rolled-out in countries with the greatest burden of MDR-TB.

Illustrative activities under this component may include the following:

- Developing and rolling-out community-based models for the treatment of MDR-TB.
- Strengthening drug and logistics systems to ensure the availability of quality second-line anti-TB drugs and ancillary drugs for side effects.
- Roll-out of rapid diagnostic tests to diagnose MDR-TB.

- Expanded coverage of TB/HIV interventions. TB continues to be one of the greatest killers of persons with HIV. Therefore we must continue to expand activities to screen all HIV-infected persons for TB and test all confirmed TB patients for HIV. Rolling out innovative diagnostics to detect TB/HIV co-infected persons will be a major component contributing to this result.

  Illustrative activities under this component may include the following:
  - Strengthening the capacity of TB staff to test all confirmed persons with TB for HIV.
  - Linking HIV care and treatment services with TB services to ensure that all people living with HIV/AIDS are routinely screened for TB.
  - Setting up strong infection control systems in health facilities and communities to block transmission of TB.

- Strengthened logistics management and other health systems. A strong backbone of core systems must be in place to support the overall TB program, including a comprehensive and functional logistics plan for quality drugs and other commodities with no stock-outs; a monitoring and evaluation system for quality data; and strong institutional, health care worker and lay worker capacity building. Countries will need strong platforms to introduce and scale-up new diagnostics, drugs and vaccines as they become available.

  Illustrative activities under this component may include the following:
  - Creating or strengthening drug and commodity logistics management systems to ensure no stock-outs.
  - Data quality control systems and routine feedback mechanisms from central to peripheral levels on TB services.
  - Training workshops and routine supervision to ensure quality and timely knowledge of TB to all public and private health care staff.

- Expanded access to prevention services. Without interventions to prevent transmission, infection and disease, the global community will not be able to work towards a significant reduction in burden and disease and eventual elimination of TB. Although resources in countries limit the extent of preventive interventions, a number of activities can still take place including focused contact investigations; promotion of latent TB infection treatment in

targeted populations and communities; and expanded infection control in public and private sector facilities.

Illustrative activities under this component may include the following:

- Developing of contact tracing guidelines and mechanisms in countries focusing on the highest risk groups.
- Latent TB infection treatment campaigns for the highest risk groups.

SECTION 2: Country and Environmental Information

Locations Affected and Local Environmental Regulations

Location conditions

USAID's TB priority countries are located in all four of the USAID regions: Africa, Latin America and Caribbean, Europe and Eurasia, and Asia and Near East. All countries where USAID is working are implementing the WHO recommended Stop TB strategy. The status of country level policies on environmental reviews varies. Procedures for disposal of waste are often detailed in national policies for injection safety and in Standard Operating Procedures of laboratories, and are typically based on the WHO Manuals "Laboratory Biosafety Manual, 3rd edition, 2004" and the WHO Manual "Safe Management of Wastes from Health Care Settings".

Site specific environmental impacts will be evaluated on a project specific basis.

SECTION 3: Evaluation of Project/Program Issues

The activities under the "ATTACk TB" program are numerous and complex. Many Program activities do not have direct adverse environmental impacts such as information, education, communication, community mobilization, planning, management, leadership, sustainable, and outreach activities. However, in the course of implementation of these activities, implementing partners should take advantage of opportunities to incorporate and improve means of addressing environmental health issues (like hazardous and infectious waste management) into health service delivery systems.

Certain activities supported by the program will directly or indirectly affect the environment, or have the potential to do so. Based on the analysis conducted by the C/AOTR these activities could affect the environment in five ways:

1) Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies and reagents.
2) Actions that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency obstetric care techniques, administration of injectables, HIV or TB testing, disease diagnosis and treatment, etc)
3) Small-scale water and water quality assurance activities

4) Small-scale rehabilitation of health or educational facilities

The potential impact is discussed in detail below, and summarized in Annex A at the end of Section 4.

Each of these potential impacts is discussed in detail below, and summarized in Annex A at the end of this section.

1) Procurement, Storage, Management and Disposal of Public Health Commodities
This activity includes procurement of pharmaceutical drugs and vaccines, personal protective gear, laboratory and medical supplies, and basic medical equipment.

Pharmaceutical drugs are chemicals used for diagnosis, treatment (cure/mitigation), alteration, or prevention of disease, health condition, or structure/function of the human body. Pharmaceuticals including vaccines, chemotherapies, and radio active have specific storage time and temperature requirements, and may expire before they are able to be used, particularly in remote areas. Pharmaceutical waste may also accumulate due to inadequacies in stock management and distribution, and lack of a routine system of disposal.

The effects of pharmaceuticals in the environment are different from conventional pollutants. Drugs are designed to interact within the body at low concentrations to elicit specific biological effects in humans, and which may also cause biological responses in other organisms. There are many drug classes of concern, including antibiotics, antimicrobials, antidepressants, and estrogenic steroids. Their main pathway into the environment is through household use and excretion, and through the disposal of unused or expired pharmaceuticals.

Effects on aquatic life are a major concern in disposal of pharmaceuticals. A wide range of pharmaceuticals have been discovered in fresh and marine waters globally, and even in small quantities some of these compounds have the potential to cause harm to aquatic life. Exposure risks for aquatic organisms are much larger than those for humans, because aquatic organisms have continual (and multi-generational) exposures, explores to higher concentrations, and possible low-dose effects.

Traditional environmental toxicology focuses on acute effects of concentrated exposures rather than chronic effects of low level exposures. Measured toxicities of some tested pharmaceuticals have shown that acute effect of single substances in the aquatic environment is very unlikely. However, effects of pharmaceuticals may be subtle because they occur in the environment in low concentrations. Some tests with combinations of various pharmaceuticals have revealed stronger effects than expected from the effects measured singly. More research is need on combination effects and chronic studies are needed to assess the environmental risk of drug residues. Certainly pollution prevention (e.g., source elimination or minimization) is preferable to remediation or restoration to minimize both public cost and human/ecological exposure.

Antibiotics and undiluted disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Additional health risks related to disposal include burning pharmaceuticals and plastic medical supplies at low temperatures or in

open containers results in release of toxic pollutants into the air, and inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public as well as storage and management of chemotherapies or radio isotope therapies. In some countries scavenging in unprotected insecure landfills is a hazard.

Likewise, the mass procurement and distribution of commodities such as medicines and medical equipment has the potential to contribute to solid waste. Many countries do not have facilities to manage solid wastes other than uncontrolled burns. Plastics and other inorganic materials pose solid waste management issues for some countries.

References for this section include:
http://www.who.int/water_sanitation_health/medicalwaste/pharmaceuticals/en/
Pharmaceuticals In The Environment: Sources, Fate, Effects And Risks (2nd ed). 2004. Klaus Kümmerer, ed (online version).

2) Activities that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste or in techniques that have a direct or indirect environmental impact.

Small-Scale healthcare initiatives, such as rural health posts or clinics, mobile clinics, urban clinics and small hospitals, and community health workers and training in health workers provide important and often critical healthcare services to individuals and communities that would otherwise have little or no access to such services. These health workers working in these underserved contexts are the front line of defense against epidemics such as HIV, TB and a key component of any comprehensive health development program. The medical and health services they provide improve newborn, child and maternal health, prevent disease, cure debilitating illnesses, and alleviate the suffering of the dying.

However, improper training, handling, storage and disposal of the waste generated in these facilities or activities can spread disease through several mechanisms. Transmission of disease through infectious waste is the greatest and most immediate threat from healthcare waste. If waste is not treated in a way that destroys the pathogenic organisms, dangerous quantities of microscopic disease-causing agents—viruses, bacteria, parasites or fungi—will be present in the waste. These agents can enter the body through punctures and other breaks in the skin, mucous membranes in the mouth, by being inhaled into the lungs, being swallowed, or being transmitted by a vector organism. Those who come in direct contact with the waste are at greatest risk. Examples include healthcare workers, cleaning staff, patients, visitors, waste collectors, disposal site staff, waste pickers, substance abusers and those who knowingly or unknowingly use "recycled" contaminated syringes and needles. Although sharps pose an inherent physical hazard of cuts and punctures, the much greater threat comes from sharps that are also infectious waste. Healthcare workers, waste handlers, waste-pickers, substance abusers and others who handle sharps have become infected with HIV and/or hepatitis B and C viruses through pricks or reuse of syringes/needles.

Contamination of water supply from untreated healthcare waste can also have devastating effects. If infectious stools or bodily fluids are not treated before being disposed of, they can

create and extend epidemics. The absence of proper sterilization procedures is believed to have increased the severity and size of cholera epidemics in Africa during the last decade.

Healthcare wastes generally fall into three categories in terms of public health risk and recommended methods of disposal:

- ***General*** healthcare waste, similar or identical to domestic waste, including materials such as packaging or unwanted paper. This waste is generally harmless and needs no special handling; 75–90% of waste generated by healthcare facilities falls into this category, and it can be burned or taken to the landfill without any additional treatment.
- ***Hazardous*** healthcare wastes including infectious waste (except sharps and waste from patients with highly infectious diseases), small quantities of chemicals and pharmaceuticals, and non-recyclable pressurized containers. All blood and body fluids are potentially infectious.
- ***Highly hazardous*** healthcare wastes, which should be given special attention, includes sharps (especially hypodermic needles), highly infectious non-sharp waste such as laboratory supplies, highly infectious physiological fluids, pathological and anatomical waste, stools from cholera patients, and sputum and blood of patients with highly infectious diseases such as TB and HIV. They also include large quantities of expired or unwanted pharmaceuticals and hazardous chemicals, as well as all radioactive or genotoxic wastes.

If a project's training activities for professional health workers or community health workers involve techniques that would generate and require disposal of hazardous or highly hazardous waste, the Implementing Partners shall be required to include training in or ensure that the training curriculum covers best management practices concerning the proper handling, use, and disposal of medical waste, including blood, sputum, and sharps.

As appropriate, the implementing partners will work with facility, local, regional and/or national officials, to implement and apply appropriate best management practices which incorporate appropriate health and safety measures and environmental safeguards, including proper disposal of medical waste in accordance with international norms as spelled out by the WHO in "WHO's Safe Management of Wastes from Healthcare Activities." National policies and laws should also be considered, though most countries follow WHO Guidelines.

References for this section include:
http://www.who.int/water_sanitation_health/medicalwaste/167to180.pdf
http://www.bchealthguide.org/healthfiles/hfile29.stm
Safe management of wastes from health-care activities, edited by A. Prüss, E. Giroult and P. Rushbrook. Geneva, WHO, 1999,
http://www.who.int/water_sanitation_health/Environmental_sanit/MHCWHanbook.htm. English
EGSSAA Chapter 8. "Healthcare Waste: Generation, Handling, Treatment and Disposal" (http://www.encapafrica.org/EGSSAA/Word_English/medwaste.doc) for additional guidance on proper handling and disposal of medical waste.

3) Small-Scale Water and Sanitation Activities

All small-scale water and sanitation activities such as the digging of wells or creation of latrines should be conducted with good design and implementation practices and with consideration of protecting human health and the surrounding environment.

Some potential environmental impacts are possible with these interventions, and will depend on the local circumstances, including:

Water Supply

- Improper siting of facilities that damages or destroys natural ecosystems (within wetlands, protected areas, or other sensitive habitats, etc.)
- Depletion or degradation of local or downstream freshwater resources (surface and groundwater)
- Creation of stagnant (standing) water near water points that could create breeding opportunities for water-borne disease vectors
- Natural or human-caused biological or chemical contamination of water sources (surface and groundwater), causing increased human health risks, including:
- High arsenic or other mineral/chemical levels
- Poor management of water points and/or poor design of pipes leading to leakage and contamination of water with fecal matter, solid waste, etc.

Sanitation

- Increased human health risks from contamination of surface water, groundwater, soil, and food by human waste and disease pathogens
- Degradation of surface and groundwater quality and land habitats due to inappropriate siting or construction of latrines or wastewater collection systems, or release of human waste from sanitation facilities
- Defecation around locked or unusable latrines or other sanitation facilities, potentially contaminating surface water and/or shallow groundwater sources, adversely affecting both human and ecosystem health
- Damage to the aesthetics of the sanitation facility site (visual, smell, etc.)

Activity/ Technology	Potential Impacts *The activity or technology may. . .*
General	
Site selection (P&D)	○ Damage sensitive ecosystems or endangered species.
Construction of buildings and structures (C)	○ Damage sensitive ecosystems or endangered species. ○ Cause erosion and sedimentation.
Soakways and drains	○ Cause erosion. ○ Alter the natural flow of rainwater runoff. ○ Create pools of stagnant water.
Water Supply	

Activity/ Technology	Potential Impacts *The activity or technology may. . .*
Facilities	
Hand-dug wells, seasonal ponds, improved springs, ground-level catchment and similar structures	○ Contaminate water with human pathogens. ○ Contaminate water with animal manure. ○ Create pools of stagnant water. ○ Exhaust water supply (not applicable to improved springs or hand-dug wells).
Wells	○ Provide water contaminated with nutrients and bacteria from animal waste. ○ Create pools of stagnant water. ○ Change groundwater flow. ○ Create saltwater intrusions. ○ Deplete aquifer (groundwater). ○ Cause land subsidence (impact from many wells).
	○
Sanitation and Treatment	
Pit latrine	○ Increase transmission of vector-borne diseases. ○ Contaminate groundwater supply with pathogens. ○ Contaminate water supplies, damage water quality and/or transmit disease at other locations if waste is not properly handled and treated during or after servicing. ○ Cause injury to people or animals.
Composting toilets	○ Increase transmission of vector-borne diseases. ○ Contaminate groundwater supply with pathogens. ○ Cause disease transmission to field workers and consumers of agricultural products.
Dry toilets	○ Increase transmission of vector-borne diseases. ○ Cause disease transmission to field workers and consumers of agricultural products.
Septic tanks	○ Contaminate groundwater supply with pathogens. ○ Contaminate surface water supplies with nutrients, biological oxygen demand (BOD), suspended solids (SS) and pathogens. (Septic tank effluent generally contains relatively high concentrations of pathogens, BOD, and SS). ○ Contaminate water supplies, damage water quality and/or transmit disease at other locations if waste is not properly handled and treated during or after servicing.
Upflow anaerobic filters	○ Damage ecosystems and degrade surface water quality. Sludge has high concentrations of nutrients, BOD, and solids. ○ Cause disease transmission to field workers and consumers of agricultural products (Sludge may still contain pathogens).

Reference for this section is
Environmental Guidelines for Small-Scale Activities in Africa
http://www.encapafrica.org/EGSSAA/Word_English/watsan.doc

4) Small-scale Rehabilitation of Health Facilities

Small-scale rehabilitation of health facilities should be conducted considering minimum impact to the physical and social environment surrounding the health facilities, use of appropriate and non-hazardous materials, and appropriate disposal of old or unused materials in the rehabilitation process. Construction of health facilities is beyond the scope of this IEE.

Some potential environmental impacts are possible with these interventions, and will depend on the local circumstances, including:

- Contamination of groundwater and surface water supplies through improper disposal of human and other biological wastes during the rehabilitation period
- Contamination of ground and surface water supplies through improper disposal or handling of toxic materials used in rehabilitation (e.g., solvents, paints, vehicle maintenance fluids (oil, coolant), and diesel fuel)
- Adverse social impacts due to displacement of local inhabitants, influx of outside workers, inequitable distribution of economic benefits of rehabilitation, etc.
- Damage to aesthetics of site/area
- Improper extraction of rehabilitation materials such as wood, stone, gravel, or clay that damages terrestrial ecosystems (e.g., wood may come from relatively intact or natural forests)
- Use of toxic materials during rehabilitation, such as lead paint.

Reference for this section is:
Small Scale Construction chapter of the USAID Environmental Guidelines for Small-Scale Activities in Africa, as the guidelines are appropriate for rehabilitation activities.
http://www.encapafrica.org/EGSSAA/Word_English/construction.doc.

Section Table 3a:
Activities Potential Negative Environmental Impacts

Investing in People: Health Program Areas	Procurement, Storage, Management and Disposal of Public Health Commodities	Direct or Indirect generation, and need for disposal of hazardous and highly hazardous medical waste (as defined in Section 3 of this IEE)	Small-Scale Water and Sanitation	Small-Scale Rehabilitation of health facilities
"ATTACk TB" Program	Such as: Laboratory reagents and supplies Micronutrient supplements Antibiotics Vaccines Other pharmaceuticals Contraceptives/condoms HIV test kits ARVs Nutritional supplements	Generation of sharps Generation of hazardous and highly hazardous medical waste, including blood. Generation of sputum and other waste	Construct or rehabilitate latrines at individual households, schools, communities, or health facilities which impact special habitats, causes impacts to existing water supplies. Construct or rehabilitate hand washing stations, laundry facilities, public showers, latrines, and wastewater and drainage at health facilities, training centers or	Rehabilitate hospitals, clinics, labs or training centers/schools generates hazardous waste such as lead and asbestos,

Investing in People: Health Program Areas	Procurement, Storage, Management and Disposal of Public Health Commodities	Direct or Indirect generation, and need for disposal of hazardous and highly hazardous medical waste (as defined in Section 3 of this IEE)	Small-Scale Water and Sanitation	Small-Scale Rehabilitation of health facilities
	TB drugs NTD drugs Antimalarial drugs Packing materials for products		laboratories.	

Section 3c: CONDITIONS FOR IMPLEMENTATION OF CATEGORIES OF "ATTACk TB" ACTIVITIES	
Key Elements of Program/Activities	Mitigation Conditions and/or Proactive Interventions
"ATTACk TB" Activities that involve: Procurement, Storage, Management and Disposal of Public Health Commodities	Conditions: Consignees for all pharmaceutical drugs and other public health commodities procured under this funding will be advised to store the product according to the information provided on the manufacturer's Materials Safety Data Sheet (MSDS). These are supplied by the manufacturer, and can also be found on the internet by using the active ingredient and MSDS as search terms. If disposal of any of these pharmaceutical drugs is required, due to expiration date or any other reason, the consignee will be advised that the preferred method of disposal is to return to the manufacturer. If this is not possible (for example if the expired or spoiled pharmaceuticals are considered hazardous and as such, if transferred across frontiers, become regulated and subject to the Basel Convention an the transfrontier shipment of hazardous wastes) then follow the guidelines in the WHO document *Guidelines for Safe Disposal of Unwanted Pharmaceuticals During and After Emergencies*, found at www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf. At the request of the Mission, subject to available funding, the implementing partner will make all reasonable attempts to facilitate the disposal of expired drugs under this activity to mitigate the impact of medical waste. Implementing partners will work with the host country as appropriate on aspects of essential medicine supply chain management, including estimating demand, distribution, and storage issues of time and temperature. Commodities that, during use, become hazardous or highly hazardous waste are managed under the conditions in the following section "Activities that involve the collection, safe handling and disposal of hazardous and highly hazardous medical waste" Packaging and disposal of all other public health commodities will be treated using the guidelines provided in Environmental Guidelines for Small-Scale Activities in Africa (EGSSAA) 2nd Edition, Chapter 15: Solid Waste (http://www.encapafrica.org/EGSSAA/Word_English/solidwaste.doc)
"ATTACk TB" Activities that involve:	Conditions:

Generation, storage, handling and disposal of hazardous or highly hazardous medical waste (as defined in Section 3 of this PIEE)	For activities entailing training of professional and para-professional health workers in methods that result in the generation and disposal of hazardous or highly hazardous medical waste, including blood or sputum testing, basic and emergency obstetric care techniques, and laboratory support, the implementing partner will include training in or ensure the training curriculum covers procedures to properly handle, label, treat, store, transport and properly dispose of blood, sharps and other medical waste, as applicable, and follows either WHO guidelines, in Environmental Guidelines for Small Scale Activities in Africa Chapter 8, "Healthcare Waste: Generation, Handling, Treatment and Disposal," and is consistent with national policy and procedure for medical waste. For all USAID-supported activities entailing service delivery, including blood testing and laboratory support, COTRs will work with its implementing partners to assure, to the extent possible, that the medical facilities and operations involved have adequate procedures and capacities in place to properly handle, label, treat, store, transport and properly dispose of blood, sharps and other medical waste. This includes annual completion of the Healthcare Waste Management Minimum Program Checklist and Action Plan (Annex 1) for all facilities where implementing partners are directly providing services. Completion of this checklist should be included in the annual workplan. Healthcare waste is most appropriately identified by color-coding bags and containers. In addition, the following are well-established practices in the safe handling, storage, and transportation of health-care waste: • Sharps should be collected together (regardless of whether or not they are contaminated), and stored in puncture-proof, impermeable, and tamper-proof containers with fitted covers. If plastic or metal containers are unavailable, then containers made of dense cardboard are recommended. • Highly infectious waste should be immediately sterilized by autoclaving. • On-site collection of waste should be handled at frequent intervals to avoid accumulation, and an adequate supply of fresh collection bags/containers should be available for replacement. • Waste should be stored in an accessible room with adequate space and protection from sunlight. • In any area that produces hazardous waste - hospital wards, treatment rooms, operating theatres, laboratories, etc., three bins plus a separate sharps container will be needed to separate these types of waste. (If hazardous and highly hazardous waste will be disposed of in the same manner, they should not be collected separately.) • For hazardous waste and highly hazardous waste the use of double packaging, e.g. a plastic bag inside a holder or container is recommended for ease of cleaning. • To make separate collection possible, hospital personnel at all levels, especially nurses, support staff, and cleaners, should be trained to sort the waste they produce.

	See EGSSAA Chapter 8, "Healthcare Waste: Generation, Handling, Treatment and Disposal" (http://www.encapafrica.org/EGSSAA/Word_English/medwaste.doc) for additional condtitions on proper handling and disposal of medical waste. Other important references to consult are "WHO's Safe Management of Wastes from Healthcare Activities" http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/
"ATTACk TB" Activities that involve: Small-Scale Water and Sanitation	All water supply and water quality assurance activities should be conducted in a manner consistent with the good design and implementation practices described in Environmental Guidelines for Small Scale Activities in Africa, Chapter 16: Water Supply and Sanitation (http://www.encapafrica.org/EGSSAA/Word_English/watsan.doc). For example, microbiological contamination of improved wells can often be prevented by aquifer protection measures and proper well design and maintenance. Separate wells should be used for human consumption and animal watering, or an overflow trough should be constructed well away from the protected water source. Another useful reference to consult for good water quality assurance and sanitation design and implementation principles is the document, "Guidelines for the Development of Small Scale Rural Water Supply and Sanitation Projects in Ethiopia," by Catholic Relief Services and USAID, July 31, 2003 (crs.org/publications/pdf/Wat0604_e/pdf). Water quality assurance and water testing is essential for determining that the water from a constructed water source is safe to drink and to determine a baseline so that any future degradation can be detected. Among the water quality tests which must be performed are tests for the presence of arsenic, nitrates, nitrites, and coliform bacteria, plus tests for any additional parameters required by the host government. Any USAID-supported activity engaged in the provision of potable water must adhere to Guidance Cable State 98 108651, which requires arsenic testing, and guidance is provided by USAID's Economic Growth, Agriculture and Trade Bureau in the document "Guidelines for Determining the Arsenic Content of Ground Water in USAID-Sponsored Well Programs in Sub-Saharan Africa" (www.usaid.gov/our_work/environment/compliance/ane/tool_shed/arsenic_guidelines.doc). Simple and cost-effective sample kits for *E. coli* and fecal coliforms are available through a variety of manufacturers (e.g., 3M Petrifilm, Idexx Colilert or Coliscan Easygel). Initial water quality testing is the responsibility of the program to assure, but when feasible the program should also set in place capacities and responsibilities to provide reasonable assurance that ongoing water quality monitoring occur. The standards for initial and ongoing testing -- types of contaminants for which testing should be conducted, testing methods, testing frequency, and issues such as public access to results -- should follow any applicable USAID guidance, as well as host country laws, regulations and policies. Furthermore, a response protocol should be established in the event that water quality testing detects contamination.

	An illustrative list of environmentally sound principles for water and sanitation activities includes: • Community mobilization to ensure sustainability of the physical infrastructure • Water sources should be located upgrade from potential sources of pollution, including latrines or toilets. • Water sources are protection from both human and animal contamination. • Ensure latrines are sited far away from shallow wells, cisterns, spring sources and boreholes. Latrine pits will be dug in the unsaturated zone above the water table, and latrine pits are protected against flooding and overflow due to intense rainfall. Establish and train community water and sanitation committees to manage, repair and maintain all water points and the watersheds immediately surrounding the water points, including watering of livestock, and to provide hygiene education to participating communities. • Training in sanitation and hygiene for health workers, community health and water committees, community area based development groups, and/or municipal water board members. • Ensure community mobilization and public awareness of human health risks associated with water-borne disease vectors. • Relevant local community rules and best practices and procedures of promotion of better environmental health are developed and adhered to. Verification through site visits and photos should be done to assure practices are in accordance with local community rules and "best practices" through community monitoring tools and municipal water board's evaluation system. • Take measures to minimize standing water. • Where water supplies for drinking or washing patients or laundry are upgraded or provided, measures will be taken to ensure that drainage from laundry and bathing facilities does not affect the water supply nor pose threats for transmittal of infectious diseases. • Provision of potable water supplies and/or latrines will follow host country or WHO standards concerning the appropriate separation of wells and latrines and measures to avoid contamination of water sources.
"ATTACk TB" Activities that involve: Small-scale rehabilitation of health posts, clinics, laboratories, hospitals or	Conditions: For the rehabilitation of existing facilities, these activities shall be conducted following principles for environmentally sound rehabilitation, as provided in the Small Scale Construction chapter of the USAID Environmental Guidelines for Small-Scale Activities in Africa, as the guidelines are appropriate for rehabilitation activities (http://www.encapafrica.org/EGSSAA/Word_English/construction.doc)

training centers Notes: If rehabilitation includes water supply and/or sanitation, see also "Water Supply and Sanitation" section above.	For the construction of any facilities in which the total surface area disturbed exceeds 10,000 square feet (1,000 square meters), the program shall conduct a supplemental environmental review according to guidance in Annex G (www.encapafrica.org/EPTM/AnnexG_EPTM_Mar2005b.pdf) of the Africa Bureau Environmental Procedures Training Manual (EPTM) (http://www.encapafrica.org/eptm.htm). Construction will not begin until such a review is completed and approved by the Mission Environmental Officer and Bureau Environmental Officer. An illustrative list of environmentally sound construction principles includes: • As part of the selection/screening for potential sites, the implementer will perform Environmental Due Diligence for proposed sites to ensure that the site is free of environmental concerns including those from off-site sources. • The majority of materials used will be of local origin and will not contain any hazardous materials (e.g., asbestos or lead). • Investigate and use less toxic alternative products. • Excess materials will be recycled wherever possible and disposal of unusable material will be done in an environmentally sound manner. • Rehabilitation/construction activities will not require the use of any heavy equipment, or in the unlikely event it does, proper safeguards will be taken to prevent destruction of vegetation and soil erosion (e.g., runoff from the site which may be high in suspended solids or which may cause disruption to local drainage patterns). • No lead-based paint will be used. When (lead-free) paint is used, it will be stored properly so as to avoid accidental spills or consumption by children; empty cans will be disposed of in a environmentally safe manner away from areas where contamination of water sources might occur; and the empty cans will be broken or punctured so that they cannot be reused as drinking or food containers. • For any TB laboratories renovated under this program, provide room(s) with negative pressure to mitigate any cross contamination potential, and provide owner/operators of the renovated facility with written guidelines for proper maintenance of the facility.

SECTION 4: Recommended Determinations and Conditions for Implementation

4a. Determination

Based on the analysis presented in Section 3, this PIEE recommends threshold decisions and conditions for implementation of the "ATTACk TB" program activities. USAID/GH acknowledges that the environmental screening and review procedures described here do not substitute for the recipient country's own environmental laws and policies.

The overall threshold determination for the "ATTACk TB" program is a **Negative Determination, with conditions**. However, various classes of activities have been grouped into two different determinations. The conditions for implementation of the activities follow in Table 4a. If the "ATTACk TB" program activities are similar to the activities in Section 3, the conditions established must be implemented as part of the program design and implementation.

Activities presented in Section 4. Table 4a of this document

Pursuant to 22 CFR216.3(a)(2)(iii), a **Negative Determination with Conditions** is recommended for any "ATTACk TB" Program activities that have potential for negative impact on the environment in the following categories, as presented in Table 2 in Section 3 of this document:

1. Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies and reagents.
2. Training professional and paraprofessional health care workers in methods that result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency obstetric care techniques, administration of injectables, HIV or TB testing, malaria diagnosis, etc)
3. Small-scale water and sanitation activities (such as covered wells and latrines)
4. Small-scale rehabilitation of health or educational facilities

Table 4a: Determinations for Activities Executed Under This "ATTACk TB" Program

Activities	**Recommended Threshold Determination and 22 CFR Part 216 citation**
Activities not involving any biophysical interventions : ○ education, training, technical assistance related to Program Name e.g. education and life skills training for OVCs, dissemination of HIV/ AIDS care message ○ document and information transfers e.g. dissemination of Program Name care message and best practices materials ○ controlled experimentation exclusively for the purpose of research and field evaluation and carefully monitored; ○ analyses, studies, academic or research workshops and meetings ○ Programs involving nutrition, health care, or family planning services except to the extent designed to include activities directly affecting the environment (such as construction of facilities, water supply systems, waste water treatment, etc.) ○ Studies, projects or programs intended to develop the capability of recipient countries and organizations to engage in development planning	Categorical Exclusion, per ○ 22 CFR 216.2 (c)(2)(i), for all activities consisting of education, technical assistance or training programs, except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.); ○ 216.2 (c)(2)(iii) for analyses, studies, academic or research workshops and meetings; ○ 216.2 (c)(2)(v) for document and information transfers; ○ 216.2(c)(2)(viii) for programs involving nutrition, health care or population and family planning services except to the extent designed to include activities directly affecting the environment (such as construction of facilities, water supply systems, waste water treatment, and treatment of water in the households); ○ 216.2(c)(2)(xiv) for studies, projects or programs intended to develop the capability of recipient countries to engage in development planning, expect to the extent designed to result in activities directly affecting the environment (such as construction of facilities, etc.)
Support to the procurement, storage and disposal of public health commodities e.g. ARV's, and treatment for opportunistic infections, condoms, nutritional supplements, etc.	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving procurement, storage, management and disposal of public health commodities
Activities involving treatment in health centers, blood testing and potential generation of hazardous medical waste	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for all the health activities likely to involve blood testing, and have potential generation of hazardous health waste.
Provision of Equipment and supplies to health and education facilities	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving procurement, storage, management and disposal of public health commodities

Small-scale construction/ rehabilitation of health facilities and education centers	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities potentially involving construction and renovation activities.
Program involving agricultural activities to improve nutrition	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) potentially involving agricultural activities to for small scale agriculture.
Use of pesticides in the Indoor residual spraying (IRS) and Insecticide-treated bed nets (ITNs);	A positive determination has been given for IRS and supplemental Environmental Assessments are required for each country engaging in IRS activities. A negative determination with conditions is recommended for activities related to ITNs pursuant to 22 CFR 216.3(a)(2)(iii) for any use of Pesticides under the IRS as part of PMI and for all supply and distribution of LLITN
Water and sanitation activities	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for household water treatment and safe storage

Monitoring Conditions

1. **Agreement Officer Responsibilities**: USAID procurement should include consideration of the implementing partner's ability to perform the mandatory environmental compliance requirements as envisioned under the "ATTACk TB" Program. The Agreements Officer (AO) shall include required environmental compliance and reporting language into each implementation instrument, and ensure that appropriate resources (budget), qualified staff, equipment, and reporting procedures are dedicated to this portion of the project.

2. **AOR Responsibilities:** The AOR and/or on-site manager or their representative of the "ATTACk TB" Program will undertake field visits, as possible, and consultations with implementing partners to jointly assess the environmental impacts of ongoing activities, and associated mitigation and monitoring conditions
    a. The AOR, in consultation with the mission activity managers and implementing partners, Mission Environmental Officers (MEO), Regional Environmental Officers (REO), and/or Bureau Environmental Officers as appropriate, will actively monitor and evaluate whether environmental consequences unforeseen under activities covered by this PIEE arise during implementation, and modify or end activities as appropriate. If additional activities are added at the primary award level that are not described in this document, an amended PIEE must be prepared.

3. **Supplemental Initial Environmental Examinations**: In the event that any new proposed activity differs substantially from the type or nature of activities described here, or requires different or additional mitigation measures beyond those described, an amendment to this PIEE will be prepared and the SIEE will reference the amended PIEE.

4. **Environmental Mitigation and Monitoring Plans**: It is expected that subsequent funds will either be core or field support funds awarded at the bi-lateral or the core level. For each major core and country activity under this program, an Environmental Mitigation and Monitoring Plan (EMMP) will be completed by the implementing partner and submitted to the AOR, the Global Health Bureau Environmental Officer (BEO), and the Mission Environmental Officer or the Regional Environmental Officer for their approval.
    a. The EMMP must be completed prior to the start of activities,
    b. Implementing partners will provide an Environmental Mitigation and Monitoring Plan (EMMP) for each for the primary award and a country specific EMMP.
    c. This EMMP will be a detailed implementation plan for the conditions prescribed in this document.
    d. The EMMP will be reviewed and approved by the GH BEO prior to the commencement of activities. The mitigation measures and monitoring criteria found in the EMMP should be incorporated into pertinent Performance Monitoring Plans and Annual Workplans.
    e. The implementing partners' Project Work Plan will identify those activities outlined in this PIEE that have potential impacts to the environment and discuss plans for environmental management, mitigation approaches, and monitoring measures. Implementing partners will be required to include Environmental

Compliance Monitoring in their project work plan and monitoring and evaluation plan

f. An evaluation of the implementation of the EMMP must be part of the mid, and end of project evaluations.
g. Operating Units will ensure that implementing partners have sufficient capacity to complete to implement mitigation and monitoring measures
h. The EMMP must be stored in project files

5. **Environmental Mitigation And Monitoring Report**: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.
   a. The environmental monitoring report should be submitted to the AOR by November 1 of each year.
   b. The EMMR will record the environmental mitigation and monitoring measures outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.
   c. Based on the process outlined in the Project Work Plan, the implementing partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.
   d. The EMMR must be stored in project files

6. **Sub-Agreements or Funds Transfers**: Any sub-agreements or fund transfers from the implementing partners to other organizations must incorporate provisions stipulating:
   a. Any sub agreement or funds transfer must include provisions that stipulate the implementation of an EMMP
   b. the completion of an annual environmental monitoring plan and report, and
   c. Any activity to be undertaken will be within the scope of the environmental determinations and recommendations of this PIEE. This includes assurance that any mitigating measures required for those activities be followed.

7. Implementation will in all cases adhere to applicable host country environmental laws and policies.

4b. The Environmental Mitigation And Monitoring Plan And Report (EMMP/R)

Operating Units for Associate Awards will use an annual Environmental Mitigation and Monitoring Plan (EMMP) to ensure programmatic compliance with 22 CFR 216. An EMMR will be completed annually so that the conditions specified and met in this PIEE and subsequent SIEE are shown to have been carried out under OEPA. The EMMPs and EMMRs are reviewed and approved by the mission activity manager and the Mission Environmental Officer.

The EMMP is described in table A below and should be filled out in detail in the prior to the start of activities. The specific mitigation measures identified in the EMMP must be integrated into the annual work-plan for the project and activities.

The Reporting Form, EMMR is below in Table B. It should be submitted in the annual performance report.

"ATTACk TB" **Table A: Environmental Mitigation and Monitoring Plan (EMMP)**

Category of Activity from Section 5 of "ATTACk TB" IEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 3 of "ATTACk TB" IEE)	Description of Specific Mitigation Measures for these activities as required in Section 5 of "ATTACk TB" IEE	Who is responsible for monitoring	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
1. Education, technical assistance, training etc.	No environmental impacts anticipated as a result of these activities	Education, technical assistance and training about activities that inherently affect the environment include discussion prevention and mitigation of potential negative environmental effects.	Activity manager, AOR or on-site designee	Discussion of environmental impact included in education, technical assistance, training and other materials	Review of materials	Annual
2. Public Health Commodities			AOR, on sight designee	Quality control check	Site review	Annual
3. Medical waste		Completion of the Healthcare Waste Management Minimum Program Checklist and Action Plan (Annex 1)	AOR, on sight designee	Quality control check	Site review	Annual
4. Small-scale construction		Review of project plan for compliance with conditions prior to implementation Random site visits to evaluate	AOR, on sight designee	Quality control check	Site review	Annual

Category of Activity from Section 5 of "ATTACk TB" IEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 3 of "ATTACk TB" IEE)	Description of Specific Mitigation Measures for these activities as required in Section 5 of "ATTACk TB" IEE	Who is responsible for monitoring	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
		implantation of conditions as set out in the environmental mitigation plan				
5. Small-scale water and sanitation			AOR, on sight designee	Quality control check	Site review	Annual

HUMAN RESOURCES FOR HEALTH AND QUALITY SERVICES (NTD)
Table B: Environmental Mitigation and Monitoring Report (EMMR)

List each Mitigation Measure from column 3 in the EMMR Mitigation Plan (EMMR Part 1 of 2)	Status of Mitigative Measures	List any outstanding issues relating to required conditions	Remarks

Annex 1. Healthcare Waste Management Minimal Program Checklist and Action Plan to be Included in Training Materials/Programs

Elements/Actions	*In Place?*	*Next Steps to be done*		
		What	*By Whom*	*By When*
Written plans and procedures				
1. *A written waste management plan* Describing all the practices for handling, storing, treating, and disposing of hazardous and non-hazardous waste, as well as types of worker training required.				
2. *Internal rules for generation, handling, storage, treatment, and disposal of healthcare waste.*				
3. *Clearly assigned staff responsibilities that cover all steps in the waste management process.*				
4. *Staff waste handling training curricula or a list of topics covered.*				
5. *Waste minimization, reuse, and recycling procedures.*				
Staff Training, Practices, and Protection*				
6. *Staff trained in safe handling, storage, treatment, and disposal.* Does staff exhibit good hygiene, safe sharps handling, proper use of protective clothing, proper packaging and labeling of waste, and safe storage of waste? Does staff know the correct responses for spills, injury, and exposure?				
7. *Protective clothing available for workers who move and treat collected infections waste* such as surgical masks and gloves, aprons, and boots.				

8. *Good hygiene practices*. Are soap and, ideally, warm water readily available workers to use and can workers be observed regularly washing.				
9. *Workers vaccinated* for against viral hepatitis B, tetanus infections, and other endemic infections for which vaccines are available.				
Handling and Storage Practices				
10. *Temporary storage containers and designated storage locations.* *11.* Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes?				
12. *Minimization, reuse, and recycling procedures.* • Does the facility have good inventory practices for chemicals and pharmaceuticals, i.e.: ○ use the oldest batch first; ○ open new containers only after the last one is empty; procedures to prevent products from being thrown out during routine cleaning; and				
13. *A waste segregation system.* • Is general waste separated from infectious/hazardous waste? • Is sharp waste (needles, broken glass, etc.) collected in separate puncture-proof containers? • Are other levels of segregation being applied e.g. hazardous liquids, chemicals and pharmaceuticals, PVC plastic, and materials containing heavy metals ((these are valuable, but less essential)?				
14. *Temporary storage containers and designated storage locations.* • Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes? • Is the location distant from patients or food?				
Treatment Practices				

15. Frequent removal and treatment of waste • Are wastes collected daily? • Are wastes treated with a frequency appropriate to the climate and season? ○ Warm season in warm climates within **24 hrs** ○ In the cool season in warm climates within **48 hrs** ○ In the warm season in temperate climates within **48 hrs**				
16. *Treatment mechanisms for hazardous and highly hazardous waste*. (The most important function of treatment is disinfection). • Are wastes being burned in the open air, in a drum or brick incinerator, or a single-chamber incinerator? • If not are they being buried safely (in a pit with an impermeable plastic or clay lining)? • Is the final disposal site (usually a pit) surrounded by fencing or other materials and in view of the facility to prevent accidental injury or scavenging of syringes and other medical supplies?				
17. If the waste is transported off-site, are precautions taken to ensure that it is transported and disposed of safely?				

*** Training should be conducted before starting activity implementation**

For more detailed checklists and guidance consult: *Safe management of wastes from health-care activities*, edited by A. Prüss, E. Giroult and P. Rushbrook. Geneva, WHO, 1999, http://www.who.int/water_sanitation_health/Environmental_sanit/MHCWHanbook.htm. English

Annex 2. Disposal and Treatment Methods Suitable for Different Categories of Healthcare Waste to be Included in Training Materials/Programs (EXAMPLE)

Method	Infectious Waste (laboratory cultures, excreta)	Sharps (needles, blades, broken glass)	Pharmaceutical Waste (expired pharmaceuticals, boxes contaminated by pharmaceuticals)	Chemical Waste (laboratory reagents, solvents)	Radioactive Waste (unused liquids from laboratory research)
Rotary kiln	✓	✓	✓	✓	✓[2]
Pyrolytic incinerator	✓	✓	✓[1]	✓[1]	✓[2]
Single-chamber incinerator	✓	✓			✓[2]
Drum or brick incinerator	✓	✓			
Chemical disinfection	✓	✓			
Wet thermal treatment	✓	✓			
Microwave irradiation	✓	✓			
Encapsulation		✓	✓	✓[1]	
Safe burial on hospital premises	✓	✓	✓[1]	✓[1]	
Sanitary landfill	✓		✓[1]		
Discharge to sewer			✓[1]		Low-level liquid waste
Inertization			✓		
Other			Return to supplier	Return to supplier	Decay by storage

1: Small quantities only
2: Low-level infectious waste