USAID | PHILIPPINES
FROM THE AMERICAN PEOPLE

Issue Date: August 7, 2017
Deadline for Questions: August 16, 2017, 1:00 P.M. Manila time
Closing Date: September 11, 2017
Closing Time: 1:00 P.M. Manila time

Subject: Notice of Funding Opportunity
Request for Application No.: RFA-492-17-00002

Program Title: TB Innovations and Health Systems Strengthening

Ladies/Gentlemen:

The United States Agency for International Development (USAID) is seeking applications from eligible U.S. non-profit nongovernmental organizations (NGOs), for-profit NGOs willing to forgo their fee, private voluntary organizations (PVOs), Philippine-based NGOs, universities, foundations, consortiums, and international organizations for a Cooperative Agreement to implement a five-year program entitled, "**TB Innovations and Health Systems Strengthening**", fully described in this Request for Application (RFA).

Eligible organizations interested in submitting an application are encouraged to read each section of this funding opportunity/RFA thoroughly to understand the type of program sought, application submission requirements, and evaluation process. The RFA consists of this cover letter and the following sections:

Section I – Activity Description
Section II – Award Information
Section III – Eligibility Information
Section IV – Application and Submission Information
Section V – Application Review Information
Section VI – Award and Administration Information
Section VII – Agency Contacts
Section VIII – Other Information

It is the applicant's responsibility to ensure that it has downloaded the RFA in its entirety. USAID bears no responsibility for data errors resulting from transmission or conversion process. This RFA may be amended. The applicant should regularly check the Grants.gov website (www.grants.gov) to ensure it has the latest information, including amendments, pertaining to this notice of funding opportunity.

Subject to the availability of funds, USAID intends to provide approximately $30,000,000 in total USAID funding to be allocated over the life of the program. Only one (1) award is anticipated as a result of this RFA. USAID reserves the right to fund any one or none of the applications received.

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To be eligible for award, the applicant must provide all information required in this RFA and must meet the eligibility standards in Section III – Eligibility Information.

An applicant being considered for award who (1) has never had a USAID grant, cooperative agreement, or contract; or (2) has not received an award from any other U.S. agency within the last five years, may be subject to a pre-award survey to determine whether it has the necessary organization, experience accounting and operational controls, and technical skills in order to achieve the objectives of the program.

Any questions on the information contained in this RFA should be sent to Grace M. Laspiñas, Acquisition and Assistance Specialist at manila-roaa-rfp@usaid.gov with subject line: "Questions on TB Innovations RFA submitted by [Name of Organization]" by the due date indicated in the cover page of this letter. If it is determined that the answers to any questions are of sufficient importance to warrant notification to all applicants, a Question and Answer document, and/or if needed, an amendment to the RFA will be posted in www.grants.gov.

Issuance of this funding opportunity does not constitute an award commitment on the part of USAID nor does it commit USAID to pay for costs incurred in the preparation or submission of questions/comments or application. Applications are submitted at the risk of the applicant. All preparation and submission costs are at the applicant's expense.

Thank you for your interest in our program. We look forward to your organization's participation

Sincerely,

Sandra Jansen
Agreement Officer
Regional Office of Acquisition and Assistance

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ABBREVIATIONS AND ACRONYMS

4P's	Pantawid Pamilyang Pilipino Program (a conditional cash transfer program)
AIDS	Acquired Immune Deficiency Syndrome
AMEP	Activity Management and Evaluation Plan
AO	Agreement Officer
AOR	Agreement Officer's Representative
aDSM	Active Drug-safety Monitoring and Management
ARMM	Autonomous Region in Muslim Mindanao
AuTuMN	Australian Tuberculosis Modeling Network
BDQ	bedaquiline
BEO	Bureau Environmental Officer
BJMP	Bureau of Jail Management and Penology
CALABARZON	Cavite, Laguna, Batangas, Rizal and Quezon Provinces (also known as Region 4A)
CBO	Community-based Organization
CDR	Case Detection Rate
CDCS	Country Development Cooperation Strategy
CLA	Collaborating, Learning and Adapting
CQI	Continuous Quality Improvement
CSO	Civil Society Organization
DBM	Department of Budget and Management
DetecTB	Diagnostic Enhanced Tools for Extra Cases of Tuberculosis
DILG	Department of Interior and Local Government
DLM	Delamanid
DOH	Department of Health
DOT	Directly Observed Treatment
DOTS	Directly Observe Treatment Short-course/ Delivery of Tuberculosis Services
DR-TB	Drug Resistant tuberculosis
DS	Drug Sensitive
DST	Drug Susceptibility Testing
DS-TB	Drug Sensitive Tuberculosis
DSWD	Department of Social Welfare and Development
EA	Environmental Assessment
EEMP	Environmental Mitigation and Monitoring Plan
EQA	External Quality Assurance
ERC	Environmental Review Checklist
FBO	Faith-Based Organization
FDA	Food and Drug Administration Philippines

FP	Family Planning
GF	Global Fund
GFATM	Global Fund to Fight AIDS, TB and Malaria
GPH	Government of the Philippines
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
HLGP	Health Leadership and Governance
HRD	Human Resources Development
HRH	Human Resources for Health
HSS	Health Systems Strengthening
ICRC	International Committee of the Red Cross
IEE	Initial Environmental Examination
IMPACT	Innovations and Multi-sectoral Partnerships to Achieve Control of Tuberculosis
IPT	Isoniazid Preventive Therapy
IRA	Internal Revenue Allocation
ITIS	Integrated Tuberculosis Information System
JATA	Japan Anti-Tuberculosis Tuberculosis Society
KMITS	Knowledge Management and Information Technology Service
KOFIH	Korean Foundation for International Healthcare
LED FM	Light-emitting diode Fluorescence Microsccopy
LGU	Local Government Unit
LOE	Level of Effort
LPA	Line Probe Assay
LTBI	Latent Tuberculosis Infection
LTFU	Lost to Follow Up
MCH	Maternal and Child Health
MDR-TB	Multi-drug resistant tuberculosis
MOFA	Japanese Ministry of Finance
MTB	Mycobacterium tuberculosis
M&M	Project Mitigation and Monitoring
NAP	U.S. National Action Plan to Combat Multidrug-Resistant Tuberculosis
NDRRMC	National Disaster Risk Reduction Management Council
NGO	Non-governmental Organization
NTP	National Tuberculosis Program
NTRL	National TB Reference Laboratory
OMNI	Organizing Medical Network Information
OR	Operations Research
PBSP	Philippine Business for Social Progress
PeHSF	Philippine eHealth Strategic and Framework Plan
PICT	Provider Initiated Counseling and Testing

PLHIV	People Living with HIV
PMDT	Programmatic Management of Drug-Resistant TB
POPCOM	Commission on Population
PPM	Public Private Mix
PHC	Primary Health Care
PLHIV	People Living with Human Immunodeficiency Virus
PhilHealth	Philippine Health Insurance Corporation
PhilSTEP 1	Philippine Strategic Tuberculosis Elimination Plan: Phase 1
PPR	Performance Plan and Report
PSCM	Pharmaceutical Supply Chain Management
PV	Pharmacovigilance
RCE	Request for Categorical Exclusion
RFA	Request for Application
RHU	Rural Health Unit
RIF	Rifampicin
RPRH NIT	Responsible Parenthood and Reproductive Health law National Implementation Team
RR TB	Rifampicin Resistant Tuberculosis
SAE	Serious Adverse Events
SBCC	Social and Behavior Change Communication
SDN	Service Delivery Network
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SI-VFM	Special Initiative on Optimizing Value for Money and Financial Sustainability
SOTA	State of the Art
STR	Shortened TB Regiment
SSTR	Standard Shorter Treatment Regimen
SS+	Sputum-smear positive
TASC	Technical Assistance Support to Country
TB	Tuberculosis
TREAT TB	Technology, Research, Education and Technical Assistance to Tuberculosis
TSR	Treatment Success Rate
USG	Unites States Government
USAID	United States Agency for International Development
WHO	World Health Organization
XDR	Extensively drug-resistant tuberculosis

SECTION I: ACTIVITY DESCRIPTION

A. OVERVIEW

The United States Agency for International Development (USAID), through a competitive process, plans to invest in a five-year cooperative agreement entitled, "TB Innovations and Health Systems Strengthening" that aims to strengthen national and regional level implementation of the National TB Strategic Plan by providing state-of-the-art capacity building and technical expertise to scale-up TB and DR-TB prevention, detection and treatment. The "TB Innovations and Health Systems Strengthening" activity will identify and help implement proven approaches to improve TB prevention, increase TB case detection rates, decrease default rates, and increase TB treatment success rates and TB cure rates.

Authorizing Legislation

The authorizing legislation for this anticipated cooperative agreement is the Foreign Assistance Act of 1961, as amended, and the award will be subject to 2 Code of Federal Regulations (CFR) 700 and 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. The following are applicable for the administration of the resultant award:

- For U.S. organizations, 2 CFR 200 and 2 CFR 700, and the Standard Provisions for U.S. Non-Governmental Recipients are applicable
- For non-U.S. organizations, the Standard Provisions for Non-U.S. Non-Governmental Recipients will apply

For purposes of this RFA, the word "activity", "program", or "project" is used interchangeably to refer to "TB Innovations and Health Systems Strengthening".

1. Introduction

In 2016, the Department of Health (DOH) embarked on its Philippine Health Agenda, which focuses on financial risk protection, better health outcomes, and a health system that is responsive and provides access to services. This agenda will require bureaucratic systems that are effective and agile, strategic approaches to engender better health outcomes and stakeholder vigilance over policies, budgets and systems. USAID's long and successful relationships with the Department of Health and other key stakeholders at both the national and sub-national level provide a platform for USAID to have an impact on the broad range of critical health problems and the underlying systems issues facing the country. USAID is committed to helping the Philippines achieve its ambitious health goals by implementing a focused, results-oriented program that fully leverages Filipino capacity, systems and resources.

USAID has developed a suite of activities - referred to collectively as the USAID/Philippines Health Project (2017-2022) - that together will seek to achieve sustainable, transformative impact. The "TB Innovations and Health Systems Strengthening" activity represents one of several activities that make up USAID's overall investments in the Philippines health sector. The

tuberculosis or TB activity will work closely with USAID, other USAID activities, the Department of Health, the Global Fund and its principal recipients and sub-recipients and a range of Filipino stakeholders and organizations to achieve the broader vision and support the attainment of the Philippine Health Agenda.

2. USAID/Philippines Health Project 2017-2022

The USAID/Philippines Health Project (2017-2022) will support the Philippines by improving the health for underserved[1] Filipinos. For the Philippines to meet its own health goals and achieve the United Nations Sustainable Development Goals for health, a far greater proportion of Filipinos must consistently practice healthy behaviors and seek and receive quality care through a functioning and sustainable health system. Embedded in the Project purpose is a three-pronged set of sub-purposes designed to: 1) strengthen individual healthy behavior; 2) fortify the quality of health services to push for more patient-centered approaches; and 3) bolster and institutionalize the key public health systems needed to support these behaviors and services. By 2022, each activity will contribute to USAID's overall goals that uphold the Government of the Philippines' Health Agenda.

In cooperation with government, non-government organizations, civil society organizations, other donors, public and private service providers, and underserved citizens, USAID will work in partnership with the Philippine government and other key stakeholders to "improve the health of underserved Filipinos" under this project. Significant changes are expected at the individual, community, services, and systems levels and many of these expected outcomes will depend on positive changes at different levels of the health system.

A more detailed description of the USAID/Philippines Health Project is located here: https://www.usaid.gov/documents/1861/redacted-health-project-appraisal-document-2017-2022.

3. Health Project Activities

USAID/Philippines will execute the 2017-2022 Health Project through a combination of state-of-the-art field platforms, roll-out of innovations and system strengthening activities, along with monitoring, evaluation, learning and adapting. The suite of project activities related to tuberculosis will include:

- Five tuberculosis technical activities that transfer state-of-the-art experience in behavior change, quality improvement and equitable access to services, as well as working with the Department of Health and other stakeholders to develop and help roll out innovations in partnering, service delivery and technologies.

- Four systems strengthening activities designed to make local ownership a reality by fortifying regional health governance, central and regional health financing and resource

[1] "Underserved" in the primary context of this Project, refers to people exposed to or with tuberculosis or multi-drug resistant tuberculosis; youth and adults at risk for unwanted, early pregnancy and childbirth; and pregnant women (and partners) in need of antenatal care and life-saving, safe delivery for themselves and their newborns.

management, supply chain management and human resources, while institutionalizing leadership and technical training, supply chain management and policy development, currently being buttressed by USAID and other donors, into the Department of Health.

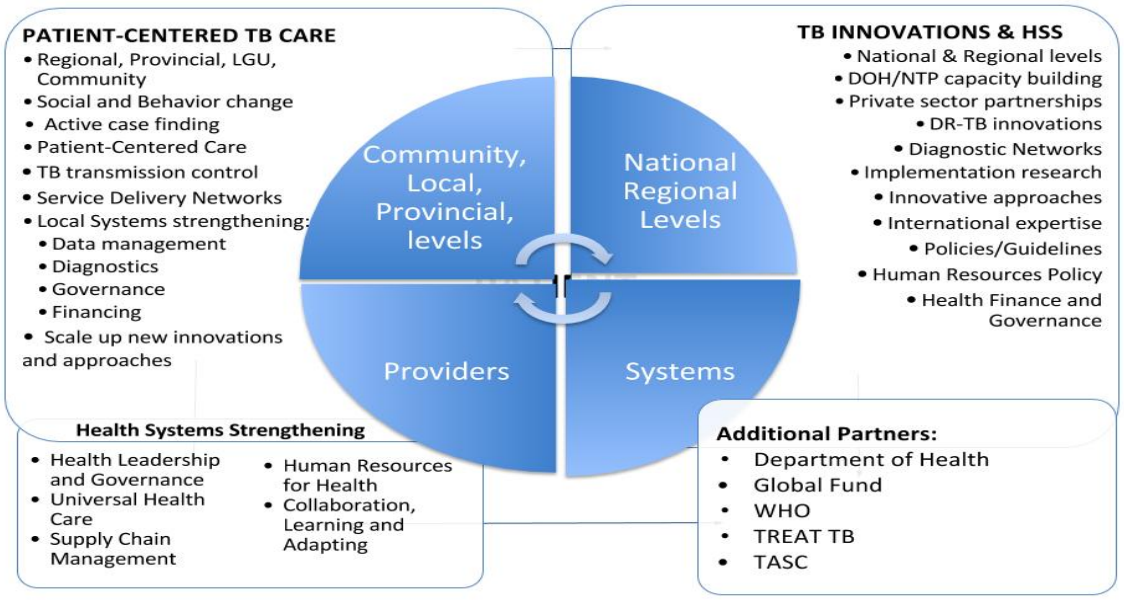
- A Collaborating, Learning and Adapting activity that will assist USAID to define and report on the quantitative and qualitative progress, define a strategic research and analysis agenda in cooperation with stakeholders, evaluate data quality, conduct impact and program evaluations and develop tools and opportunities for dissemination and adaptation.

Table 1 and Chart 1 provide information of Health Project Activities. For descriptions of USAID's implementing activities please refer to *Annex A.*

Table 1: USAID Health Project TB Activities

Tuberculosis	**Health Systems Strengthening**
Patient-Centered TB Care	Health Leadership and Governance Program
TB Innovations & Health Systems Strengthening	Universal Health Care
Treat TB Technical Assistance	Supply Chain Management
World Health Organization Technical Advisor	Human Resources for Health
Technical Assistance and Support Contract Technical Advisor	Collaboration, Learning and Adapting

Chart 1: USAID/Philippines TB Activities



B. BACKGROUND

1. Tuberculosis in the Philippines

According to WHO Global Tuberculosis Report 2016, the Philippines met the 2015 TB targets of declining incidence rate in 2011, halving prevalence and mortality rates compared with the 1990 baseline. Despite this, TB continues to be a significant health problem for the country. It is the eighth leading cause of morbidity and mortality (Philippine Health Statistics, 2013). In 2015, there were an estimated 324,000 new cases of TB, and 286,544 cases were registered with the National TB Program (NTP). The number of estimated multidrug-resistant TB (MDR-TB)/ rifampicin-resistant TB (RR-TB) incident cases was 17,000 (WHO Global Tuberculosis Report 2016). In terms of absolute number of incident cases of TB and MDR-TB, the Philippines is listed as one of the 30 high burden countries in both of these categories.

As a *high TB burden* country, the Philippines is performing relatively well in terms of case-finding and treatment outcomes, with a case detection rate (CDR) of 85 percent, and a 90 percent treatment success rate (TSR) according to 2016 WHO TB report. However, only cases notified to the NTP are included in the analysis of Case Detection Rate and Treatment Success Rate. As a result, there are a significant number of undiagnosed or unreported missing cases that are excluded from this analysis. Also, the Philippines has recently completed the 2016 National TB Prevalence survey, which demonstrates that TB prevalence is significantly higher than what was found in the 2007 prevalence survey.

As a *high MDR-TB burden* country, the Philippines is struggling with drug-resistant (DR-TB) in terms of case-finding (with 24 percent CDR) and treatment outcomes (with approximately 43 percent TSR in DR-TB). This means that of the roughly 17,000 estimated cases, only about 4,080 cases were detected and initiated on treatment; and of those who were initiated on treatment, only about 1,750 cases were successfully treated. The number of those diagnosed with MDR-TB who refused to start treatment is unknown. The Philippines is conducting drug susceptibility testing (DST) for only five percent of people with newly notified DR-TB cases, which is significantly lower than the WHO target of 20 percent. Sixty-seven percent of people who are DR-TB retreatment patients undergo drug susceptibility testing. This is also lower than the WHO target of 100 percent, therefore, more work is needed in this area.

The country has data from three national TB surveys (1981–1983, 1997, 2007, and 2016) with the 2016 survey results to be released in August 2017. Between 1997 and 2007 there was a trend of gradual, but modest decline in terms of incidence, prevalence (annual reduction of two percent of sputum-smear positive [SS+] and 4.7 percent of culture positive), and annual risk of infection. However, this rate of decline is not rapid enough to achieve TB elimination by 2035, which WHO has defined to be an incidence rate of 10 per 100,000 population. In fact, at the current incidence rate decline of 1.5 percent per year, the Philippines may reach elimination only in another 150-200 years. There is an urgent and pressing need for more strategic, innovative, and impactful interventions to achieve this goal of TB elimination. Please see *Annex B* for statistics about TB.

2. Government of the Philippines TB Elimination Activities

The Department of Health's National TB Control Program (NTP), is mandated to provide technical leadership to implement the TB control program through development and issuance of national policies, standards and guidelines; management of program logistics and data; coordination with key stakeholders in harmonizing resources; and monitoring and evaluation. Some public and private hospitals and a few Public-Private Mix (PPM) Directly Observed TB Short-course (DOTS) units are also part of the TB referral network which means that they either refer or directly provide TB services to their patients. Thus far, the NTP has not taken steps to include private stand-alone physicians into the TB referral network.

Nationwide expansion of TB testing in children has been part of the NTP since 2004 but to date, execution remains highly variable per region (between 2-27 percent of notified cases) and is plagued by drug and commodity stockouts.

Legal framework: Since 1929 when Republic Act 3573 was approved, tuberculosis has been included as reportable cases. This was reiterated by Department Circular No. 176 in 2001. However, in 2008, the Department of Health removed tuberculosis from the list of reportable cases by virtue of Administrative Order No. 2008-0009. In 2016, Republic Act 10767 was approved and is otherwise known as the *Comprehensive Tuberculosis Elimination Plan Act*. It

stipulates that all public and private health centers, hospitals and facilities shall observe the national protocol on TB management and shall notify the DOH of all TB cases. The law, however, is unclear about the role of private practitioners and reporting. Although the law does not explicitly mention mandatory reporting, the law's implementing rules and regulations provide guidance on mandatory reporting but do not describe a mechanism or discuss the consequences of not reporting.

Section 4 of Republic Act No. 9711, also known as the Food and Drug Administration Act of 2009, stipulates that one of the Food and Drug Administration's (FDA) roles and responsibilities is to reinforce the post-market surveillance system in monitoring health products as defined in this Act as well as incidents of adverse events involving such products. In 2016, the DOH decided to establish some pharmacovigilance and post-market surveillance activities under the responsibility of the Pharmaceutical Division of the DOH. It will be a new challenge for this division to coordinate with the FDA to implement the reporting responsibilities required by the Act. To date, the policy issuance on this has yet to be released.

National Strategic Plan: In 2016, the implementation period of the National Strategic Plan for TB Control known as the Philippine Plan for Action to Control Tuberculosis ended. Thus, the Government of the Philippines (GPH) developed the Philippine Strategic TB Elimination Plan Phase 1 (PhilSTEP1), the first of a series of three medium-term plans, intended to steer the NTP towards its vision of a "TB-free Philippines". The six-year plan is mandated by Republic Act 10767 or the *TB Elimination Plan Act of 2016* to reduce TB incidence and mortality, reduce catastrophic costs for affected families and provide responsive TB services. Targets may change pending the release of the 2016 National TB Prevalence Survey (NTPS) results.

Box 1: NTP "ACHIEVE" Strategy for TB:

Activate communities and patient groups.

Collaborate to reduce out-of-pocket expenses and expand social protection programs.

Harmonize efforts on human resources.

Innovate TB information generation and utilization.

Enforce standards on TB care and prevention.

Value clients and patients through integrated patient-centered TB services.

Engage local government units on multi-sectoral implementation of TB elimination plan.

Box 2: PhilSTEP1 Impact Targets by 2022

- Reduce number of TB deaths by 50 percent from 14,000 to 7,000 deaths
- Reduce TB incidence rate by 25 percent from 322/100,000 to 243/100,000
- Reduce to zero the percentage of TB-affected households that experience catastrophic costs due to TB (baseline will be determined by the ongoing catastrophic cost study)
- At least 90 percent of patients are satisfied with services from DOTS facilities

Table 2: PhilSTEP1 Outcome Targets by 2022

Indicators	Baseline 2015	Target in 2022
Treatment Coverage (Case Detection Rate) ● Susceptible TB ● Multi-Drug Resistant TB	 92%* 32%	 ≥ 92% 90%
TB Treatment Success Rate ● Susceptible TB ● Multi-Drug Resistant TB	 92% 49%	 ≥ 92% 85%
Case Fatality Ratio	4%	<4%
Latent TB Infection treatment coverage ● Household child contacts (<5 years) ● PLHIV	 14% 43%	 90% 90%

*Based on underestimated TB incidence and over-diagnosed TB cases

In order to achieve the key targets for the National Strategic Plan, the NTP is planning to roll out several new TB policies in 2017. These policies include adopting the 9-month regimen as a standard regimen for MDR-TB; introduction of the new drugs, Bedaquiline (BDQ) and Delamanid (DLM) to treat DR-TB; changing the TB service delivery model into one that combines both drug sensitive (DS) TB and DR-TB diagnosis and treatment at peripheral facilities (e.g., rural health unit (RHU) level); adopting an inclusive approach where all health providers and facilities are engaged; and further expansion of Xpert mycobactrium tuberculosis/rifampicin (MTB/RIF) to eventually become the primary diagnostic tool for TB. All of these changes will require the NTP to update, modify and roll-out current algorithms, standard operating procedures and guidelines.

3. Donor Support and Other Partners

Domestic funding, Global Fund resources and non-Global Fund donor funding for TB have grown in recent years. USAID is the U.S. government's lead agency for international TB work. The Philippines is considered a USAID priority country in the fight to eliminate TB and aids the Philippines government’s objective to reach every person with TB, cure those in need of treatment and prevent the spread of the disease and new infections.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) is the single most important source of external funding in the Philippines for TB prevention, treatment, and care. The GFATM has been providing assistance to the Philippines for over ten years. The current GFATM TB grant’s Principal Recipient is the Philippine Business for Social Progress (PBSP). This grant started in January 2014 and will end in December 2017, and has a total approved budget of $113,731,624. While almost half of the grant budget is allocated for supplies and

consumables (such as TB medications), PBSP also focused on MDR-TB case detection and laboratory strengthening. PBSP works closely with USAID so that there is no duplication of work and support is complementary. A major challenge for the Government of the Philippines will be sustaining and institutionalizing priority components of the Grant, particularly patient enablers and manpower augmentation. There is also a need to bolster the Grant's technical approach and monitoring and evaluation activities.

The GFATM recently approved the NTP's funding request of $78.5 million, for a grant covering the period 2018-2020. It also approved the country's request for a separate tranche of $10 million of "catalytic funding" that is focused on finding missing TB cases, initially estimated to be at least 37,500 cases. An additional $34 million was approved for additional activities under the prioritized above allocation request. The three investment areas of the GF grant are mainstreaming service delivery systems for drug-resistant TB cases; finding missing cases through strategic engagement of non-RHUs, including private facilities; and expanding TB-HIV collaboration. Close collaboration among the Recipients of this activity and the Patient-Centered Care TB activity, and the GFATM activities in the Philippines will be essential.

From 2008-2012, the Japanese Ministry of Foreign Affairs (MOFA) and Japan Anti-Tuberculosis Association (JATA) funded a quality TB control project in urban areas of Metro Manila and Quezon City. Its focus was on reaching underprivileged people in the community by bridging the gap through networks among the non-governmental organizations, faith-based organizations and local government units to expand access to quality DOTS services.

From 2012-2016, the Korean Foundation for International Healthcare (KOFIH) funded the Diagnostic Enhanced Tools for Extra Cases of Tuberculosis (DetecTB) project. Project sites included Puerto Princesa City and chosen municipalities of Palawan province. The project's main objective was to increase case detection of all forms of TB to 10 percent or more in target areas. The KOFIH employed modern, fast and reliable diagnostic equipment such as digital chest radiography, light-Emitting diode fluorescence microscope (LED-FM) and molecular identification of TB bacilli through the Xpert MTB/RIF Assay.

The International Red Cross and Red Crescent Movement (ICRC) focuses its work to find cases in jails and prisons. Since 2013, the ICRC has worked in two pilot sites to implement a four-year pilot project with technical support from USAID's IMPACT project. Moving forward, the organization plans to work in Regions 3 and 4A jails but will shift its focus to improving access to primary health care through integrating TB services in detention centers.

With the backing of the NTP in the Philippines and financial support from the GFATM through the Special Initiative on Optimizing Value for Money and Financial Sustainability (SI-VFM), the Australian Tuberculosis Modeling Network (AuTuMN) conducted an analysis aimed at providing epidemiological projections of the TB epidemic in the Philippines and the impact of interventions on the TB epidemic. Some of the findings from the analysis may be used to

determine the best use of resources to maximize health outcomes to enhance country TB programs.

The World Health Organization through its Western Pacific Regional Office is expected to continue its technical assistance for activities such as regional Green Light Committee missions, the Joint Program Review, and other upcoming activities.

4. United States Government (USG) Priorities for Tuberculosis

The U.S. government's global tuberculosis efforts are led by USAID to prevent tuberculosis transmission, renew endeavors to find unidentified cases, strengthen the capacity of national tuberculosis programs, build country capacity to use existing resources, and expand the development of new tuberculosis diagnostics, drugs and vaccines. Since 2000, USAID has provided technical support for TB prevention, treatment, and care in the Philippines. USAID will guarantee that all current programming is aligned with the U.S. Government's Global TB Strategy 2015-2019 and the U.S. National Action Plan to Combat Multidrug-Resistant Tuberculosis (NAP), which will accelerate the achievement of the WHO End TB Strategy and the Global Plan to END TB.

The new USAID/Philippines Health Project (2017-2022) builds on decades of experience from past USAID programming, including an external 2016 health portfolio evaluation. This evaluation recommended that USAID assist to expand access to TB care, encourage expanded use of rapid tests for diagnosis, improve mandatory notification systems, provide quality communication programs and roll-out the shorter MDR-TB treatment regimen nationwide. The next phase of USAID programming will closely align with the objectives of the Government of the Philippines as outlined in the Philippine Health Agenda 2016-2022 and in the National Strategic Plan and PhilSTEP1.

The NAP identifies a set of targeted interventions that address the core domestic and global challenges posed by MDR-TB and extensively drug resistant TB (XDR-TB). Recommended interventions represent the U.S. Government's contributions to reversing the worldwide spread of MDR-TB and should inform policy-development processes around the world. The National Action Plan is an attempt to articulate a comprehensive strategy, mobilize political will and spur additional financial and in-kind commitments from bilateral and multilateral donor partners, the private sector and the governments of all affected countries.[2]

[2]https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_action_plan_for_tuberculosis_20151204_final.pdf

Box 3: Government of the Philippines and USG Plans and Strategies

Government of the Philippines National Plans and Strategies:

- Philippine Health Agenda
- Comprehensive TB Elimination Plan Act of 2016
- Philippine Strategic Tuberculosis Elimination Plan 2017-2022 (PhilSTEP1)
- Philippine eHealth Strategic and Framework Plan 2016 and beyond (PeHSP)
- DOH Information System Strategic Plan 2015-2017
- Healthcare Financing Strategy of the Philippines 2010-2020

United States Government and USAID Strategies:

- USAID Philippines Country Development and Cooperation Strategy 2013-2018 (CDCS)
- United States Government Global TB Strategy 2015-2019
- National Action Plan for Combating Multi-Drug Resistant TB 2015-2022 (NAP)

The goals of the National Action Plan are to:

1. Strengthen domestic capacity to combat MDR-TB;
2. Improve international capacity and collaboration to combat MDR-TB; and
3. Accelerate basic and applied research and development to combat MDR-TB.

USAID/Philippines has performed an analysis of actions needed to fulfill the NAP milestones and determined the following to be necessary for implementation in coordination with the NTP and other partners under this funding opportunity:

- Under the NAP milestone 2.1.3, the Philippines is required to establish a link between the TB laboratory and DR-TB information management system to enable rapid reporting and registration of DR-TB cases and early initiation on a treatment regimen which contains second line medications.

- Under the NAP milestone 2.2.2, the Philippines must adapt and apply the "adherence assessment tool" which measures DR-TB treatment adherence and identifies risks related to poor compliance. Once risks have been identified, the NTP should develop a sustainable, patient-centered DR-TB care package that will be provided to all DR-TB patients to improve adherence and treatment results.

- Under the NAP milestone 2.2.3, the NTP in collaboration with technical assistance partners should develop a national infection control strategic plan and roadmap. The plan should include the parties who will be responsible for completing each intervention. In addition by December 2018, the Philippines should begin implementation of healthcare worker surveillance and screening in all facilities responsible for diagnosis and treatment.

Health worker surveillance and screening should be scaled-up in all high-burden regions by the end of 2020.

C. KEY ISSUES AND CHALLENGES

1. Healthy Behaviors

In order to achieve desired social and behavior change outcomes to eliminate tuberculosis, evidence-based interventions before, during and after the provision of TB services are essential. Additional focus to generate demand should be matched by supportive community norms that motivate clients to consult and seek TB care. When clients access services, they should feel empowered through heightened knowledge about the disease and through the respectful care they receive from trained health providers. As patients undergo treatment, supportive systems should boost their adherence, secure zero interruptions in treatment and enhance their ability for better self-care after treatment. More data gathering, assessment and analysis is needed to develop and shape appropriate and targeted approaches and interventions that will result in improved case detection, appropriate treatment seeking behavior and treatment adherence.

Inadequate health-seeking behavior

Initial reports of the 2016 National TB Prevalence Survey show that among people with TB symptoms, around 41 percent take no action, approximately 40 percent self-medicate, and only 19 percent seek consultations with a medical provider. Thus, the initial estimates suggest that National TB Program is missing over 80 percent of all TB cases. Health-seeking behavior is determined by many socio-cultural and socio-economic factors that include age, gender, social stigma, self-stigma, distance to health care services, direct and opportunity costs, awareness of TB as well as provider backing. Some patients are not accessing the health system or are accessing services late. Advocacy around TB has been weak, contributing to limited political commitment. Additionally, civil society and patient engagement has been insufficient, thus marginalizing the involvement of key affected populations in TB policy-making and program planning, operationalization, monitoring and evaluation.

Missing TB cases and slow initiation on treatment

According to 2015 data, it is estimated that 20-40 percent of TB cases are missed in both the public and private sectors. This percentage is expected to be even higher when the 2016 National TB Prevalence Survey is published. Case finding is largely passive and there is limited active contact tracing. Since close contacts of TB patients have a five to ten times higher risk of acquiring TB, outreach activities and screening of close contacts will help the NTP detect more TB cases. An understanding of vulnerable groups is not yet guiding targeting of interventions. There is also a need to promptly initiate on treatment all those who are diagnosed. Patients need easy access to TB services which should ideally be available at the first point of contact. Slow

initiation on treatment is due to factors such as limited availability of laboratory and treatment services, out-of-stock consumables and medications, treatment initiation delays and unwillingness of patients to initiate treatment. Last but not least, TB surveillance and screening among primary health care staff and staff dealing with infectious diseases needs to be conducted regularly.

Weak adherence to DR-TB treatment

Barriers to accessing and continuing TB treatment include financial, geographic, lack of knowledge about the disease and inadequate provider support that is focused on addressing the needs of patients. Also, for patients treated for DR-TB, poor management of adverse drug reactions leads to lost to follow up, according to the recent study, implemented in the Philippines. Bringing services closer to the patients and being flexible in addressing individual patient needs will be important to improve quality of TB and DR-TB care. The next few years will be critical as the NTP moves into a different model of TB service provision where both DR and DS-TB services will be available at the rural health unit level.

2. Quality of Services

Insufficient and limited engagement of private sector and private health care providers

The scale and importance of the private medical sector cannot be underestimated; about half of all people with symptoms of TB seek healthcare from hospitals or private physicians, and an estimated 50 percent of TB patients are managed outside of the NTP. The management of TB cases outside the NTP is unmonitored and unregulated. Chest x-rays are often employed without sputum examination, and even if diagnosis is made correctly, TB treatment is far from standard. As a result, with no default tracing mechanisms and case-holding mechanisms in place, providers struggle to ensure that their patients complete TB treatment. Also, there is a need for stricter enforcement of the mandatory reporting provision of the TB Law for stand-alone physicians.

Pharmacies need to be engaged as they are also major sources of care--especially for people who prefer to self-treat. Another major challenge is that the sale of drugs in private pharmacies is not strictly regulated. A study using 2007 to 2011 procurement and sales data of TB treatment drugs in the Philippines showed that in 2011 alone, 2.4 times the number of notified cases could have been placed on treatment and treated for at least the intensive phase.[3] This suggests significant out-of-pocket expenditures and severe underreporting of TB cases and/or misuse of drugs due to over-diagnosis, overtreatment or improper dispensing. There is a need for more stringent implementation of the Pharmacy Law.

Public Private Mix (PPM) approaches worldwide have suffered from limited sustainability as

[3] Islam T, van Weezenbeck C, Vianzon R, Garfin AMCG, Hiatt T, et al. (2013) Market size and sales pattern of tuberculosis drugs in the Philippines. Public Health Action 3(4); 337-341, 2013.

there has been no plan for national expansion or for financing after the end of a project cycle. Thus, any initiative undertaken should include a clear plan for both expansion and sustainability, with an emphasis on building on local institutions and health system processes. Explicit policies articulating the acceptance of private sector engagement as a long-term sustainable strategy is crucial as is the clear outlining of their collaborative and regulatory relationship with the NTP. This means that meaningful and sustainable inclusion of the private sector by the NTP into its TB diagnostic and treatment network needs to be undertaken. Government contracting mechanisms should be reviewed and reexamined to pave the way for contracting the private sector. The NTP should consider all potential partners which may include stand-alone physicians, hospitals, medical and allied medical professional schools and training institutions, pharmacies, workplaces, and various types of non-government, government, and community based organizations.

Although several PPM models have been successfully piloted in the Philippines institutionalizing PPM practices and ensuring that activities continue once the pilots end have been challenging. Furthermore, these pilots have not always considered governance tools which have a greater likelihood of being applicable and sustainable nationwide. There is a need to examine the governance tools that are currently used or could be used by the public sector to improve the performance of private providers in general, with TB as a specific tracer condition. Of particular importance is the need to review, possibly revise and strictly monitor the implementation of the Comprehensive and Unified Policy for TB Control in the Philippines which was signed in 2003 to strengthen coordination of TB control efforts at all levels and within all agencies of government and private sector.

Inconsistent quality of TB services

Neither the rapid increase in clinically diagnosed cases, nor the reasons for the high proportion of negative Xpert MTB/RIF results in presumptive MDR-TB patients are well understood. Quality diagnostic and treatment services need to be made available at point-of-care establishments. There is also limited attention to and low detection of pediatric TB. There is a need to progressively and significantly transition Programmatic Management of Drug-Resistant TB (PMDT) services from the Global Fund Principal Recipient to the NTP. Decentralization of diagnostic and treatment services to expand access is paramount. One important area is also the integration of TB services with other Department of Health programs such as maternal and child health, nutrition, HIV, and non-communicable diseases. Service delivery at the peripheral level is performed by the same individuals, even if program management from national to provincial levels is siloed. Further, there is a need to define the parameters and operationalize a “patient-centered approach” at the local level. The capacity of health providers to deliver patient-centered, respectful care that is free from stigma and discrimination at all levels of the system needs to be strengthened, maintained and monitored.

In order to improve the safety of patients receiving new drugs and regimens, WHO recommends NTPs to adapt and apply special pharmacovigilance practice, called active TB drug safety management and monitoring - aDSM. Currently only 10 treatment centers in the country are applying aDSM to patients on the shortened treatment regimen and on bedaquiline. Drug safety management and monitoring will need to accompany the roll out of new drugs and shorter treatment regimen in more than 700 treatment facilities.

Insufficient infection control practices

In the past, limited attention had been given to TB infection control. Today, addressing the issue of TB infection control in congregate and health care settings is a key component in combating the spread of TB nationwide. However, this will require additional attention and resources beyond routine activities. Special attention should be paid to TB infection control in health facilities, in congregate settings, and among healthcare workers among whom there is an elevated risk of TB transmission. These are all significant concerns for the TB elimination push.

Limited integration of health services

In order to make quality TB services easily accessible, functional Service Delivery Networks (SDN) are needed in every local government unit (LGU) to improve access for patients and clients. The SDN for TB is a network of public and private facilities and health care providers that can provide TB diagnostic and treatment services as per clinical practice guidelines and the NTP Manual of Procedures. It also includes community-based organizations (CBOs), patient support groups, and non-governmental organizations that can provide referral and support services and may also serve as treatment partners. It is imperative that services are located close to the patient and are easily accessible in order to eliminate the need for multiple visits and multiple service delivery points to visit. In addition, routine TB screening needs to be fully integrated into all primary health care services (maternal and child health, family planning, immunization, etc.) so that every patient is screened for TB during every point of contact with the health system. This is a challenge since DOH programs are siloed vertically at the central and regional levels but need to be horizontally integrated at the service delivery level. Complicating this problem is a devolved system where policies and guidelines are crafted at the national level yet the implementation unit is at the provincial levels and below where prioritization rests on the Local Government Executives. Policies and guidelines need to be crafted with operational issues in mind.

Services for DR-TB at all levels of the health system, including diagnosis, treatment, and management of the supply chain, are currently provided separately from services for drug-sensitive TB and are centralized in large health facilities and hospitals. This has resulted in a parallel program which constrains access to health services for DR-TB patients and severely limits sustainability and performance of the program. In response to the urgent need to make services more patient-focused, the NTP has recently begun to decentralize and integrate DR-TB

services at local health facilities. The NTP has an ambitious plan to offer the shorter treatment regimen for DR-TB in every treatment facility in the country but the uptake of these services has been slow.

Underperforming TB diagnostic and laboratory system

A successful TB control program should have an accessible, fully functional, and quality-assured laboratory and diagnostic system supported by a strong specimen transport and referral network. Despite significant allocations of financial and human resources to strengthen the National TB Reference Laboratory and laboratories at the decentralized and health facility levels, data quality and analysis, utilization rates and turnaround time to report results vary. In public sector facilities, the external quality assurance (EQA) system which is designed to check the quality and accuracy of sputum smear microscopy tests, is not fully functional nationwide because of limited human resources at the provincial level. For private laboratories, there is no EQA system, thus very few private labs are quality-assured. High contamination rates, low recovery rates, and a long backlog of tests for culture and drug susceptibility testing (DST) pose further challenges to quality assurance and access to treatment. Furthermore, not all laboratories are adequately staffed and not all laboratories are open daily during weekdays.

Many facilities have not established systems designed to facilitate access for patients. Deterrents to accessing testing and diagnostic services include lengthy travel and waiting times to submit samples and return for results, and high out-of-pocket costs for chest x-rays and transportation to testing sites. Absence of a reliable and consistent specimen transport system forces many patients to travel to facilities for testing. Although new molecular testing technologies such as GeneXpert are being rolled out nationwide, some GeneXpert sites are under-utilized. As new technologies such as GeneXpert and Line Probe Assay (LPA) are scaled up, considerable investments in training and supervision must be made to prepare and link the diagnostic and laboratory system to quality treatment and counseling services.

3. Health Systems

Limited data and insufficient monitoring and evaluation

There is a need for quality and timely recording and reporting of technical and financial program data to guide patient and program management. TB and other primary health care (PHC) staff at all levels do not have sufficient knowledge and experience with data analysis or how to analyze and use this data for future planning. Also, very little data is collected on the behavior of patients and affected communities. Improving data analysis and interpretation will help TB staff to properly program new activities, modify existing ones and adopt behavioral components. In consideration of the internet connection problems in the country, both online and offline methods of recording and reporting must be available to RHUs. The development of the Integrated Tuberculosis Information System (ITIS), the system that tracks TB data nationwide, is

significantly behind schedule. Challenges with the system include: an incomplete laboratory and other additional modules, poor or absent internet connection in some areas and the unavailability of a purely offline version of ITIS for data entry, patchy geographic implementation, delayed data entry, and inconsistent data validation processes. The process of conducting data quality checks also needs improvement. Monitoring and evaluation activities must be conducted frequently and regularly with upper level supervisors engaging RHU staff in discussions on how to address identified challenges. In this case, supportive supervision may be explored as a useful approach.

Persistent financing challenges and program sustainability

Despite steady increases in the overall national budget for health, the NTP budget has remained flat-lined over the past six years due to slow utilization of its allocated funds. Furthermore, efficiency of spending of the NTP sub-allotted budget to the Regional Offices is unknown. Use of the budget for TB has been constrained largely due to the cumbersome government procurement process, which affects outsourcing of technical services and supply of TB medicines. As a result, the NTP is limited in the type of financial assistance that it can provide to TB patients -despite increasing costs of care- and it must rely heavily on donor funding to support health personnel, equipment and other operational costs. This situation presents a significant risk for the sustainability of the TB program. The DOH and NTP must optimize spending, promote programmatic efficiencies, and advocate for improved procurement systems and budget allocations. Significant increases in both domestic funding and absorptive capacity are warranted.

Since 1992, health services have been decentralized to local government units, but there is still a lack of barangay, municipal, and provincial ownership as well as inadequate financing of health programs. Although Internal Revenue Allotments (IRAs) for health have increased, local health spending has not moved forward at the same pace. In an attempt to compensate for insufficient allocation of resources at the decentralized level, the national health and national TB budgets have increased in recent years. However, as described above, persistent and systematic challenges prevent full utilization of funds at the national and regional levels. Some LGUs support the TB program through procurement of drugs and supplies, but the availability of a TB line-item budget at local levels is inconsistent. LGUs must play a greater role on health care issues to identify health issues, mobilize the community and enhance financial aid for health programs.

Although a PhilHealth TB DOTS package is available, utilization rates are low partly because of unclear guidelines on how allocation of PhilHealth payments should be made. These differences in payment allocations have led to health workers, health facilities, and referrers not receiving their due share, demotivation of health facility staff to file for PhilHealth accreditation and claims, and the deprivation of potential assistance to patients. Moreover, PhilHealth has not yet developed a benefit package to fund MDR-TB care.

Significant gaps in supply and capacity of human resources

Recent NTP program evaluations, as well as other analyses have revealed critical shortages of trained and qualified health personnel at all levels. As a result, the Philippines suffers from a wide variation in the quality of TB service delivery and implementation of critical management and supervision functions. While many of these gaps are being filled through donor support and donor-funded staff, this practice is unsustainable. A resilient TB workforce requires a sufficient number of qualified and trained staff. During the next three to five years of the Global Fund grant, the DOH and NTP must develop an action plan for maintaining investments in the health workforce at the national, regional and local levels. Initial results from the 2016 TB Prevalence Survey suggest that country's TB prevalence has not shown a statistically significant decline in the past 9 years, therefore more health personnel will be needed to find missing cases, initiate patients on treatment and successfully cure them. The DOH has identified the need to improve all aspects of human resources for health including staff development, quality, hiring, and retention. The DOH also recognizes that additional resources are needed at all levels of the health system to maintain sufficient numbers of qualified health personnel.

New and existing health personnel currently do not have the skills and knowledge to implement new DR-TB treatment regimens nor many of the tools needed to shift their approach to more patient-centered, gender-sensitive and respectful care. More health providers need to have the skills and capacity to deliver care that is free from stigma and discrimination.

To improve the performance of health workers, there is a need to develop and put in place a systematic plan and methodology for performance monitoring and evaluation at all levels of the health system that goes beyond data collection and data quality checks. Regular and meaningful encouraging supervision visits should be conducted by appropriate staff who can provide on-the-job training, help solve problems and provide feedback. Follow-up visits should also be conducted to document progress.

Fragmented and inefficient Supply Chain Management and Pharmacovigilance

Uninterrupted supply of quality TB drugs and supplies is a cornerstone of a good TB control program. In recent years, there have been stock-outs of the Purified Protein Derivative used in Tuberculin Skin Testing and there have been problems with the quality and availability of pediatric TB drugs. Procurement issues should be addressed and delivery processes should transition to a pull system. There is also a need to clarify the roles, willingness and ability of DOH Regional Offices and local government units to purchase drugs and supplies. Without a policy in place, stock-outs of streptomycin are a continuing problem for most health facilities.

In addition to pharmaceutical and technology management, proper pharmacovigilance (PV) is a necessary step to provide for the safe use of medications, especially for DR-TB patients because of the number of drugs they take. WHO has created an active drug safety management and

monitoring approach to help NTPs better manage adverse drug reactions among TB patients and record and report these adverse reactions to higher authorities. While the Philippines NTP has introduced an aDSM system, more substantial work is needed to finish the pilot phase and scale it up.

D. KEY RESULTS BY 2022

Listed below are some expected indicators, for which the "TB Innovations and Health Systems Strengthening" activity will need to contribute. The required PPR indicators include:

- Number of multi-drug resistant tuberculosis cases detected
- Number of multi-drug resistant tuberculosis cases that have initiated second line treatment
- Percent of successfully treated multi-drug resistant tuberculosis cases
- Tuberculosis case notification rate, all forms

It is expected that the Recipient will develop an Activity Monitoring and Evaluation Plan (AMEP) that will capture TB indicators at both the national and regional levels. The activity will be expected to contribute to achieving the targets of the PhilSTEP1 and USG TB strategies and provide data that will be reported in the USAID/Philippines annual Performance Plan and Report (PPR). Detailed expected results and indicators are located in Section E.4.c.

The expected results described in Section E below do not replace the Activity Management and Evaluation Plan. *Applicants should propose additional relevant indicators to monitor.*

E. ACTIVITY FRAMEWORK, ASSUMPTIONS AND IMPLEMENTATION PRINCIPLES

1. "TB Innovations and Health Systems Strengthening" Framework

The "TB Innovations and Health Systems Strengthening" activity is designed to strengthen national and regional level implementation of the National TB Strategic Plan by providing state-of-the-art capacity building and technical expertise to scale-up TB and DR-TB prevention, detection and treatment. The activity will support the development of TB strategies, policies and guidelines; build the capacity of the Department of Health (DOH) and regions to implement an effective and responsive national TB program; and develop, design and test new approaches and tools for TB prevention, detection and treatment. The "TB Innovations and Health Systems Strengthening" activity will identify and help implement proven approaches to improve TB prevention, increase TB case detection rates; decrease default rates, and increase TB treatment success rates and TB cure rates.

This activity's interventions will contribute to achieving the Health Project's Sub-purpose 1.1 (improved individual adoption of healthy behaviors), Sub-purpose 1.2 (improved community

ownership/participation in healthy behaviors), Sub-purpose 2.1 (improved quality services through patient-centered approaches), Sub-purpose 2.2 (innovative approaches to improving quality of care tested and rolled out), and Sub-purpose 3.3 (improved fiscal, financing and human resource management). This activity will also contribute to other Sub-purposes in Sub-purpose 3 (key health systems bolstered and institutionalized) by collaborating with other activities that will work on cross-cutting areas. The "TB Innovations and Health Systems Strengthening" activity will provide targeted technical assistance at the national and regional levels based on disease burden and Government of the Philippines priorities. For more information on the 2017-2022 USAID/Philippines Health Project Results Framework, please refer to *Annex C*.

The "TB Innovations and Health Systems Strengthening" activity is intended to bring high-quality international technical expertise to assist the Government of the Philippines to roll out international standards and best practices in TB detection, prevention, and treatment. By developing, testing and documenting new tools and approaches for TB services, the activity will contribute to the evidence base for scaling up promising practices throughout the country. Within the four project objectives described below, the activity will focus on technical areas that include: expanding evidence-based approaches for prevention, case detection, appropriate treatment-seeking behavior and treatment adherence; improving the quality of care for patients with drug-sensitive (DS) and DR-TB; institutionalizing and sustaining partnerships with the private sector for TB prevention, detection and treatment; and bolstering the TB diagnostic network system. The activity will also implement activities to address human resource and financial barriers that prevent quality TB service delivery.

The "TB Innovations and Health Systems Strengthening" activity will focus on four objectives to achieve the expected results described below:

Table 3: Objectives and Expected Results

Objectives	**Expected Results**
Objective 1 - Rapidly expand state-of-the-art case detection, appropriate treatment seeking behavior and treatment adherence interventions for vulnerable and high risk populations	1.1 Strategies for improving case detection, appropriate treatment-seeking behavior and treatment adherence developed and disseminated in the public and non-public sectors 1.2 Innovations and new tools for case detection, appropriate treatment-seeking behavior and treatment adherence developed, tested and adopted 1.3 National and regional Department of Health capacity to implement strategic demand generation policies bolstered

Objective 2 - Integrate and institutionalize high-impact practices to improve TB and DR-TB quality of care for public and non-public sectors	2.1 Comprehensive support policies and practices to reduce transmission of TB and DR-TB and create preventive programs for patients, providers and communities 2.2 Quality of care for adults and children with TB and DR-TB improved through innovative approaches, tools and scaling up treatment with new TB medicines and regimens 2.3 New tools and models for private sector and non-NTP provider engagement established and sustained to contribute to quality treatment outcomes for both TB and DR-TB
Objective 3 - Optimize TB diagnostic networks to utilize existing tools and incorporate innovative approaches	3.1 Comprehensive diagnostic networks for TB and DR-TB detection developed and strengthened 3.2 New diagnostic tools and interventions for rapid TB and DR-TB detection (including XDR-TB) expanded and deployed 3.3 Quality assurance system across all diagnostic platforms and systems established
Objective 4 – Fortify Department of Health system and capacity to implement and effective and responsive national TB program	4.1 Budget planning, execution and utilization as well as engagement with PhilHealth strengthened to sustain investments in TB 4.2 Technical and human resource management capacity of NTP and regional level staff bolstered 4.3 Governance, management and financing of TB private sector and non-NTP partners developed and improved

2. Objectives and Expected Outcomes

Objective 1 - Rapidly expand state-of-the-art case detection, appropriate treatment seeking behavior and treatment adherence interventions for vulnerable and high risk populations

Sub-objective 1.1 Strategies for improving case detection, appropriate treatment-seeking behavior and treatment adherence developed and disseminated

To achieve the End TB and PhilSTEP goals to reduce TB incidence and mortality, the Philippines must evaluate its current approach and dramatically ramp up its strategies to improve case detection, appropriate treatment-seeking behavior and treatment adherence. The Philippines must address the persistent challenges that hamper case finding, particularly barriers related to stigma and discrimination, individual and community understanding and knowledge of TB, lack of engagement of the non-public sector and lack of access to TB diagnostic services. A comprehensive approach to improve TB prevention, diagnosis, treatment and care must consider all aspects of demand generation for TB services. It will be imperative to identify and clearly link community-based TB activities with improved TB notification, treatment adherence and outcomes.

Despite the introduction of various interventions to detect TB cases, encourage people with TB symptoms to seek treatment, and improve patient adherence to treatment, many of these approaches have not been analyzed for their effectiveness or are still in the pilot stage. Comprehensive policies and strategies to generate demand for TB services must be developed using solid evidence and experience at the country and international levels. To achieve the greatest impact, these strategies must define and prioritize specific risk groups, settings and methods of service delivery and should be linked to measurable benchmarks and indicators for monitoring program performance. Best practices of engaging communities, civil society, non-public sector entities and government officials should be documented, consolidated and applied in relevant settings. Evidence-based strategies for reducing stigma and discrimination must also be codified into policies and rigorously implemented. The NTP and the Health Promotion and Communication Service should also develop a process for implementing, monitoring and institutionalizing the operational plans developed as part of these strategies. The activity will support the NTP and Health Promotion and Communication Service at all stages of the process of developing, disseminating and measuring the effectiveness of these strategies, policies and plans.

Illustrative outputs/outcomes:

- New policies and strategies for TB detection, prevention and treatment regimens and innovations developed, disseminated and accelerated
- Linkages between outreach and clinical services to improve case detection, health-seeking behavior and treatment adherence for vulnerable and high risk populations established and institutionalized
- National strategy for TB demand generation developed, disseminated and rolled out
- Healthcare providers and other stakeholders apply best practices and evidence-based approaches to TB case-detection, appropriate treatment seeking behavior and treatment adherence nationwide

Sub-objective 1.2 Innovations and new tools for case detection, appropriate treatment-seeking behavior and treatment adherence developed, tested and adopted

In order to identify and convince the thousands of people with symptoms of TB to seek treatment and receive appropriate care and to reduce stigma, the Philippines must rapidly identify, introduce, and scale up proven innovations, tools, platforms, technologies, and methodologies. Interventions must demonstrate technical rigor, innovation and application of international best practices and standards to address normative, attitudinal barriers and broader health systems and implementation challenges. Well-crafted pilot studies and implementation research projects on health seeking behavior and patient satisfaction will help inform the NTP's overall demand generation strategy.

The activity will provide technical support to the DOH to develop proven, evidence-based and targeted interventions for high risk groups and vulnerable populations. Interventions should include the development and dissemination of tailored communication materials, treatment adherence interventions or support packages for TB patients, and job aids for health providers that include guidance on specific topics such as TB in children, stigma reduction, and finding the missing TB cases among vulnerable populations. All interventions should employ a rigorous approach that includes: a design process that reviews best practices and lessons learned from TB and non-TB health programs; analysis that defines the appropriate role of actors for specific settings and interventions; routine monitoring, supervision and reporting of defined indicators to monitor outputs, deliverables, and impact of the interventions.

Illustrative outputs/outcomes:

- Increased knowledge and evidence base of health-seeking behavior, causes of patient delay to access treatment, patient-centered TB care, patient satisfaction, and patient costs as well as other barriers to treatment
- Pilot studies and implementation research measure effects of demand generation and informs overall national TB strategy
- Outreach solutions designed and deployed to increase prompt treatment initiation and reduce high treatment discontinuation rates
- New evidence-based approaches for case detection and treatment adherence designed, introduced and adopted into national policy
- New approaches to combat stigma and discrimination tested and rolled out
- Patient-centered care interventions (i.e. strategies to reduce out of pocket expenditures, community-based DOTs) tested and adopted into national policy

Sub-objective 1.3 National and regional Department of Health capacity to implement strategic demand generation strategies bolstered

The sustainability, effectiveness and agility of demand generation interventions are dependent upon the people and institutions responsible for implementation. The NTP and the Health Promotion and Communication Service must possess national and regional capabilities for the

formulation, implementation, adaptation, monitoring, and review of evidence-based strategies, policies and plans concerning demand for TB services. The two departments must have expertise to design high-level strategies and develop state-of-the-art, evidence-based materials and resources that will be disseminated to health providers, communities and individuals. Both departments may require support to develop management and administrative capacities to implement demand generation strategies and plans at the national and regional levels. At the national level, the NTP and the Health Promotion and Communication Service should articulate and oversee cohesive strategies and operational plans for case detection, treatment seeking behavior and treatment adherence for vulnerable and high-risk populations. At the regional levels, regional health and health promotion departments should have the capacity for adaptation of national strategies and resources, oversight of regional campaigns, coordination of implementers, and monitoring behavior change communications and social marketing interventions via appropriate channels and approaches. The activity will provide technical assistance to build the skills and capacities of the NTP and Health Promotion and Communication Service in all of the areas described above.

Illustrative outputs/outcomes:

- National and regional DOH (NTP and Health Promotion and Communication Service) staff implement and coordinate evidence-based, gender-sensitive and strategic social and behavior change communication (SBCC) programming for TB detection, prevention and treatment
- National and regional DOH (NTP and Health Promotion and Communication Service) staff analyze data to tailor demand generation TB programs to meet needs of vulnerable populations
- Health providers and supervisors use new methods and interactive approaches to implement demand generation interventions for TB detection, prevention, and adherence to treatment
- SBCC campaign activities reflect both national level strategies, are responsive to local priorities and adhere to defined standards of design and implementation
- National and regional DOH (NTP and Health Promotion and Communication Service) staff oversee, supervise and evaluate implementation of demand generation strategies and plans

Objective 2 - Integrate and institutionalize high-impact practices to improve TB and DR-TB quality of care for public and non-public sectors

Sub-objective 2.1 Comprehensive support policies and practices to reduce transmission of TB and DR-TB and create preventive programs for patients, providers and communities

In order to eliminate TB in the Philippines, bold steps must be taken to address the problem at its roots and across sectors. Socioeconomic factors such as poverty and overcrowded living conditions can play an equally important role as lack of access to health care in spreading the disease. Government agencies in addition to the entire Department of Health, must consider how to integrate TB policies and guidelines into their operations and across programs. Some

examples of policies and guidelines are in Box 4. The activity will assist the NTP and the DOH to identify, advocate for and implement multi-sectoral approaches and policies which can have an immediate impact on reducing the spread of TB.

Box 4: Suggested TB Policies and Guidelines

- Standard TB diagnosis and reporting guidelines for high risk groups such as smokers, diabetics, people living with HIV (PLHIV), children, and elderly populations
- Policies for routine screening for latent TB infection (LTBI) and TB chemoprophylaxis among health staff as well as close contacts of TB patients
- Best practices and guidelines for engagement with local government units, communities, private companies and employers, private providers, patients groups and other stakeholders
- Policy to include TB patients as beneficiaries in social welfare programs such as the "4Ps" program (*Pantawid Pamilyang Pilipino Program*)
- Department of Social Welfare and Development (DSWD) policy on TB control in congregate settings
- Bureau of Jail Management and Penology (BJMP) and Department of the Interior and Local Government (DILG) guidelines on overcrowding in jails and prisons and ensuring proper isolation of diagnosed TB patients to prevent further transmission
- National Disaster Risk Reduction and Management Council (NDDRMC) policy to include TB commodities in its prepositioning for disasters
- National policies and plans in place to maintain TB prevention, care and treatment services during disasters and other humanitarian emergencies
- Policies for Philippine Overseas Employment Agency and Department of Labor and Employment to mandate all institutions providing pre-employment medical services to notify diagnosed TB patients

The NTP is taking action to decentralize all TB services with the goal to fully integrate these services into the comprehensive primary health care system. All primary health care providers should include TB screening for all of their patients during every encounter. TB screening is particularly important for children and can be easily incorporated into maternal, child health and nutrition visits. A challenge will be to ensure that core TB prevention, care, and control functions are not compromised as decentralization and integration are rolled out. The NTP may need technical assistance on all aspects of integrating DR-TB services including development and implementation of policies and guidelines; continued capacity building and support of health providers; expansion of community-based and other decentralized service delivery models; improving treatment adherence and outcomes; and accurate reporting, monitoring and supervision systems.

Under the PhilSTEP, the NTP must develop, disseminate and rapidly scale up a wide range of strategies, policies and guidelines to prevent, detect and treat TB. Routine screening for latent TB infection (LTBI) and TB chemoprophylaxis among health staff as well as close contacts of TB patients must be enhanced and scaled up. Health providers need improved job aids and

motivation to actively identify and provide services to adults and children who are close contacts of TB patients. Infection control policies and practices in health facilities and congregate settings need to be developed and implemented using international best practices and guidelines. When new LTBI regimens are recommended by WHO, the NTP will need to develop policies and plans for introduction and expansion. The activity will play an important role assisting the NTP in all of these areas. The activity will also assist the DOH and NTP to document national and international best practices in integrated TB care and incorporate them into guidelines and policies that will be implemented nationwide.

Illustrative outputs/outcomes:

- NTP and other GPH departments develop, disseminate and monitor implementation of comprehensive TB policies and guidelines that reduce TB transmission and improve prevention programs. (Please also see Box 4 for example of guidelines and policies)
- Latent TB infection screening and chemoprophylaxis among high risk and vulnerable groups expanded nationwide (NAP)
- Healthcare workers and close contacts of TB patients routinely screened at health service delivery points (NAP)
- WHO standards and benchmarks to support TB surveillance implemented (NAP)
- National and regional infection control plans developed and implemented (NAP)

Sub-objective 2.2 Quality of care for adults and children with TB and DR-TB improved through innovative approaches and tools and scaling up treatment with new TB medicines and regimens

The Philippines must rapidly scale up powerful new technologies and tools that can dramatically improve adherence to treatment, improve quality of care and as a result, reduce the spread of TB. The NTP will soon expand nationwide the availability of new TB drugs such as bedaquiline and delamanid as well as the shorter treatment regimen for DR-TB (SSTR). Comprehensive technical assistance will be needed to increase enrollment in the SSTR and reduce lost to follow up (LTFU) rates. To improve the quality of care, USAID has developed a standard DR-TB care package tool and guide, which will need to be adapted, scaled up and used for all TB patients. The NTP will also need to assure availability and access to pediatric drug formulations (both for treatment of active TB disease and latent TB infection) and improve adherence and completion of these new treatments. To accompany the roll out of new regimens and drugs, the NTP will need to develop principles and algorithms for active TB drug safety management and monitoring implementation in clinical practice. The NTP will also need support to establish linkages and collaboration between the NTP and pharmaceutical division of the DOH to ensure that all DR-TB patients are managed according to aDSM standards and that all serious adverse events (SAEs) are reported.

Using evidence-based approaches and appropriate tools, the activity shall assist the NTP to strengthen quality TB and DR-TB treatment systems including appropriate patient monitoring, better management of adverse events, and functional pharmacovigilance. It shall support analysis

to assess shorter, less toxic, and more effective DR-TB regimens using existing drugs and evaluate new, shorter TB and DR-TB regimens containing new anti-TB drugs. When new TB regimens are recommended by WHO, this activity shall support the NTP to develop policies and plans for introduction and expansion. The activity is also expected to pilot and test methods to increase enrollment in treatment and measure quality of TB care by determining patient perceptions of quality. The activity may also pilot and document processes for establishing patient support groups to inform national guidelines and procedures.

Illustrative outputs/outcomes:

- Primary health care staff provide efficient and quality integrated TB and DR-TB services
- New treatment regimens for DR-TB have been scaled up nationwide, including shorter regimen, and new anti-TB medications (such as BDQ and DLM)
- New strategies and systems to accelerate enrollment on DR-TB care tested and integrated nationwide
- Essential package of DR-TB services to improve quality of care has been piloted and scaled up (NAP)
- New tools to improve adherence to TB treatment piloted and evaluated
- New information, communication and technologies to improve TB detection, prevention, care and adherence tested, evaluated and scaled up
- TB pharmacovigilance system (aDSM) tested and implemented for all DR-TB patients
- Improved monitoring system for TB and DR-TB treatment sites implemented and institutionalized
- DR-TB patient records and registers are integrated into standard NTP reporting

Sub-objective 2.3 New tools and models for private sector and non-NTP provider engagement established and sustained to contribute to quality treatment outcomes for both TB and DRTB

The Philippines' Department of Health estimates that over a third of Filipinos seek services for TB from the private sector, and the NTP estimates that the majority of the missing TB cases are likely in this sector. Recognizing that this is a significant issue, one of the main principles of the PhilSTEP is the engagement of the private sector, civil society organizations, and communities in order to accelerate early diagnosis and strengthen treatment outcomes achieved by all care providers. More intensive community-based TB services are needed to strengthen TB and DR-TB service delivery and to optimize the participation of the community in prevention, case-finding, and care and treatment of patients as well as in treatment adherence and interrupter tracing.

Although many Public Private Mix pilots have been implemented, institutionalization of PPM practices has been difficult to sustain once these projects have ended. This activity will need to determine what has and has not worked, and then will need to build upon these models to determine what should actually be piloted and implemented. The activity should consider how to

shift the perceptions of the private sector by the public sector and vice versa to enable them to better understand each other and improve coordination. For example, this activity should specifically consider how both curative and public health functions (including reporting, adherence monitoring, and contact investigation) are funded, and consider using innovative payment mechanisms, incentive structures or support organizations to motivate or facilitate the private sector and non-NTP providers to deliver on these public health functions. Since the quality of care, including treatment outcomes, can often be a challenge with private providers, these interventions should include mechanisms and safeguards to promote and regulate quality treatment standards, especially with regard to the regulation of TB drugs being sold in the private sector. The activity should also consider the appropriate monitoring and recording tools needed to improve treatment outcomes in the private sector. Finally, this activity will need to provide assistance to the DOH and NTP to create the conditions for PPM sustainability and expansion.

Illustrative outputs/outcomes:

- Country-wide action plan for engagement of private and public non-NTP providers, based on the WHO/USAID tool for PPM action plans, rolled out and implemented
- Private and non-NTP providers utilized DOH/NTP standards and guidelines to provide quality TB and DR-TB health services
- Private sector providers as well as providers outside of NTP network increased detection of new cases
- Mandatory case notification system developed, introduced and implemented nationwide
- NTP recording and reporting system expanded to cover non-NTP providers
- Policies, operational plans and guidelines developed and disseminated to support provision of TB services through the private sector
- Supervision and monitoring systems for private sector and non-NTP providers developed, tested and rolled out nationwide
- Evidence-based models of provision of TB services through the private sector introduced and scaled up
- Evidence-based guidelines and sustainability strategy for building partnerships with professional, community-based and other organizations developed and applied nationwide
- Information, communication and technology platforms and digital tools to facilitate reporting and monitoring by the private sector tested, rolled out and integrated into national systems

Objective 3 - Optimize TB diagnostic networks to utilize existing tools and incorporate innovative approaches

Sub-objective 3.1 Comprehensive diagnostic networks for TB and DR-TB detection developed and strengthened

A functional, comprehensive and high-quality laboratory and diagnostic network is essential for maintaining a successful TB program. Diagnostic networks should have adequate specimen collection and transport systems, sufficient quantity and appropriate management of quality diagnostic equipment and supplies, trained personnel deployed throughout the system, and timely reporting of results and initiation on treatment. These networks should be designed to meet patient needs and be flexible and responsive to expand access to services. Approaches to strengthening laboratories must be comprehensive and strategic to address programmatic gaps at different levels of the system and these should be aligned with internationally recommended policies, tools and standards. In designing diagnostic networks, policymakers must look beyond the public sector and consider the private sector and other non-public sector actors who could deliver these services.

The development and establishment of an organizational framework and operational plan for patient-centered TB diagnostic and laboratory networks should be an immediate priority for the National TB Program. All aspects of the TB laboratory and diagnostic support system should be considered including human resources, certification and evaluation, maintenance, accreditation, quality assurance, and most importantly, improving patient access to services. The activity will support the National TB Reference Laboratory (NTRL) to develop and implement a strategy for engaging private/non-NTP laboratories and providers with the information, tools, training and financing schemes needed to support high-quality diagnostic services. The activity will also support the Department of Health and National TB Reference Laboratory to develop and enhance the policy, management, supervisory and quality assurance systems for smear microscopy, culture, drug susceptibility testing, GeneXpert, chest X-rays and all other new diagnostics. Biosafety, including internationally-recommended processes for infection control within TB laboratories and facilities should be introduced and made part of routine practice. Commodities management systems to ensure quality and appropriate diagnostic equipment and supplies should be in place.

Illustrative outputs/outcomes:

- National and regional laboratory strategic and operational plans developed/revised and implemented
- Mapping of diagnostic networks completed, including specimen transport, human resources, and placement of diagnostics
- Institutional roles and responsibilities established and documented for diagnostic and laboratory services
- Approaches to integrate private/non-NTP laboratories and providers are developed and piloted
- The time from specimen collection to treatment action is reduced throughout each level of the diagnostic network
- Local capacity to strengthen and maintain TB diagnostic networks is established
- All laboratories implement standardized waste disposal practices

- Biosafety processes and guidelines implemented
- Uninterrupted supply of GeneXpert cartridges, laboratory reagents and supplies

Sub-objective 3.2 New diagnostic tools and interventions for rapid TB and DR TB detection (including XDR-TB) expanded and deployed

New diagnostic and molecular technologies are transforming and improving detection and diagnosis of TB and MDR TB. In the Philippines, these new technologies, particularly GeneXpert, will be expanded and scaled up nationwide. The NTP and NTRL will require significant technical assistance to deploy and maintain its planned network of 3,000 GeneXpert as well as 3 to5 LPA machines to test for second-line drug resistance. It is necessary to identify the diagnostic network and health system challenges that prevent optimal utilization and uptake of each technology, including GeneXpert and Hain Genotype MTBDRplus Line Probe Assay tests. National and international diagnostic network and laboratory strengthening guidance and tools should be incorporated into routine practice. New TB and DR-TB diagnostic algorithms utilizing the best combination of diagnostic tools must be developed and implemented using international guidelines and standards. Electronic platforms or mobile health solutions that allow real-time specimen tracking and results reporting should be adapted to ensure that bacteriologically confirmed patients are rapidly initiated on appropriate treatment. Last but not least, the NTP and NTRL will need assistance to rapidly transfer and apply skills and knowledge of new technologies throughout the national and regional levels.

Illustrative outputs/outcomes:

- GeneXpert operational plan integrated into laboratory network systems
- GeneXpert machines distributed, deployed and optimally utilized
- Quality-assured DST and second line LPA labs established
- New technologies to link diagnosis and patient treatment/case management systems deployed nationwide
- Diagnostic algorithms, based on new WHO guidance, revised and disseminated nationwide
- New approaches to increase access to diagnostic services identified and piloted
- Effective and efficient (and integrated where appropriate) specimen transport systems developed, tested and deployed nationwide

Sub-objective 3.3 Quality assurance system across all diagnostic platforms and systems established

An essential element to maintaining the integrity of the TB diagnostic and laboratory system is consistency and quality of services and results. Successful TB programs must have quality-assured laboratories that are capable of diagnosing and monitoring DS and DR-TB consistent with international standards. Strong diagnostic networks should have adequate supervision, quality assurance, and robust monitoring, evaluation, data collection and analysis at every level.

Reliable supply chains are also needed to ensure uninterrupted supply of reagents and other commodities. Continuous quality improvement (CQI) approaches should be developed and/or strengthened for all diagnostic technologies, including external quality assurance (EQA). Feedback mechanisms will be in place to make timely improvements to improve TB laboratory services. The activity will support the NTP and NTRL to assess the efficacy of existing quality assurance systems and bolster the current monitoring and evaluation system for both public and non-NTP laboratories.

Illustrative outputs/outcomes:

- All TB laboratory tests, including culture, DST, GeneXpert and LPA met national and international quality standards
- Continuous quality improvement system fully implemented throughout the diagnostic, including private/non-NTP laboratories
- Laboratory recording and reporting processes improved and standardized
- Laboratory monitoring and supervision systems established

Objective 4 – Fortify Department of Health system and capacity to implement an effective and responsive national TB program

Sub-objective 4.1 Budget planning, execution and utilization as well as engagement with PhilHealth strengthened to sustain investments in TB

Improving the allocation, efficiency, and utilization of government funding for TB is essential for the success and future sustainability of the TB program. The Government of the Philippines, the DOH and all relevant stakeholders must start immediately to systematically address each financing bottleneck that impacts the delivery and sustainability of TB prevention, care and treatment services. Of paramount concern is the need for consistent and sustained TB financing at the national, regional and decentralized levels. The new TB law offers opportunities to codify and recommend appropriate levels of TB funding across many agencies and at the local government unit level. The DOH should also consider how it can collaborate with other government agencies such as the Department of Interior and Local Government (DILG) and the Department of Social Welfare and Development (DSWD) to access resources for TB patients and their families. PhilHealth is another important resource but deeper engagement and technical assistance is needed to improve funding and reimbursement for TB and DR-TB services. Lastly, the DOH must develop and begin implementation of a financing strategic plan that takes into consideration the eventual phase out or reduction of Global Fund and other donor support by 2020. An equally important consideration is the need for the DOH and LGUs to efficiently use existing resources and develop strategies to disburse and use funds given system challenges. The NTP may need support identifying and using mechanisms to support implementation of the TB program. The incorporation of a new TB module into the National Health Accounts could be a powerful tool for measuring and tracking expenditures on TB.

The activity will play a critical role assisting the DOH and the NTP to develop and implement a strategic and operational plan for TB financing. The activity will bring state of the art technical assistance and capacity building support to address these bottlenecks and help transition the government to new sources and expanded government financing by 2020.

Illustrative outputs/outcomes:

- TB program is fully integrated into Philippine Health Agenda and prioritized
- Agencies contribute a fixed percentage of budgets to the TB program
- TB line-item budgets are sustained and increased at central and regional levels
- National health accounts include a TB module and TB expenditures are assessed annually
- DOH implements transition plan for Global Fund exit or reduction
- PhilHealth implements an adequate TB reimbursement package for all types of TB
- New sources and partnerships for TB financing mobilized
- LGUs implement bottom-up budgeting for TB projects based on DOH guidance
- TB patients reduce average out-of-pocket expenditures due to new financing mechanisms
- New approaches designed, tested and introduced to increase governance and ownership of TB at decentralized levels

Sub-objective 4.2 Technical and human resource management capacity of NTP and regional level staff bolstered

An effective national TB program should have sufficient, capable and well-trained staff located at every level of the health system. At the central level, TB experts and policy makers should have access to and knowledge of the latest developments in the international sphere and the technical expertise to adapt, guide and administer the program to meet these international standards. At decentralized levels, TB staff and administrators should have the capacity and skills to understand, apply and tailor national guidance and policies to fit the needs of their particular region, province or locality. Health providers must have adequate training, resources and compensation to provide quality, patient-centered TB services. All individuals must understand the complexities of their work environment and the resources that can be deployed to help achieve program results. They all must be able to assess and analyze data and adapt their programs to improve these results.

Perhaps the most important challenges for the DOH, the NTP and NTRL will be to develop strategies to fill the many staffing gaps for TB services at every level of the health system and transition approximately 750 donor-funded health personnel to other funding mechanisms without harming the TB program. Another priority is to clearly delineate the roles and responsibilities of all of the actors who support the TB program, namely the NTP, NTRL, FDA, and other departments within the DOH. Working in partnership with the DOH, Department of Budget and Management (DBM), LGUs and other policymakers, the NTP must develop national policies and plans for sustaining and transitioning their TB workforce; streamline human

resource functions by integrating disease management at the primary health care level; shifts tasks and responsibilities to make best possible use of available staff; implement decentralized TB treatment via households, communities, and technologies; and develop comprehensive approaches to pre-service and in-service training. The NTP will also need to analyze and study, via operations research, which models are best suited to different settings.

Under this sub-objective, the activity will support the DOH and the NTP to address the many human resources challenges that impact the provision of sustainable and high-quality TB detection, prevention, care and treatment services. The activity shall provide technical support to build the capacity of the NTP, NTRL and regional TB staff to oversee the TB program. This may involve seconding staff to build and institutionalize capacities at the national and regional levels. A priority will be to support the DOH to establish, institutionalize and put into practice the tasks and responsibilities of key TB stakeholders. The activity will also identify the highest impact human resources interventions that will result in sustainable and improved TB service delivery in the short, medium and long-term. At a minimum, the activity should support the NTP to develop systems, tools and processes that facilitate increased knowledge and skills of TB service providers and maintain quality at all levels of the system. The activity will not be focused on delivering training, rather, it will support the design of monitoring and supervision programs and other approaches that build and maintain health worker skills.

Illustrative outputs/outcomes:

- National and regional NTP staff implement and oversee a world class national TB program that adheres to national and international standards and best practices
- National and regional NTP staff collect, analyze and use TB data to adapt and adjust program to ensure quality services are delivered nationwide
- Roles and responsibilities, including supervisory and reporting responsibilities, are clearly delineated and understood for all TB personnel nationwide for both laboratory and treatment functions
- NTP and NTRL roles and responsibilities are delineated in national policies and guidelines and applied
- DOH/NTP transitions partner-funded TB workforce into the health system
- Human resource allocations/deployment for TB increased and rationalized
- Supervision system, policy and guidelines implemented nationwide
- System of formal continuing education implemented for TB staff at all levels
- TB curriculum in medical and paramedical schools reviewed and updated
- New models to build capacity and transfer skills piloted, tested and implemented nationwide
- Decentralized DR-TB services are delivered by trained, competent and confident HCWs

Sub-objective 4.3 TB governance, management and financing of the private sector and non-NTP partners developed and improved

The elimination of TB in the Philippines will not succeed unless there is a transformation in how the public sector engages and maximizes support from private and non-NTP partners. Public Private Mix interventions can only be sustained by strengthening governance and stewardship, assuring sustainable financing, and conducting routine monitoring and evaluation. There is a strong need to prepare an overarching policy document that clarifies the stewardship role of the NTP to ensure high-quality care for TB symptomatics and patients in both the public and private sectors. The DOH must develop explicit policies articulating the acceptance of private sector engagement as a long-term sustainability option. At the same time, the DOH will need assistance to develop sustainable financing mechanisms, such as expansion of access to PhilHealth empanelment, to cement this engagement. Regulatory tools related to TB including mandatory notification, and certification and accreditation requirements will be needed – both for the development of policies and for enforcement. Public sector staff will also need to build the skills and capacity to oversee, manage and supervise private and non-NTP providers. Direct engagement with professional associations will be particularly critical, since these organizations can link the public and private sectors in the longer term.

The activity will play a vital role assisting the DOH in transforming its relationship with the private and non-public sector. The activity will support an updated institutional analysis to map opportunities and threats. The activity will provide technical assistance to strengthen institutional structures and systems and build the skills and capacity of DOH staff to manage and oversee private sector partners. The activity will also support the development of governance, regulatory and financial tools. Another important area will be to conduct operations research to assess and analyze the effectiveness and sustainability of different interventions.

Illustrative results and outcomes:

- Development, dissemination and implementation of new policies that expand the role of the private sector in TB detection, care and treatment
- DOH and NTP staff apply regulatory tools and resources to oversee, regulate and manage TB detection and service delivery
- Sustainability plan for private sector engagement in place and implemented for both national and regional levels
- Funding barriers and policies analyzed and addressed as needed, resulting in more private providers engaged in TB diagnosis and treatment
- Sustainable financing mechanisms for private sector engagement tested, rolled out and integrated into national systems
- Effective payment mechanisms and partnership models to improve delivery of TB services by non-NTP providers tested, documented and institutionalized
- New policies and approaches increase private providers access to PhilHealth accreditation and empanelment
- Guidelines, tools and communication materials for partnership building with professional organizations, government and non-government organizations, academe, workplaces to expand the service delivery network developed and disseminated
- Improved knowledge and evidence base of effective regulatory and governance interventions for private sector engagement

3. Key Assumptions

Applicants are encouraged to discuss how their technical approaches will respond to the evolving nature of the health sector. The following are a few key assumptions that should be considered:

a. The Government of the Philippines (GPH) continues to prioritize the NTP as part of the Philippine Health Agenda.
b. The Government of the Philippines enforces the provisions of RA 170769 and delivers on its commitment to implement the Philippine Strategic TB Elimination Plan.
c. The Global Fund implementation of a three year (2018-2020) grant functions and fills critical gaps in the NTP activities.
d. PhilHealth continues to finance TB programs.
e. The U.S. assistance for TB remains stable, at a minimum.

4. Implementation Principles

a. Innovative and Health Systems Focused

Box 5: Standard Principles for TB Innovations and Health Systems Strengthening Activity

- Aligned with Philippines and USG Priorities
- Innovative and Health Systems Focused
- Patient-Centered
- Focus on sustainability and institutionalization
- Data-driven approach
- Geographically focused
- Gender-sensitive and gender-transformative
- Coordination and collaboration with all partners

USAID defines innovation as novel business or organizational models, operational processes, or products or services that lead to substantial improvements in addressing development challenges. Innovation may incorporate science and technology but is often broader and may include new processes or business models.[4] Under the "TB Innovations and Health Systems Strengthening" activity, USAID considers innovation to be a key tool that will help to achieve sustainable and efficient solutions while respecting the fundamental values of inclusiveness, equity, patient-centeredness and access to high quality, effective and safe TB services. While there have been some advances in TB diagnosis and treatment in recent years, the models used to deliver these services often do not put the patient at the center. Innovative models and processes should focus on understanding patients' needs and creating value for all TB stakeholders, including TB patients, their families, the national TB program, and other partners. The innovations introduced by the "TB Innovations and Health Systems Strengthening" activity should bolster health outcomes, create new service delivery approaches, empower patients, strengthen the

[4] www.usaid.gov, Innovation in Development

relationships between patients and their healthcare providers, and make services more affordable and accessible to the patient. Most importantly, they must be sustainable so that patient-centered TB services can be continued in the future.

USAID's overarching goal for health systems strengthening is to partner with countries to provide sustained, equitable access to essential, high-quality health services responsive to people's needs without financial hardship, thereby protecting poor and underserved people from illness, death, and extreme poverty.[5] In order to achieve this overarching goal, USAID implements four strategic outcomes: financial protection, essential services, population coverage, and responsiveness. These outcomes are aligned with the six health system building blocks identified by the WHO: service delivery, health workforce, health/strategic information, access to essential medicines, health financing, and leadership and governance. All interventions conducted under the "TB Innovations and Health Systems Strengthening" activity should directly contribute to the achievement of sustained equitable access to responsive high-quality TB services without financial hardship.

b. Patient-Centered Care Approach

The patient-centered care approach of the WHO TB strategy consists of enabling patients to exercise their rights and fulfill their responsibilities with transparency, respect and dignity, by giving due consideration to their values and needs. Patient-centered care treats the patient as a partner instead of just a recipient, empowering patients and providers and allowing for empowered individuals. This leads to a higher likelihood of successful treatment outcomes, improved wellbeing, and financial risk protection by improving adherence to treatment.[6] The "TB Innovations and Health Systems Strengthening" activity will consider patient needs first in order to design interventions and approaches to best address their needs.

Successful patient-centered care requires strong interpersonal and behavior change communication at all levels of the health system and among individuals, communities, and providers in order to transform how health services are accessed and delivered. For example, success will be measured by the number of individuals and communities who have the knowledge and awareness to get tested for TB, start treatment, and complete the course of treatment. Health providers and health facilities will possess the skills and knowledge to routinely provide quality, patient-friendly, respectful and gender-sensitive services without stigma and discrimination. At the health systems level, national policies, guidelines and processes will take into consideration the needs of patients and clients and are designed to provide respectful and patient-centered care. Social and behavior change communication

[5] USAID's Vision for Health Systems Strengthening (2015-2019)
https://www.usaid.gov/sites/default/files/documents/1864/HSS-Vision.pdf
[6] TB CARE I and USAID. "Patient-Centered Approach".
http://www.challengetb.org/publications/tools/ua/TB_CARE_I_Patient_Centered_Approach.pdf

interventions must therefore be designed with these individual, community, provider and system level needs in mind.

Box 6: Core Values of Patient-Centered Care

Some core values of a patient-centered care approach include:

- universal access to care and support
- consideration for needs, perspectives, and individual experiences
- respect for the right to be informed and receive the best quality of care based on individual needs
- established of mutual trust and partnership in the patient-care provider relationship
- create opportunity to provide input into and participate in the planning and management of own care
- empowerment and activation to increase self-efficacy, independence, and involvement at all levels

c. Data-driven approach

High-quality data about the TB epidemic is central for the development of sound interventions and for making informed decisions. For TB care, health providers and program managers use information to identify causes and contributing factors to the spread of TB and to identify effective health promotion interventions to boost TB programs and outcomes. For TB interventions to be successful, they must be based on the best available data to inform planning frameworks and interventions, and subsequently to systematically engage the community and other stakeholders. All interventions must be evidence-based, their effectiveness must be evaluated and their cost-efficiency analyzed, if possible. Pre- and post-intervention analyses are also important. Conducting regular monitoring of activities to identify areas where expected outputs are not being met or where quality may need improvement and sound evaluation of interventions to determine which merit scale up are also part of this approach.

Additional information about how the activity will be expected to work with other implementing partners and donors to achieve these results is discussed in greater detail in Section F - Partner and Donor Coordination and in Section K - Monitoring, Evaluation and Learning.

Specific results to be achieved:

Level 1: The “TB Innovations and Health Systems Strengthening” activity will be expected to contribute to achieving the results below. Most of these indicators are collected and reported on by the National TB Program.

PhilSTEP1 indicators to be achieved by 2022[7]:

- Reduce number of TB deaths by 50 percent from 14,000 to 7,000 deaths
- Reduce the TB incidence rate from 322/100,000 to 243/100,000
- Increase TB treatment success rate among drug sensitive TB from 55 percent to 95 percent
- Improve treatment success rate among drug resistant TB patients to achieve 85 percent
- Reduce to zero the percentage of TB affected households that experience catastrophic costs due to TB
- At least 90 percent of patients are satisfied with services from DOTS facilities
- Increase coverage for latent TB infection screening for household child contacts from 14 percent to 90 percent
- At least 90 percent of DOTS facilities that are providing integrated patient-centered TB care and prevention services

Performance Plan and Report (PPR) and USG TB Strategy indicators include:

- Number of multi-drug resistant TB cases detected
- Percent of successfully treated multidrug-resistant TB cases
- TB case notification rate, all forms
- Number of multi-drug resistant tuberculosis cases that have initiated second line treatment.

Level 2: The "TB Innovations and Health Systems Strengthening" activity will be expected to report on activity specific indicators. Some suggested indicators are listed below. The applicant is encouraged to develop additional indicators that will measure activity results.

- Number and percent of notified TB cases, all forms, contributed by non-NTP private providers (e.g., GPs, specialists, private hospitals)
- Percent of all notified TB cases from non-NTP private providers that come from schemes that do not require external, donor support {denominator for this indicator is the same as the numerator from the indicator above}
- Reduction in time between duration of symptom/s to medical consultation
- Reduction in time between TB diagnosis to enrollment in treatment
- Percent of coverage for latent TB infection screening for household child contacts
- Reduction in treatment interruptions for DS and DR-TB patients
- Number/Percent of TB patients accessing a support package of services
- Number of DR-TB patients provided with shorter treatment regimen
- Number of DR-TB cases enrolled on BDQ-containing regimen
- Number of SAE reported for DR-TB patients

[7] PhilSTEP indicators may change based on the results of the 2016 National TB Prevalence Survey.

- Percent of newly notified TB patients tested using WHO-recommended rapid tests
- Percent of DR-TB patients who undergo drug susceptibility testing
- Percent of annual TB budget disbursed or executed by NTP and Regional Health Offices
- Percent of supervising units (province and region) conducting regular monitoring site visits to conduct supportive supervision
- Number/percent of private providers accessing TB financing schemes
- Percent of TB patients whose treatment was reimbursed by PhilHealth

F. PARTNER AND DONOR COORDINATION AND IMPLEMENTATION ARRANGEMENTS

To achieve the objectives and targets of the PhilSTEP1, close coordination between the National TB Program, the Global Fund Principal Recipient and other USAID activities will be essential. The "TB Innovations and Health Systems Strengthening" activity must prioritize work to align interventions with, complement, and fortify the activities of other partners and the DOH. The activity will participate in established NTP or USAID-led coordination mechanisms including, but not limited to: annual technical assistance harmonization meetings; USAID implementing partner and expanded technical assistance partner meetings; technical working groups; and regional, provincial, LGU, barangay coordination meetings among others. Should this activity work in the same location (e.g., region, province, LGU, barangay, health facility or RHU) as another USAID activity or partner, the "TB Innovations and Health Systems Strengthening" activity must make every effort to jointly plan work, implement interventions and if appropriate, provide complementary assistance.

TB Innovations and Health Systems Strengthening - The "TB Innovations and Health Systems Strengthening" activity will be the lead USAID partner for helping to coordinate TB interventions at the national and regional levels. Given that many USAID-funded and Global Fund partners will be providing technical expertise to the NTP at the national level, close coordination and delineation of areas of responsibility will be critical. At both the national and regional levels, "TB Innovations and Health Systems Strengthening" will provide assistance to the NTP to organize and expand coordination among implementing partners. This activity is expected to closely collaborate with all partners who are working on related health systems strengthening interventions such as those that address governance and finance, human resources and TB supply chain management. The activity will also need to collaborate with USAID-funded activities that are working on related aspects under this funding opportunity, particularly for laboratory strengthening and scaling up the shortened DR-TB treatment regimen. The activity may test and put in place new approaches at the regional, provincial and community levels, collaborating closely with the "Patient-Centered TB Care" activity.

Patient-Centered TB Care - The "Patient-Centered TB Care" activity will be expected to help scale-up and institutionalize the new approaches and models pioneered and developed by the "TB Innovations and Health Systems Strengthening" activity in the regions and provinces where it is working. This activity will also play an important role putting in place and helping to roll out national policies, guidelines and approaches. The activity will inform the development of and report on execution of national strategies and plans through their experience on the ground and at lower levels of the health system. Therefore, the "Patient-Centered TB Care" activity will be expected to participate in national-level and in regional-level planning and coordination meetings to shed light on implementation issues, challenges, and opportunities on the ground.

TB Innovations and Patient-Centered Care Coordination - The "Patient-Centered TB Care" activity will be expected to host an international expatriate TB and DR-TB technical expert throughout the life of the project, who will be funded by and seconded from the "TB Innovations and Health Systems Strengthening" activity. The seconded technical expert will be expected to provide technical expertise and be fully incorporated into daily operations of the "Patient-Centered TB Care" activity. The technical expert will serve as a bridge between the two activities to foster coordination and harmonization of interventions.

While most USAID-backed TB activities will have distinct technical areas and/or distinct government counterparts, USAID implementing partners may work on the same technical issue or with the same government counterpart. An important nexus for coordination between the "Patient-Centered TB Care" and "TB Innovations and Health Systems Strengthening" activities will be in the regions where both partners are providing capacity-building support. Both partners will need to coordinate with the regional offices to determine appropriate roles and responsibilities and assure that activities are not duplicative. In most cases, the "TB Innovations and Health Systems Strengthening" activity will be the lead partner for coordinating the activities of different partners at the regional level.

The "Patient-Centered TB Care" activity must closely coordinate USAID-funded TB activities in the provinces and communities in which it will work. Should TB-related activities be introduced by other USAID implementing partners in those same provinces and communities, that partner must coordinate with the "Patient-Centered TB Care" activity.

For more information about USAID's planned health activities please see *Annex A.*

Coordination with the Global Fund to Fight AIDS, TB and Malaria - The United States is Global Fund's largest donor and also provides funding for oversight and execution of Global Fund grants. By collaborating with the Global Fund, the U.S. Government seeks to catalyze contributions from other donors, expand the reach of U.S. Government bilateral programs, promote country ownership and improve the sustainability of national health programs.

The Global Fund provides countries with predictable, performance-based financing and USAID strives to expand the engagement and coordination of its programs with their Global Fund counterparts to bolster results to build country-level capacity to design and operationalize sustainable programs that meet citizens' needs. The relationship between the Global Fund and USAID involves close coordination of resources so that funding and programs are complementary and not duplicative. This activity is expected to provide technical expertise and wrap-around technical support to the Global Fund Principal Recipient. Regular meetings and joint work planning and monitoring visits will be essential. Please see *Annex D* for more information about how USAID and Global Fund activities will assist the Department of Health.

G. GEOGRAPHIC FOCUS

The "TB Innovations and Health Systems Strengthening" activity will operate primarily at the national and regional levels. Regions will be selected based on the geographic areas with the highest TB burden (i.e., regions with the highest number of estimated TB cases in 2016). Throughout the life of the activity as new data become available, USAID, in collaboration with the DOH and NTP, may identify other geographic areas where the TB burden is high and where the need for technical assistance and capacity building is greatest to focus TB interventions.

Given the currently available TB burden data, USAID, in collaboration with the NTP, will work with the Recipient to prioritize activity interventions in two to three regions at the beginning of the activity. In some cases, the activity may test models or conduct activities below the regional level in facilities, cities or provinces.

The activity will be expected to coordinate closely with the NTP, USAID and other partners to select regions and sites, determine specific interventions, and agree on principles of engagement in order to maximize efficiency of investments in TB. More information about activity collaboration is located in Section F. Partner and Donor Coordination. Please also see *Annex B* for statistics about TB.

H. GENDER CONSIDERATIONS

USAID/Philippines staff completed a Gender analysis to inform the design of new activities for the Philippines Health Project. Key findings related to tuberculosis detection, prevention, treatment and care from the analysis are summarized here. A full description of expected approaches for Gender is located in *Annex E*.

In the Philippines, TB is twice as common among males compared to females. Men and women may also experience different risk factors and exposure to TB, which can be addressed through gender-sensitive tailored interventions. Determinants and differences in accessing TB knowledge, decision-making to seek care and preferred health care site are other important

gender-related factors. Once an individual decides to seek care, subsequent barriers to care also differ: women may lack the financial resources or autonomy to visit a clinic and/or men may be unable to miss work to attend a clinic during regular hours. Adherence and treatment success rates may also differ between the two sexes.

The success of TB programs and progress towards the elimination of TB requires gender-sensitive and gender-transformative programming because it is important for delivering patient-centered care. USAID expects the applicant to delve into the gender-based differences related to TB in order to thoughtfully design, execute and monitor interventions that most effectively reach target groups while contributing to equitable access to quality care.

The "TB Innovations and Health Systems Strengthening" activity is expected to contribute to reducing gender disparities in accessing and benefitting from tuberculosis care and treatment services. As gender barriers often prevent men and boys from seeking services, this activity is expected to transform negative masculinities that prevent men and boys from taking care of their own health. To a lesser extent, the activity is encouraged to contribute to empowering and increasing the capability of women and girls to realize their right to seek healthcare services and to influence decision-making regarding health care.

To provide greater focus on gender equality and women's empowerment in this activity, the activity will prepare a Gender Action Plan that, among others, will include the following:

- Collection of sex-disaggregated data and monitoring of all people-level indicators and use of gender analysis tools to identify potential gender gaps and constraints as well as recommend and take actions to address the gaps.
- Incorporation of gender-sensitive and gender-transformative situational analyses of behavior change strategies and activities.
- Completion of gender-responsive consultations to encourage the active participation of females and males and guarantee that all voices are heard and reflected in activity plans and activities.

I. PARTNERSHIP IN SUPPORTING DISASTER RESPONSE

The Philippines is vulnerable to natural hazards. Due to its geographic location, the country is one of the world's most disaster prone countries, particularly vulnerable to tropical cyclones and floods, earthquakes, landslides, and volcanic eruptions. These disasters can easily wipe-out development gains in the country.

USAID, in responding to large-scale disasters may request mobilization of implementing partners to assist in delivering humanitarian assistance. Hence, project implementation frameworks of partners are encouraged to have the agility to dispatch resources and re-align budgets to support rapid delivery of humanitarian assistance.

On a case-by-case basis, USAID may request its implementing partners to re-align the distribution of project resources to disaster affected areas and vulnerable populations, and contribute in alleviating human suffering and expedite social and economic recovery. The scope

and deliverables expected from the re-alignment of project resources will be mutually agreed by USAID and the implementing partner

J. SUSTAINABILITY AND INSTITUTIONALIZATION

This activity begins with the end in mind. USAID's definition of sustainability is "the capacity of a host country entity to achieve long-term success and stability and to serve its clients and consumers without interruption and without reducing the quality of services after external assistance ends." An activity contributes to sustainability when it fortifies the local system's ability to produce valued results as well as its ability to be both resilient and adaptive in the face of changing circumstances. In this case, an intervention is considered successful if it can be incorporated into and sustained by the NTP and at lower levels of the health system.

The "TB Innovations and Health Systems Strengthening" activity *must design its technical approach to maximize the institutionalization and sustainability of all its interventions*. When designing interventions, the activity must carefully consider how all aspects of the activity e.g., program design, capacity building and administrative support will be sustained at the end of the activity. The implementing partner should plan its exit strategy as part of program design including how it will transition its interventions to counterparts. Equally important will be a process to constantly monitor and evaluate for sustainability. The activity will be expected to develop a sustainability plan at the outset of the award.

K. MONITORING, EVALUATION, AND LEARNING

The "TB Innovations and Health Systems Strengthening" activity will develop a robust, well-rounded Activity Monitoring and Evaluation Plan (AMEP) that will serve as the road map to determine how well project objectives are being met and monitor outcomes, results and impact of the interventions for each technical objective and sub-objective. The AMEP will include the following information, at the minimum:

1. Fully defined performance indicators using the standard USAID Performance Indicators Reference Sheet template;
2. Baseline values, annual targets and end-of-project targets for outcome, outputs, and required PPR indicators, as well as targets for gender integration and institutionalization and sustainability;
3. Objectively measurable benchmarks or milestones for performance that cannot be measured via standard performance indicators;
4. Data collection methods and frequency of data collection for each indicator;
5. Proposed plan and tools for conduct of data quality assessments;
6. Planned evaluation, learning and adaptation activities.

The AMEP will be updated annually and reported on as part of quarterly and annual reports.

Through its AMEP, the "TB Innovations and Health Systems Strengthening" activity will monitor interventions, collect program performance data, measure progress towards results, and undertake data collection and verification strategies that provide for reliability and accuracy of progress toward expected accomplishments. Triangulation of data sources is required. *The Applicant must present how they will regularly analyze process, output, and outcome indicators using the appropriate methodology to improve project implementation, and document results.*

In order to achieve the targets, in coordination with USAID, the "TB Innovations and Health Systems Strengthening" activity will conduct detailed work planning with the NTP, Global Fund Principal Recipient and other implementing partners to clearly delineate technical interventions and activities by geographic area (province level). The recipient will be expected to collaborate in monitoring efforts with other USAID implementing partners, the DOH, and other donor/partner programs, to ensure that monitoring and evaluation systems are cost-effective and do not create parallel systems. The methodologies for collection and actual data collected may need to be harmonized for ease of aggregation or other specialized reporting needs.

Plans, design, methodology, and scopes of work of activity-initiated monitoring and evaluation activities as well as evaluation reports will be reviewed and approved by USAID prior to implementation and dissemination.

The "TB Innovations and Health Systems Strengthening" activity will track all required indicators as established by USAID's Operational Plan and the USAID TB Implementation Approach, among others. Additional indicators may be necessary to monitor changes in the status of key indicators. Comparison of data between U.S. and non-U.S.-supported sites is desired. Indicators will be appropriately disaggregated by age, sex, and geographic region. The recipient should also include indicators on sustainability. The activity will be expected to review progress towards these targets with USAID/Philippines on at least an annual basis with quarterly progress meetings at the operational level. The recipient should be prepared for revisions in required indicators and reporting requirements during the lifetime of this activity.

"TB Innovations and Health Systems Strengthening" is expected to make an important contribution to learning, specifically around the increased access to high impact interventions and the adoption of key healthy TB-related behaviors in the Philippines. The activity should plan to conduct implementation research or other types of evaluations for select interventions in order to assess the impact of approaches and to adjust the program to bolster program results. In addition, the "TB Innovations and Health Systems Strengthening" activity will be expected to collaborate and partner with the "Collaboration, Learning and Adapting" activity (CLA) by using CLA analytical studies and reports, providing project data information and results, and jointly conducting select operations research projects. Information generated by

the CLA activity will be used to inform policy recommendations and programmatic decision-making for the USAID Health Office.

USAID may commission an independent performance evaluation during the course of the activity implementation. The "TB Innovations and Health Systems Strengthening" activity will work closely with the evaluators to ensure successful implementation, including the identification of appropriate baseline indicators. Results of the performance evaluation may lead to modifications in the implementation of the mechanism and will be shared in a public report.

L. ENVIRONMENTAL COMPLIANCE

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 (https://www.ecfr.gov/cgi-bin/text-) 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. The Applicant/Recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this RFA.

In addition, the Recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this Cooperative Agreement must be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in an Initial Environmental Examination (IEE) duly signed by the Bureau Environmental Officer (BEO). Hereinafter, said document is described as "approved Regulation 216 environmental documentation."

An IEE (IEE #Asia 17-038) has been approved for the "USAID/Philippines Health Project" that is funding this RFA. *See Annex F*. This IEE covers the activities expected to be implemented under the TB Innovations and Health Systems Strengthening program. USAID has determined that a ***Negative Determination with conditions*** applies to one or more of the proposed activities. This indicates that if these activities are implemented subject to the specified conditions, they are expected to have no significant adverse effect on the environment. The Applicant shall be responsible for implementing all IEE conditions pertaining to activities to be funded under this RFA.

As part of its initial Implementation Plan, and all Annual Implementation Plans thereafter, the Recipient, in collaboration with the USAID Agreement Officer's Representative (AOR) and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, must review all ongoing and planned activities under this Cooperative Agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approve Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

When the approved Regulation 216 documentation is an IEE that contains one or more Negative Determinations with conditions, the Recipient shall:

1. Unless the approved Regulation 216 documentation contains a complete environmental mitigation and monitoring plan (EMMP) or a project mitigation and monitoring (M&M) plan, the Recipient shall prepare an EMMP or M&M plan describing how the Recipient will, in specific terms, implement all IEE conditions that apply to proposed project activities within the scope of the award. The EMMP or M&M plan shall include monitoring the implementation of the conditions and their effectiveness. The conditions are as follows:

    a. Conditions for (a) the procurement, use, storage, management and disposal of public health commodities used for delivery of services in tuberculosis treatment and prevention; and (b) clinical training in health facilities and in communities that directly or indirectly result in the generation, storage, handling and disposal of hazardous medical waste, or in techniques that have a direct or indirect environmental impact;

        USAID must work with implementing partners to ensure that:

        - When training professionals or community health workers in service delivery procedures that result in the generation and disposal of potentially hazardous medical waste, the curricula should cover best management practices concerning the proper handling, use and disposal of medical waste, as applicable, and that it is consistent with current DOH protocols; and

        - The medical facilities have procedures in place to properly handle, label, treat, store, transport and properly dispose of blood, placenta, sharps and other medical

waste such as used sputum cups, slides, applicator sticks, syringes and cartridges for GeneXpert as well as sputum specimens, based on standards of DOH and USAID or based on guidelines developed from these standards.

At the start of each activity, the implementing partner, in consultation with the AOR, will formulate an EMMP. The implementing partner will validate the plan's consistency with DOH and USAID guidelines as well as with internationally accepted standards for medical waste disposal. As appropriate, the implementing partner will work with facility, local, regional and/or national officials to implement and apply appropriate best management practices which incorporate appropriate health and safety measure and environmental safeguards, including proper disposal of medical waste. The management of potential health and environmental hazards from health service delivery and health systems management may include ensuring LGUs are aware of and adhere to local standards of medical waste disposal.

Implementing partners may require selected medical facilities to complete a Healthcare Waste Management Minimum Program Checklist and Action Plan (see http://www.usaidgems.org/Documents/SectorGuidelines/Healthcare%20Waste%20Guideline%20Final_w_GCC_Addition_May11.pdf) as part of monitoring.

b. Conditions on the use/disposal of medical equipment and supplies;

Implementing partner(s) should ensure and provide the AOR with evidence that equipment is procured from certified retailers and include environmental safety and quality certificates that conform to national and/or international standards. The recipient of the equipment should be provided with information on the proper use of and instructions on proper disposal of electronic waste. The recipient should also be provided with a list of Government of the Philippines-accredited recyclers for proper disposal of the equipment after its useful life.

c. Conditions on the use and disposal of small electric and electronic equipment, such as cellular phones, netbooks and tablets;

No special mitigation measures are needed. Normal good practices will be used. The proposed action is that the implementer should provide evidence that equipment is procured from certified retailers and include environmental safety and quality certificates that conform to national and/or international standards. The recipient of the equipment should follow all applicable national and international laws to ensure that it is used in an environmentally sound and safe manner. Equipment should be properly disposed of (when applicable) at the end of its useful life in a manner consistent with best management practices according to USG, European Union or equivalent standards acceptable to USAID.

d. Conditions and best practices for general classes of activities involving healthcare waste;

- All interventions shall be conducted following principles for environmentally sound development, as provided in the USAID Sector Environmental Guidelines—Healthcare Waste. This document can be found at http://www.usaidgems.org/Sectors/healthcareWaste.htm .

- An EMMP shall be developed that includes the principles of the guidelines.

- Each activity that has healthcare waste should have a sound healthcare waste management plan and system to minimize adverse health and environmental impacts caused by their wastes. A program to manage healthcare waste includes the minimum elements: (a) written plan; (b) clear responsibilities; (c) written internal rules; (d) staff training; (e) protective clothing; (f) good hygiene practices; (g) vaccinated workers; (h) designated storage locations; (i) waste minimization; (j) waste segregation; (k) waste treatment; (l) final disposal site; and (m) periodic reviews. The format and guidance of this report will be provided by the AOR and should include the qualities of the Minimal Program Checklist and Action Plan from the abovementioned environmental guidelines.

- With activities involving health commodities, the implementing partner should have a written plan to ensure appropriate procurement, storage, management and/or disposal of public health commodities, including pharmaceutical drugs and nutritional supplements such as established adequate procedures and capacities in place to properly manage and dispose of such commodities.

- The checklist found at the following website should be used for monitoring: http://www.usaidgems.org/Documents/VisualFieldGuides/medwastJan2010.pdf .

e. Conditions and best practices for general classes of activities involving Healthcare Facilities;

- All activities shall be conducted following the principles for environmentally sound development, as provided in the USAID Sector Environmental Guidelines—Health Facilities. This document could be found at: http://www.usaidgems.org/Sectors/healthcareFacilities.htm.

- Design for waste management.

- Ensure sufficient water supply and sanitary management capacity.

- Support to activities that include healthcare waste should have a sound healthcare waste management plan and system to minimize adverse health and environmental impacts caused by their waste. See healthcare waste management guidelines found at: http://www.usaidgems.org/Sectors/healthcareWaste.htm .

- An EMMP shall be developed that includes the principles of the aforementioned guidelines.

- The checklist found at the following website can be used for monitoring: http://www.usaidgems.org/Documents/VisualFieldGuides/medwastJan2010.pdf

f. Contingency Provision. Construction is not among the current planned actions under this RFA. Should the need for construction arise during the period covered by this IEE, USAID will take into consideration the conditions listed below.

a. Conditions and best practices for general classes of activities involving Small-Scale Health Facility Construction:

- All construction activities shall be conducted following the principles for environmentally sound construction, as provided in the USAID Sector Environmental Guidelines – Small Scale Construction, which can be found at: http://www.usaidgems.org/Sectors/construction.htm.

- For the rehabilitation of existing facilities and for construction of facilities in which the total surface area disturbed is less than 10,000 square feet, the implementing partner shall conduct and prepare a supplemental Environmental Review Checklist (ERC) documenting a site specific environmental review. A link to the ERC template is below. The ERC should include an EMMP. Construction will not begin until such a review and report is completed and approved by the AOR in consultation with the Mission Environment Officer.

- For the construction of any facilities in which the total surface area disturbed exceeds 10,000 square feet (1,000 square meters) or is considered to have a significant effect on the environment, the IEE must be amended and may need an Environmental Analysis.

- The implementing partner should design activities to minimize vulnerability of facilities to climate change.

- A USAID Engineer is available to review all construction design.

- A template for the ERC can be found under the Asia section at the following website: http://www.usaidgems.org/compliance.htm . The checklist at http://www.usaidgems.org/Documents/VisualFieldGuides/ENCAP_VslFldGuide--Construction_22Dec2011.pdf should be used to monitor activities.

2. Integrate a completed EMMP or M&M plan into the initial implementation plan.

3. Integrate an EMMP or M&M plan into subsequent Annual Implementation Plans, making any necessary adjustments to activity implementation in order to minimize adverse impacts to the environment.

M. CLIMATE RISK MANAGEMENT

To comply with the new Agency guidance on Climate Resilient International Development as defined in ADS 201 Mandatory Reference, https://www.usaid.gov/sites/default/files/documents/1876/201mat.pdf , USAID conducted an initial climate risk assessment of all Health Activities including the TB Innovations Program as evidenced in the approved IEE, Asia 17-038. *See Annex F.* The Implementing Partner should review the completed climate risk analysis prepared by USAID and describe its approach to conduct a more in-depth climate risk assessment and how it will inform activity implementation, if deemed necessary.

END OF SECTION I

SECTION II: AWARD INFORMATION

A. ESTIMATED FUNDING AND EXPECTED NUMBER OF AWARDS

Subject to funding availability, USAID intends to provide approximately $30,000,000 in total USAID funding over a five-year period to support the activity described in Section I. It also intends to issue one (1) award under this RFA. USAID reserves the right to fund any one or none of the applications received.

B. START DATE AND PERIOD OF PERFORMANCE

The period of performance for this activity is five (5) years. The estimated start date will be upon the signature of the award, on or about December 2017.

C. SUBSTANTIAL INVOLVEMENT

USAID anticipates award of a cooperative agreement. A cooperative agreement implies a level of "substantial involvement" by USAID in certain programmatic elements during the performance of the activity. This substantial involvement will be through the Agreement Officer, except to the extent that he/she delegates authority to the Agreement Officer's Representative (AOR) in writing.

The anticipated substantial involvement elements for this award are as follows:

1. Approval of the Recipient's Implementation Plan

   Implementation plans include, but are not limited to, annual work plans, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, and event planning/management.

   USAID requires the approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the Recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the Recipient and the AOR. The annual implementation plans and subsequent revisions thereto, are subject to prior written approval by USAID's AOR.

2. Approval of Key Personnel

   The following positions have been designated as key to the successful implementation of the program objectives of this Agreement. These personnel are subject to prior written approval by the Agreement Officer:

   a. Chief of Party
   b. Drug Resistant Tuberculosis (DR-TB) Technical Advisor
   c. TB Demand Generation Advisor

d. Laboratory and Diagnostic Advisor
e. Private Sector Advisor

3. USAID and Recipient Collaboration or Joint Participation

The Recipient's successful accomplishment of program objectives will benefit from USAID's technical knowledge; thus, the Agreement Officer (AO) may authorize the collaboration or joint participation of USAID and the Recipient on the program. USAID involvement may include but are not limited to:

a. Site Selection. Prior written USAID AOR concurrence is required on final decisions concerning site selection for pilot interventions of the "TB Innovations and Health Systems Strengthening" activity.

b. Approval of the Recipient's Activity Management and Evaluation Plan (AMEP). In consultation with USAID through the AOR, the Recipient will develop the AMEP which will align with the monitoring and reporting framework, and other relevant reporting mechanisms required by USAID/Philippines. During the first ninety (90) days from award date, the Recipient will work closely with the AOR to establish major milestones, program monitoring indicators, as well as baseline data and performance targets which will demonstrate successful achievement of the results expected from this activity.

c. Joint participation in Steering or Technical Committees. The Recipient and USAID will jointly participate in steering or technical committees, including but not limited to NTP planning meetings, TB technical working groups and other TB-related committees.

d. Monitoring the Activity. USAID will monitor the "TB Innovations and Health Systems Strengthening" activity to ensure activities are supporting Mission purpose, to share best practices and capture lessons learned and will authorize direction and/or redirection of interventions specified in the Activity Description due to GPH and US foreign policy objectives and priorities, as well as interrelationships with other programs, including those of USAID's. Monitoring includes but will not be limited to site visits; reviewing terms of reference, quarterly and other types of reports, deliverables and other products; and participating in technical meetings as appropriate.

e. Approval of Subawards. Per 2 CFR 200.308, all subawards not included and approved in the original cooperative agreement will require prior written Agreement Officer's approval. In addition, prior written AOR concurrence with substantive provisions of subawards is required.

4. Agency authority to immediately halt a construction activity

The Agreement Officer may immediately halt any construction that may be undertaken under this activity.

For purposes of this activity, "construction" means: construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.

No construction activities are authorized under this cooperative agreement.

D. TITLE TO PROPERTY

Property title under the resultant award shall vest with the Recipient.

E. AUTHORIZED GEOGRAPHIC CODE

The geographic code for the procurement of goods and services under this activity is 937 (the United States, the cooperating country, and developing countries other than advanced developing countries, but excluding any country that is a prohibited source).

F. PURPOSE OF THE AWARD

The principal purpose of the relationship with the Recipient is to transfer funds to accomplish a public purpose of support or stimulation of the "TB Innovations and Health Systems Strengthening" activity which is authorized by Federal statute.

The successful Recipient will be responsible for ensuring the achievement of the program objectives and the efficient and effective administration of the award through the application of sound management practices. The Recipient will assume responsibility for administering Federal funds in a manner consistent with underlying agreements, program objectives, and the terms and conditions of the Federal award. The Recipient using its own unique combination of staff, facilities, and experience, has the primary responsibility for employing whatever form of sound organization and management techniques may be necessary in order to assure proper and efficient administration of the resulting award.

END OF SECTION II

SECTION III: ELIGIBILITY INFORMATION

A. ELIGIBLE APPLICANTS

To be considered eligible to apply under this RFA, Applicant must either be:

- A U.S. non-profit nongovernmental organization (NGO), for-profit NGO willing to forgo their fee, private voluntary organization (PVO), Philippine-based NGO, foundation, consortium, university/college, or an international organization.

Individuals are not eligible to apply.

Eligible organizations which have not previously received financial assistance from USAID are encouraged to submit applications.

Applicant submitting an application *must*:

1. Have a valid DUNS number (http://fedgov.dnb.com/webform) and provide this information in its application;

2. Be registered in SAM (www.sam.gov); and,

3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award, or an application, or plan under consideration by a Federal awarding agency.

USAID/Philippines will not make an award to an applicant if the applicant has not fully complied with the DUNS and SAM requirements by the time it is ready to make the award.

Applicants must have established financial management, monitoring and evaluation processes, internal control systems, and policies and procedures that comply with established U.S. Government standards, laws, and regulations.

The "successful" Applicant may be subjected to a responsibility determination assessment (Pre-award Survey) by the Agreement Officer (AO). Based on the results of the pre-award survey, the Agreement Officer will determine whether the prospective recipient is a responsible entity – whether it has the necessary organization, experience, accounting and operational controls, and technical skills—or has the ability to obtain them in order to achieve the objectives of the program and to comply with the terms and conditions of the award.

B. COST SHARE

A cost share equivalent to $1,500,000 is required for an applicant to be eligible. Applications that do not meet the cost share requirement will not be considered.

For guidance on cost share, please see ADS 303.3.10 (https://www.usaid.gov/sites/default/files/documents/1868/303.pdf). Specific for U.S. NGOs, see

2 CFR 200.306 (https://www.gpo.gov/fdsys/pkg/CFR-2014-title2-vol1/pdf/CFR-2014-title2-vol1-part200.pdf). For non-U.S. NGOs, all cost sharing will be subject to the Required as Applicable Standard Provision "Cost Share" in ADS 303 mab (https://www.usaid.gov/sites/default/files/documents/1868/303mab.pdf).

C. OTHER

Eligible organizations may submit only one (1) application in response to this RFA.

Projects proposed with an implementation period of more than five (5) years will not be considered.

END OF SECTION III

SECTION IV: APPLICATION AND SUBMISSION INFORMATION

A. POINTS OF CONTACT

The RFA can be downloaded from Grants.gov website (www.grants.gov). The points of contact for this RFA are:

Sandra Jansen
Agreement Officer
USAID/Philippines
E-mail: sjansen@usaid.gov

Grace Laspiñas
Acquisition and Assistance Specialist
USAID/Philippines
Email: glaspinas@usaid.gov

B. QUESTIONS AND CLARIFICATIONS

Questions regarding this RFA should be sent by email to Ms. Grace Laspiñas at manila-roaa-rfa@usaid.gov with subject line: "Questions on TB Innovations RFA submitted by [Name of Organization]".

All questions must be submitted not later than the due date and time indicated on the cover letter. If it is determined that the answers to any questions are of sufficient importance to warrant notification to all applicants, a Question and Answer document, and/or if needed, an amendment to the RFA will be posted in www.grants.gov. Please check regularly the Grants.gov website for any amendments.

C. APPLICATION SUBMISSION

Applicants are expected to review, understand, and comply with all aspects of the RFA before submitting their applications. Applicants must ensure that all necessary documentations are complete and received by USAID on time. All applications received by the deadline will be reviewed for eligibility, completeness, responsiveness and programmatic merit in accordance with the requirements outlined in these guidelines and application format. Failure to do so may result in the application being considered non-responsive and may not be evaluated.

Applicants must submit applications in **both** electronic and paper/hard copy form. The Applicant must sign the application and certifications and print or type its name on the cover page of the technical and cost applications.

For an application to be considered timely, the electronic application must be submitted by email to manila-roaa-rfa@usaid.gov and received by the USAID/Philippines internet server not later than the date and time indicated on the cover letter of this RFA. Hard copies of applications must be received not later than 3:00 pm Manila time two days after the RFA's closing date.

1. Electronic Application Submission Procedure

a. Applications submitted electronically must be no larger than 5MB per email. Applicants MUST NOT submit zipped files.

b. USAID's preference is that technical application and cost application be submitted as single email attachments, i.e., consolidate the various parts of the technical application into a single document before sending it, the same manner for the cost application. If this is not possible, please provide instructions on how to collate the documents. USAID will not be held responsible for errors in compiling submitted electronic applications if no instructions are provided or if instructions are unclear.

c. To facilitate the review of applications, applications must conform to the format described below:

1) The Technical Application in Adobe Acrobat portable document format (.pdf). If necessary to comply with email size restrictions, this may be broken into separate, but sequential parts.

2) The Cost Application – one (1) copy cost application in Adobe Acrobat portable document format (.pdf) and one (1) copy with all spreadsheets in unprotected Microsoft EXCEL format (the same requirement applies to all subgrantees' spreadsheets). If necessary to comply with email size restrictions, the cost application may be broken into separate, but sequential parts.

3) If multiple emails are needed to submit a complete application, please indicate in the subject line of the email whether the email relates to the technical or cost application, and the desired sequence of multiple emails (if more than one) and of attachments (e.g. "1 of 4", etc.). For example, if your technical application including attachments is being sent in three emails, the first email's subject line will state "[organization name],Technical Application, 1of 3" and if your cost application is being sent in two emails, the first email must have a subject line which says: "[organization name], Cost Application, Part 1 of 2".

d. After submitting their applications electronically, applicants must immediately check their own email to confirm that all the emails and attachments were indeed sent. If you discover an error in your transmission, please send the material again and indicate in the email's subject line that it is a "corrected" submission. Do not send the same email more than once unless there has been a change, and if so, please note that it is a "corrected" email.

e. Faxed applications are not acceptable.

2. Hard Copy Application Submission

a. Applicants must submit hard copies of the applications. For the technical application, one (1) original and seven (7) copies are required. For the cost application, one (1) original and one copy are required.

b. Technical and cost applications must be separately identified, with the name and address of the Applicant and the RFA number "RFA-492-17-000002".

c. Submissions may be by post, commercial courier, or hand-carried. Please ensure the hard

copy application package/s are submitted in sealed envelopes and are received not later than 3:00 pm Manila time two days after the RFA's closing date, as indicated on the Cover Page of the RFA.

d. Hard copies of applications must be addressed to:

Ms. Sandra Jansen
Agreement Officer

The address for hand-carried and courier-delivered applications is:

Regional Office of Acquisition and Assistance
USAID/Philippines
U.S. Embassy Compound
1201Boulevard, Ermita, Manila 1000
Telephone No.: +632 301-6000 ext 4929

Applications that are received late or are incomplete run the risk of not being considered in the review process. USAID's Agreement Officer may review and consider late or incomplete applications if:

1) USAID's treatment of the material is consistent with the terms of the RFA;
2) All late applications are treated the same;
3) They are evaluated before any agreements are awarded under the RFA; and,
4) The Agreement Officer consents in writing to the review of late or incomplete applications.

D. PREPARATION OF APPLICATION

1. Each Applicant shall furnish the information required by the RFA. Applications shall consist of two separate parts: (a) the technical application, and (b) the cost application. The Applicant must submit the application in both electronic and hard copies.

2. All information shall be presented in English.

3. Each Applicant organization must print or type its name on the Cover Page of both the technical and cost applications. All applications and certifications must be signed by an authorized representative of the organization. Erasures and changes to the application must be initialed by the person signing the application. Applications signed by an agent must be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the Agreement Officer of this RFA.

4. Applicants who include data that they do not want disclosed to the public for any purpose or used by USAID except for evaluation purpose must:

a. Mark the title page with the following legend:

"This application includes data that shall not be disclosed outside the U.S. Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this application. If, however, a grant is awarded to this Applicant as a result of, or in connection with, the submission of this data, the U.S. Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting grant. This restriction does not limit the U.S Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in pages {insert page number/s}"; and

b. Mark each sheet of data it wished to restrict with the following legend:

"Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this application."

5. Applicants must retain for their records one copy of their application including all enclosures that accompany their application.

E. TECHNICAL APPLICATION FORMAT

The Technical Application is the most important factor for consideration in selection for award of a Cooperative Agreement under this RFA.

The "apparently successful" Applicant's Technical Approach, as revised during negotiations, will become the Activity Description of the resulting Cooperative Agreement. It must include a clear description of the conceptual approach and the general strategy (i.e. methodology and techniques) being proposed. It must outline specific, focused activities; identify how and where (e.g. country and level: local, national, or regional) those activities will be implemented; explain how the approach is expected to achieve the proposed objectives; and describe a plan that will enable the activities to continue after the activity is completed. Applicants are encouraged to propose innovative programs designed to reach the desired outcomes/results. Creativity and innovation will be a key factor to the Applicant's success.

The technical application must be specific, complete and presented concisely. The application must demonstrate the Applicant's approach, capabilities and expertise with respect to achieving the goals of this program. The application must take into account the requirements of the program and merit review criteria found in this RFA.

The Technical Application must be written in English, typed on standard 8-1/2" x 11" paper, single spaced, using Times New Roman 12-pt font, with margins no less than one inch on all sides.

The Technical Application must include the following sections:

1. Cover Page, which includes:
   a. Program Title: TB Innovations and Health Systems Strengthening

b. RFA reference number: RFA-492-17-00002
c. Name of Applicant organization and business address
d. Partnerships, if any
e. DUNS Number
f. Name of sub-awardees, if any
g. Technical Application contact person, title, email address, mobile and telephone numbers
h. Cost Application contact person, title, email address, mobile and telephone numbers
i. Name(s) and title(s) of person(s) who prepared the application and which sections they prepared
j. Name and signature of organization's authorized representative

2. Table of Contents listing all page numbers and attachments. Follows the technical application format outlined herein

3. List of Acronyms

4. Executive Summary (2 pages maximum)

5. Technical Application
   a. Technical Approach and Proposed Outcomes/Results
   b. Key Personnel
   c. Management Approach and Staffing Plan
   d. Organizational Capacity

6. Annexes

The Technical Application is limited to twenty-five (25) pages only. Anything above that will not be included in the review process. Annexes specifically requested are not included in the page limitation. However, any information included as an annex that was not specifically requested in the RFA will not be reviewed or considered. The following are the only allowed annexes:

- Case Study (5 pages maximum)
- Key personnel resumes/Curriculum Vitae/Major accomplishments (maximum 3 pages per person plus maximum of 2 pages each for major accomplishments and references
- Letters of intent from key personnel
- Letters of commitment from partners and/or sub-grantees
- Proposed Organizational Chart
- Proposed matrix of staff with skills and capabilities
- Draft Year 1 Implementation Plan
- Draft Year 1 Activity Monitoring and Evaluation Plan (AMEP)
- Past performance summary tables and references
- Branding Strategy and Marking Plan
- Draft Environmental Management & Monitoring Plan (EMMP)

The following pages do not count against the 25 page limit: Cover page, Table of Contents, Acronym list, and dividers.

Graphs, charts, exhibits, tables, executive summary, etc. contained in the body of the Technical Application must be numbered and shall be included in the 25 page limit.

Applicants must 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.
The Applicant is requested to state the name(s) of the individual(s) who prepared each part of the application.

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

F. SPECIFIC TECHNICAL APPLICATION INSTRUCTIONS

The Technical Application must address how the Applicant intends to implement the Activity Description detailed in Section 1 of the RFA. Applicants must briefly describe their overarching implementation strategies and 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. It should also highlight how the project will work with the NTP and other implementing partners to promote sustainability, and promote potential game-changing TB interventions that could be supported at all levels of the health system to bring about TB elimination.

The narrative section of the application should contain the elements outlined below:

1. Technical Approach

Applicants must address the requirements of the activity description, including the objectives and sub-objectives and consider the key issues and challenges in Section I of this RFA. The approaches presented by the applicant for each section of the technical application selection criteria must be aligned with the priorities of the NTP and the US Global TB strategy, and must address how the applicant will work with the NTP and local government to strengthen capacity. Specifically:

1) The Applicant must provide a comprehensive yet concise summary of their overall strategic and technical approach to reach the project's objectives, and to implement and perform the four objectives and twelve sub-objectives outlined in Section I of the RFA. There should be synergistic linkages between the approaches across the objectives and themes, and there should be a focus on complementarity and coordination with local health systems and other partners including Global Fund principal recipients and sub-recipients.

2) The Applicant must discuss the critical challenges to achieving TB elimination and should present potential game-changing TB interventions under each objective that could be supported at the national and regional levels to bring about TB elimination. There must be an analysis of the selection of interventions to demonstrate the most cost-effective approach to achieving the objectives.

3) The Applicant must present the most optimal interventions that can be successfully implemented to expand case detection, appropriate health-seeking behavior and treatment adherence. The applicant should also describe how it will integrate and institutionalize high-impact TB and DR-TB practices and strengthen the TB diagnostic network. The applicant should clearly articulate how they will reinforce and sustain the capacity of the Department of Health's National TB Program.

4) The Applicant should describe how it will institutionalize and scale up evidence-based best practices and approaches that build on national and international evidence. All approaches should include a strategy for promoting sustainability and engagement with partners beyond the life of the project.

5) The Applicant should describe how it will provide complementary wrap-around capacity building to the National TB program and how it will coordinate with partners to maximize investments for TB elimination in the Philippines and assist with transitioning external funding to sustainable community-led approaches.

6) The Applicant should demonstrate its understanding of and commitment to responding to gender issues in TB programming. The applicant must describe its gender-sensitive and gender-transformative approach to achieving expected results.

7) The Applicant must describe how they would develop a strong, cost-effective, evidence-based Activity Monitoring and Evaluation Plan (AMEP) with a data quality assurance strategy. This plan should consider how contributions of the "TB Innovations and Health Systems Strengthening" activity will be measured as it contributes to achievement of PhilSTEP objectives and targets. The Applicant must include a detailed strategic framework for evaluating performance towards achieving the outcomes of the four objectives and twelve sub-objectives as part of the application. The plan should include how best practices and lessons learned will be disseminated, how data will be collected, and how the quality of the data will be reviewed and improved. The applicant should also identify how it would develop a system with the NTP and other partners so that the data is regularly analyzed to inform the effectiveness of interventions.

8) As part of the technical approach (may be included as an annex), the applicant must provide a case study that highlights its proposed strategy for supporting implementation of new policies and strategies at lower levels of the health system considering the devolved system. This should be limited to no more than five (5) pages, and should focus on how the applicant plans to support operationalization and implementation of national policies and guidelines at lower levels of the health system and how interventions will be institutionalized and sustained. The case study must:

   a. Explain the principles and overarching strategy of development, dissemination and implementation of new policies and guidelines in the context of a devolved system.
   b. Explain how the "TB Innovations and Health Systems Strengthening" activity will collaborate with local government, local partners, communities, and the Global Fund and other USAID partners.
   c. Explain how interventions will be institutionalized and sustained at lower levels of the health system.

d. Describe the metrics that will be used to measure the success of each intervention.

2. Key Personnel

As part of the 25-page limit of the technical narrative, Applicants shall provide a summary of the scope of experience, skills and expertise of its proposed Key Personnel as listed below.

As an annex, the Applicant shall provide a resume of no more than three (3) pages each for each of the five (5) required Key Personnel. In addition, for each proposed Key Personnel, the Applicant shall provide a list of significant accomplishments (no more than 2 pages each) and any relevant supporting documents to supplement the resumes.

The Applicant shall submit a signed letter of intent 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 five Key Personnel, a list of three (3) professional references from 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. Applicants should validate the most suitable contact information.

Each of these five 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 activity.

Chief of Party: 100 percent LOE

The Chief of Party will be responsible for leading a high-quality, results-oriented activity to achieve the objectives and sub-objectives outlined in this RFA. S/he will provide overall strategic and managerial leadership of the project in collaboration with all major stakeholders. S/he will bring a strong perspective on health systems strengthening to the activity, particularly significant expertise in health finance, governance and human resource management. S/he will work closely with the Drug Resistant TB (DR-TB) Technical Advisor who will be seconded to the Patient-Centered TB Care activity to provide strategic technical guidance to the activity. This position should be filled by an expatriate who can bring his or her international experience and insights to the activity.

Required qualifications:

- Advanced degree (Medical Degree, Masters, or PhD) in health, social sciences, or a relevant field
- At least 15 years working on health sector and health systems strengthening projects, as well as demonstrated leadership and management skills to effectively and efficiently implement

complex and politically sensitive international health projects
- At least five (5) years of experience working on infectious disease, particularly TB programs
- Demonstrated experience in collaborating and implementing programs with the private and non-public sectors
- Demonstrated ability to lead and manage diverse teams and ensure high performance and staff retainment
- Ability to develop and manage relationships with a wide range of stakeholders, including government officials
- Experience and skills in financial management and performance monitoring

Desired qualifications:
- Knowledge of and experience working with USAID or other international donor projects
- Strong organizational and management skills
- Exceptional communication skills, particularly in English, both verbally and in writing

Drug Resistant Tuberculosis (DR-TB) Technical Advisor: 100 percent LOE

The Drug-Resistant TB Technical Advisor will be seconded to the "Patient-Centered TB Care" Activity throughout the life of the project. The DR-TB Technical Advisor will play an essential role as a "bridge" between the two activities in order to transfer interventions developed by the "TB Innovations and Health Systems" Activity to the implementation level and also transfer local experiences and recommendations to the national level. S/he will also provide technical expertise and guidance across all objectives and sub-objectives of the "Patient-Centered TB Care" Activity to help the activity develop and implement an evidence-based strategic vision. This position should be filled by an expatriate who can bring his or her international experience and insights to the activity.

Required qualifications:
- Advanced degree (Medical Degree, Masters, or PhD) in medicine, public health, nursing, applied clinical research, or other relevant medical or public health field
- Minimum 10 years of demonstrated experience providing technical support to TB and DR-TB programs outside of the Philippines (in at least two countries)
- Supervisory experience working in organizations or as part of projects that address TB issues
- Knowledge, understanding and technical expertise in the application and implementation of global TB policies, strategies and technical guidance
- Experience introducing and implementing new TB policies, such as new pediatric TB drug formulations, shortened treatment regimens for MDR-TB, new TB drugs , and GeneXpert
- Knowledge of and experience implementing patient-centered health care
- Demonstrated capacity to build and maintain productive working relationships with a wide network of partners and stakeholders

Desired qualifications:

- Strong organizational and management skills
- Ability to communicate effectively in English, both verbally and in writing

TB Demand Generation Advisor

The TB Demand Generation Advisor will lead the approach to develop evidence-based and patient-centered interventions to reach vulnerable and high risk populations with tailored and appropriate TB outreach and services. S/he will ensure that activities are technically sound and adhere to internationally endorsed or recognized guidance, or have demonstrated proof of concept when supporting new interventions. S/he will provide technical assistance to the relevant government programs to design, implement and evaluate programs that expand utilization of, treatment-seeking and adherence to TB detection and treatment services. This position should be filled by an expatriate who can bring his or her international experience and insights to the activity.

Required qualifications:

- Advanced degree (Medical Degree, Masters, or PhD) in health/public health, sociology, epidemiology, monitoring and evaluation, or related field
- At least 12 years of experience designing, implementing, and evaluating infectious disease outreach programs for vulnerable and high risk populations, including but not limited to urban/rural poor, indigenous people, congregate settings, prisoners, migrant workers, elderly, children or people living with HIV
- At least five (5) years of experience developing and implementing infectious disease outreach programs in countries other than the Philippines
- Experience designing, implementing, monitoring and evaluating programs designed to reduce stigma and discrimination
- Demonstrated understanding of health-seeking behavior and patient support needs
- Experience and demonstrated success in involving patients or key affected populations and civil society in project design and execution

Desired qualifications:

- Demonstrated experience developing and implementing effective communication and community engagement programs
- Strong organizational and management skills
- Ability to communicate effectively in English, both verbally and in writing required

Private Sector Advisor: 100 Percent LOE

The Private Sector Advisor will lead the activity's engagement and partnerships with the private sector to contribute to quality TB detection and treatment outcomes. S/he will lead the review of existing private sector strategies and work closely with national stakeholders to develop and implement new strategies and pilot innovative private sector activities. S/he will advise the National TB Program and other relevant government departments to develop new programs based on international best practices and experience. S/he will also provide guidance and

technical support to develop private sector governance and management tools to promote sustainability and institutionalization of interventions.

Required qualifications:

- Advanced degree in public health, international affairs, economics, business, or social sciences
- At least 12 years of experience developing governance and management tools and programs that support sustainability of programs with the private sector
- At least five (5) years working on private sector governance and management in countries outside of the Philippines
- Experience working with national TB programs
- Knowledge of and experience working in the field of health financing
- Demonstrated ability to coordinate multiple stakeholders and create and maintain effective relationships with Government personnel

Desired qualifications:

- Strong organizational and management skills
- Ability to communicate effectively in English, both verbally and in writing

Laboratory and Diagnostics Advisor: 100 Percent LOE

The Laboratory and Diagnostics Advisor will provide relevant technical guidance and oversight for all activities related to the TB diagnostic network and laboratory services. S/he will ensure that activities are technically sound and adhere to internationally endorsed or recognized guidance, or have demonstrated proof of concept when supporting new interventions. S/he will advise the relevant government programs and laboratories on best practices and provide capacity building support as needed.

Required qualifications:

- A PhD or Master's degree in laboratory science, infectious diseases, public health or an equivalent field
- At least 12 years of experience working on projects related to strengthening diagnostic network/laboratory services in more than one country and in similar country contexts, with at least five (5) of these years working on tuberculosis diagnostic network/laboratory services
- Demonstrated capacity to function as a technical expert for new technologies within the TB diagnostic network/laboratory community
- Demonstrated ability to work with multiple partners on collaborative projects
- Demonstrated ability to create and maintain effective working relations with senior Government personnel, international organizations, NGO partners, host country governments, and U.S. Government Agencies

Desired qualifications:

- Strong organizational and management skills
- Ability to communicate effectively in English, both verbally and in writing required

G. COST APPLICATION INSTRUCTIONS

The Cost Application must be submitted separately from the Technical Application. There is no page limit for the Cost Application. Unnecessarily elaborate brochures or other presentations beyond those sufficient to present a complete and effective application in response to this RFA is not desired. Elaborate art work, expensive paper and bindings, and expensive visual and other presentation aids are neither necessary nor wanted.

The Cost Application is to be submitted in both electronic (via email) and paper versions.

The Applicant shall submit a budget broken down by program years with an accompanying detailed budget narrative which provides in detail the total costs for implementation of the program as further detailed below. The application must provide evidence that the funds requested are reasonable and would be used in a cost-effective manner. The review committee will assess whether the overall costs are realistic for the work to be performed, whether the costs reflect that the Applicant understands the requirements, and whether the costs are consistent with the technical application. The application will also be assessed for cost effectiveness. Applications that minimize administrative costs in order to maximize program, outreach, and capacity building activities will generally be considered to be of better value.

The Agreement Officer requires from the Applicant certain documents to be submitted in order for the Agreement Officer to determine the Applicant's responsibility as well as to assess USAID's risk should an award be made.

If the Applicant has established a consortium or another legal relationship among its partners, the cost application must include a copy of documents that show the legal relationship between the parties. The documents should include a full discussion of the relationship between the Applicant and partners including identification of the Applicant with whom USAID will work with 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/s.

The following describes the documentation that Applicants must submit. While there is no page limit for this portion, Applicants are encouraged to be as concise as possible, but still provide the necessary details. The cost application must cover the full period of performance using the budget format in SF 424A. Budget should be expressed in US dollars using the exchange rate of P49 = $1.

1. **Cover Page** containing the same information as the Technical Application cover page.

2. A summary of the budget must be submitted using **Standard Form 424, 424A and 424B**. These forms can be downloaded from the grants.gov website at: https://www.grants.gov/web/grantsforms/sf-424-family.html#sortby=1

   Instructions on how to complete these forms are found at https://www.grants.gov/web/grants/form-instructions.html

a. Summary budget should have the budget categories as shown in SF424A, with costs breakdown by year
b. Detailed/itemized budget
c. Budget narrative explaining costs to be incurred
d. Other administrative documentation

The forms must be signed when submitted by an authorized representative of the Applicant's organization.

3. **Detailed budgets and narrative** with supporting notes and justifications that include the following:

a. The name, daily and annual salary, fringe benefits and expected level of effort of each person charged to the program and salary escalation factors
b. Specify the applicable fringe benefit rates for each category of employee, and all benefits covered by the rate.
c. The same information shall be provided for individual consultants as for regular personnel.
d. Allowances must be broken down by specific type and by person and must be in accordance with the applicant's policies. All salaries, benefits and allowances must be based on written compensation policies of the employer organization.
e. Details of all home office support to be provided.
f. Travel, per diem and other transportation expenses must be detailed in the financial plan to include number of international trips, from where to where, number of per diem days and rates. Per Diem and other travel allowances must be based on written travel policies of the employer organization. (Applicants may choose to refer to the Federal Standardized Travel Regulations for cost estimates).
g. Detail all equipment to be purchased, including the type of equipment, the manufacturer, the unit cost, the number of units to be purchased and the expected geographic source.
h. Detail all materials and supplies expected to be purchased, including type, unit cost, and number of units.
i. Detail of all proposed Contractual arrangements including proposed subawards.
j. Other Direct Costs such as visas, passports and Other General and Administrative costs must be presented as separate cost line items.
k. Specific budget details and narrative information, in addition to the percentage and total dollar amount of the proposed cost-share contribution.
l. Indirect Costs must be supported with information (i.e., NICRA) to substantiate the calculation of the indirect cost.
m. For commercial organizations, no profit or fee shall be included in the prime award. All reasonable and allowable expenses, both direct and indirect, which are related to the agreement and are in accordance with applicable cost principles under 2 CFR Subpart E may be paid under the anticipated award.
n. Information regarding the cost share should be indicated in the SF424. Cost share details – who is providing cost share, how cost share will be used, how it will contribute to the objectives, etc.

The budget notes/narrative should explain all budget assumptions and how the costs are derived. It will provide information regarding the basis of estimate for each line item,

including reference to source used to substantiate the cost estimate (e.g. organization's policy, payroll document, vendor quotes, etc.)

4. **Required "Certifications, Assurances, Other Statements of the Recipient"** signed by an authorized representative of the Applicant's organization. The certifications are found at: https://www.usaid.gov/sites/default/files/documents/1868/303mav.pdf

5. Applicants shall submit any additional evidence of responsibility deemed necessary for the Agreement Officer to make a determination of responsibility. The information submitted shall substantiate that the Applicant:

   a. Has adequate financial, management and personnel resources and systems or the ability to obtain such resources as required during the performance of the award.
   b. Has the ability to comply with the award conditions, taking into account all existing and currently prospective commitments of the Applicant, non-governmental and governmental.
   c. Has a satisfactory record of performance. Past relevant unsatisfactory performance is ordinarily sufficient to justify a finding of non-responsibility, unless there is clear evidence of subsequent satisfactory performance.
   d. Has a satisfactory record of integrity and business ethics; and
   e. Is otherwise qualified and eligible to receive a cooperative agreement under applicable laws and regulations.

6. 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.

7. Foreign Government Delegations to International Conferences will not be funded under this agreement. See Standard Provision entitled "**FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES".**

8. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM). Unless excepted by USAID from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by USAID under 2 CFR 25.110(d) must be registered in SAM provide a valid DUNS number and continue to maintain an active SAM registration with recent information at all times during which it has an active Federal award or an application or plan under consideration by USAID.

9. Federal awarding agencies may not make a Federal award to an Applicant until the Applicant has complied with all applicable DUNS and SAM requirements and, if an Applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

An award will be made only when the Agreement Officer makes a positive determination that the Applicant possesses, or has the ability to obtain, the necessary management competence in planning and carrying out assistance programs and that it will practice mutually agreed upon methods of accountability for funds and other assets provided by USAID. For the organizations that are new to USAID, or organizations with outstanding audit findings, it may be necessary to perform a pre-award survey.

Unsuccessful applications will not be returned to the Applicants.

Please note that Applicants are encouraged to ask questions regarding the application process or for technical clarification during the open question period by submitting questions in a single document by the deadline listed on the cover letter of this RFA. Questions must be submitted to manila-roaa-rfa@usaid.gov. The answers to all questions submitted will be posted to www.grants.gov.

H. BRANDING AND MARKING PLAN

It is a Federal statutory and regulatory requirement that all overseas program, projects, activities, public communications, and commodities that USAID partially or fully funds under an assistance award or sub-award must be appropriately marked with the USAID identity.

Under 2 CFR 700.16. USAID requires the submission of a Branding Strategy and Marking Plan from only the apparently successful applicant; therefore, applicants do not need to submit a draft Branding Strategy and Marking Plan in the initial applications. More information on Branding Strategy and Marking Plan are available at http;/www.usaid.gov/branding/assistance.html.

I. FUNDING RESTRICTIONS

USAID policy is not to award profit under assistance instruments. However, all reasonable, allocable and allowable expenses, both direct and indirect, which are related to the agreement program and are in accordance with applicable cost principles under 2 CFR 200 Subpart E may be paid under the anticipated award.

J. LIMITATION ON SUB-AWARDS

By submission of an application and execution of the award, the Applicant/Recipient agrees that at least fifty (50) percent of the cost of award performance incurred for personnel must be expended for employees of the prime/local organization.

END OF SECTION IV

SECTION V: APPLICATION REVIEW INFORMATION

A. OVERVIEW OF REVIEW AND SELECTION PROCESS

USAID anticipates the award of one (1) cooperative agreement as a result of this RFA. However, USAID reserves the right to make an award or no award if it determined to be in the best interest of the US Government.

All applications received by the deadline stated in the RFA cover letter or amendment, if any, will be reviewed, first for eligibility, checked for completeness and responsiveness, and finally will be evaluated against the merit review criteria set forth in this Section.

Applications received after the RFA deadline will be considered late and may not be evaluated. Incomplete submissions risk not being considered in the review process.

A Selection Committee (SC) will conduct a technical merit review of all applications received that comply with the requirements in this RFA.

USAID may award without seeking clarifications/additional details from the applicants. However, if the Agreement Officer determines that an application or several applications can be improved, then the Applicant or group of Applicants will be given the opportunity to do so through verbal and/or written engagement. Therefore, Applicants are encouraged to submit initial applications that contain their best terms from both technical and cost standpoints.

After technical evaluations have been completed, the SC will recommend the "*apparently successful*" applicant. The Agreement Officer (AO), considering the SC recommendation and the cost review, will make the final selection.

1. Eligibility

Each application received by the RFA deadline will be reviewed against eligibility requirements outlined in Section III – Eligibility Information. This includes the cost share requirement of $1,500,000. Applications that do not meet the eligibility requirements will not be evaluated.

2. Responsiveness

Eligible applications will be reviewed for responsiveness. Applications not conforming to Section IV – Application and Submission Information, may be considered nonresponsive and may be eliminated from further consideration.

3. Merit Review

Eligible, responsive applications will be evaluated in accordance with the established merit review criteria. The merit review criteria are tailored to the requirements of this RFA. The evaluation will be conducted using an adjectival rating system.

Applicants must note that these technical merit review criteria serve to: (1) identify the

significant matters which applicants should address in their applications, and (2) set the standard against which all applications will be reviewed and evaluated.

To facilitate the review of applications, applicants must organize the narrative sections of their technical applications with the same headings and in the same order as the merit review criteria.

B. APPLICATION REVIEW INFORMATION

1. Merit Review

Technical applications will be evaluated and ranked in accordance with the following criteria shown in their order of importance:

- "**Technical Approach**" and "**Key Personnel**" are the two most important criteria and constitutes the highest priority in the ranking of applications
- "**Management and Approach and Staffing Plan**" constitutes the second highest priority
- "**Organizational Capacity**" is the third criterion for ranking applications

a. **Technical Approach**: The extent to which the application proposes a Technical Approach to the "TB Innovations and Health Systems Strengthening" activity that lays out innovative, programmatic interventions in a clear, logical and realistic manner in order to achieve program objectives efficiently.

The review will look for:

- A clear, logical, and game-changing strategy as well as a detailed understanding of those efforts needed for effective and successful achievement of the objectives outlined in the Activity Description;
- A comprehensive and complementary approach including wrap-around technical assistance and scaling up new approaches, to transform and expand patient-centered TB care;
- Institutionalization and sustainability to improve the likelihood that the programs being supported will continue beyond and without USAID funding; and
- A comprehensive monitoring, evaluation, learning and operations research strategy and plan to measure, assess and document activity interventions and innovations.

b**. Key Personnel:** The extent to which the proposed Key Personnel (Chief of Party, Drug-Resistant TB Technical Advisor, TB Demand Generation Advisor, Laboratory and Diagnostics Advisor, and Private Sector Advisor) have the required qualifications and convincingly demonstrate the Applicant's ability to effectively implement proposed activities responsive to this RFA.

Candidates will be considered based on the variety of their skills – and how they complement each other – and their appropriateness to the technical approach outlined in the application, as well as on their academic background, expertise, including their effectiveness and success in similar positions, and years of related experience.

c. **Management Approach and Staffing Plan:** The extent to which the management and staffing plans demonstrate the Applicant's ability to effectively implement proposed activities responsive to this RFA. The application contains a sound management plan and organizational structure to convincingly manage the award and to achieve desired results and outcomes. This includes a clear and realistic description of timely plans for office establishment (locations and balance of head and field offices), staffing and mobilization (hiring of personnel, initiating communications systems and operations. If the application is from a consortium or partnership with more than one organization, or includes significant implementation sub-grantees, the management plan must identify the formal relationships, roles, and responsibilities of each consortium member, partner organization, or implementing sub-grantee.

The elements of this review factor include:

- The overall quality of the management and staffing plan to implement the "TB Innovations and Health Systems Strengthening" activity, taking into consideration the type of interventions and roles of other partners;

- The coherence of a supporting organizational structure that matches required skills to accomplish the full range of program objectives; and

- Detailed explanation of any proposed consortium and/or partnerships that the Applicant will participate in to carry out Activity interventions.

d. **Organizational Capacity:** The extent to which the Applicant's corporate and institutional capability demonstrates its ability to effectively implement similar activities/programs (in kind and magnitude) in the immediate past five (5) years, including activity performance and management, and client relations.

Applicant's capacity will be reviewed based on its experience and institutional technical expertise in implementing TB prevention, detection, diagnosis, treatment and care interventions in terms of approach, magnitude and complexity. Relevant information on the Applicant's ability to attract and retain high-quality personnel will also be considered.

2. Cost Review

The cost application of the "apparently successful" applicant will be reviewed for cost reasonableness, allowability, allocability, cost effectiveness and realism, and adequacy of budget detail.

USAID will assess whether the overall costs are realistic for the work to be performed, whether the costs reflect the applicant's understanding of the requirements, and whether the costs are consistent with elements of the technical application.

Proposed costs may be adjusted based on the results of the cost review/analysis and the Agreement Officer's assessment of reasonableness, completeness, and credibility.

3. Cost Share

As part of the analysis, the "apparently successful" applicant's proposed cost share contribution will be reviewed for cost realism. The cost application must demonstrate the Applicant's plan for providing the required cost share. The proposed contributions will be verified that it meets the standards set in 2 CFR 200.306 for U.S. organizations or the Standard Provision "Cost Share" for non-U.S. organizations.

END OF SECTION V

SECTION VI: AWARD AND ADMINISTRATION INFORMATION

A. FEDERAL AWARD NOTICE

1. USAID plans to award one cooperative agreement resulting from this RFA to the apparently successful Applicant whose application best meets the merit review criteria (see Section V of this RFA). The Agreement Officer will only do so after making a positive responsibility determination that the successful Applicant possesses, or has the ability to obtain, the necessary management competence in planning and carrying out assistance programs and that it will practice mutually agreed upon methods of accountability for funds and other assets provided by USAID.

2. The Agreement Officer can only award the cooperative agreement after funds have been appropriated, allocated and committed through internal USAID procedures. While USAID anticipates that these procedures will be successfully completed, potential Applicants are hereby notified of these requirements and conditions for the award.

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

4. Following the selection for award and successful negotiations, the successful Applicant will receive an electronic copy of the notice of the award signed by the Agreement Officer which will serve as the authorizing document. No costs chargeable to the cooperative agreement may be incurred before receipt of either a fully executed Agreement or a specific, written authorization from the Agreement Officer.

B. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

The cooperative agreement will be administered in accordance with:

1. USAID's Automated Directives System (ADS) Part 303
   https://www.usaid.gov/sites/default/files/documents/1868/303.pdf

2. 2 CFR 200, Subpart E—Cost Principles; and if applicable
   http://www.ecfr.gov/cgi-bin/text-

3. 48 CFR 31.2, Federal Acquisition Regulations, and 48 CFR 731.2, USAID Acquisition Regulations—Cost Principles for Commercial Organizations
   http://www.ecfr.gov/cgi-bin/text

C. PRE-AWARD SURVEYS

For organizations that are new to working with USAID or for organizations with outstanding audit findings, USAID may perform a pre-award survey to assess the apparently successful

Applicant's management and financial capabilities. **If** notified by USAID that a pre-award survey is necessary, the apparently successful Applicant must prepare, in advance, the required information and documents.

The additional documents that may be requested are By-laws, constitution, articles of incorporation, organizational policies on travel, procurement, financial management, personnel, etc. When requested, the apparently successful Applicant shall provide copies of the requested additional documents.

Please note that a pre-award survey does not commit USAID to make any award.

D. REPORTING REQUIREMENTS

The format of the activity performance reports, final annual work plan, financial reports and success stories will be determined in conjunction with USAID/Philippines. The Applicant needs to meet all country-specific USG reporting requirements. Reports must be submitted in English.

1. Program Reporting –

Table 1: Program Reports and Schedule

Report	**Submission Date**
Annual implementation plan (includes Gender and Environment Risk Mitigation Plans)	Within 45 days of award
Activity Monitoring and Evaluation Plan (AMEP)	Within 90 days of award
Sustainability Plan	Within 60 days of award
Quarterly Reports (includes progress to date on sustainability, gender, and environment)	Within 30 days of the completion of US fiscal quarter
Annual Reports (includes progress to date on sustainability, gender, and environment)	Within 30 days of the completion of US fiscal year (September 30 of each year)
Close-out Plan	6 months prior to agreement end date
Final Report	Within 90 days of completion of agreement

a. Annual implementation plan – The Recipient is encouraged to design innovative implementation approaches to reach the desired results. The Recipient will develop annual

implementation plans in concert with other key USAID/Philippines partners, and are aligned to each USG fiscal year of the agreement. ***Note: The Applicant will prepare a draft Year 1 implementation plan to be submitted with its application. This draft will be finalized with the AOR within 45 calendar days of award.***

The Year 2 implementation plan, and other subsequent implementation plans, will be prepared and submitted to the AOR no later than 45 days before the close of current USG fiscal Year 1.

The implementation plan must include, at a minimum:

- Proposed accomplishments and expected progress towards achieving program results and performance measures tied to the AMEP
- Timeline for implementation of the year's proposed interventions, including target completion dates
- Information on how interventions will be put in place
- Gender action plan that will define how gender will be integrated in the activity cycle
- Environmental Risk Mitigation Plan which will describe how environmental compliance and climate risk management will be integrated into activity interventions
- Personnel requirements to achieve expected outcomes
- Details of collaboration with other major partners
- An annual budget with estimates of projected monthly expenditures.

b. Activity Management and Evaluation Plan (AMEP) – Within 90 days of award, the Recipient will submit an Activity Management and Evaluation Plan (AMEP) for the life of the activity that derives from the activities outlined in the Activity Description. The AMEP will outline key program interventions, indicators of achievement, and associated annual and life-of-activity targets. The plan will be reviewed and approved by the AOR. ***Note: The Applicant will prepare a draft Year 1 AMEP to be submitted with its application. This draft will be finalized with the AOR within 90 calendar days of award.***

c. Sustainability Plan – The Recipient will submit a sustainability plan for the "TB Innovations and Health Systems Strengthening" Activity within the first 60 days of the agreement. This plan should describe specific interventions that are expected to be sustained after the Cooperative Agreement ends. The sustainability plan will be updated annually and progress and updates to the implementation of the plan should be reported on quarterly and annually as part of regular reports.

d. Quarterly and Annual Progress Reports –

Quarterly Reports – The Recipient will submit to the AOR and other relevant stakeholders (i.e., GPH agencies like DOH and NEDA), quarterly progress reports based on the USG fiscal quarters, i.e., Quarter 1 covers October – December; Quarter 2, January – March; Quarter 3,

April – June, and Quarter 4, July – September. The quarterly report is due within 30 days after the fiscal quarter's end. In lieu of the fourth quarter progress report, the Recipient will submit an Annual Report that covers the fiscal year that just ended. During the final year of implementation, the Recipient will continue to submit quarterly reports except for the fourth quarter when, instead of an Annual Report, the Recipient will be required to submit a Final Report (see letter f below).

Annual Reports – The Recipient must submit the annual report within 30 days after the end of the fiscal year to cover annual performance from October – September of the fiscal year.

At a minimum, both quarterly and annual reports will contain:

- Progress (interventions completed, benchmarks achieved, and performance standards completed) made since the last report by region and province as applicable
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to new or ongoing problems
- Success stories
- Security concerns
- Information on new opportunities for program expansion
- Qualitative data on program achievements and results
- The updated AMEP, as an attachment
- Documentation of best practices that can be taken to scale
- Progress to date on sustainability, gender and environmental risk mitigation plans
- Update on monthly expenditures for the quarter vis-à-vis annual budget

e. Closeout Plan – No later than six (6) months prior to the completion date of the agreement, the Recipient will submit a demobilization plan for Agreement Officer approval. The demobilization plan shall include: 1) draft property disposition plan, 2) plan for the phase-out of in-country operations, 3) delivery schedule for all reports or other deliverables required under the agreement, and 4) timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

f. Final Report – At the end of the program period, the Recipient will prepare a final report for submission to the AOR, Agreement Officer and other relevant stakeholders (i.e., GPH agencies like DOH and NEDA) which highlights accomplishments against implementation plans; gives the final status of the benchmarks and results; documents lessons learned during implementation and suggests ways to resolve constraints identified. The report will describe the achievements of the activity in light of the history of USAID programming, the legacy that USAID will leave in the TB sector and the status of the operating environment.

The Final Report must contain a three-page executive summary, an index of all reports and information products produced under the agreement and a summary of the activity's finances, disaggregated at the program area and contain, at a minimum:

- Total award budget
- Total funds awarded by USAID.

Within ninety (90) calendar days following the estimated completion date of this award, the Recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

1) Electronically: http://www.usaid.gov/results-and-data/information-resources/development-experience-clearinghouse-dec

2) By U.S. Postal Service delivery to:

U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

Note: For the Quarterly, Annual and Final Reports, the following essential bibliographic information should be included on the cover page:

1) descriptive title;
2) author(s) name;
3) award number;
4) the recipient's name;
5) development objective; and
6) date of publication or issuance date of the report.

2. Financial Reporting –

The Recipient will account for expenditures for interventions carried-out under this project to ensure funds are used for their intended purposes.

Quarterly Financial Reports – The Recipient shall submit quarterly financial reports to USAID no later than ten (10) calendar days prior the end of each USG fiscal quarter. They should be disaggregated at the program area and contain, at a minimum:

- Total award budget;
- Total award funds obligated to date;
- Total funds previously reported as expended by applicant by main line items;
- Total funds expended in the current quarter by budget line items;
- Total funds expended (actual plus estimated accrued) towards the end of the report period
- Total un-liquidated obligations by main line items;
- Unobligated balance of USAID funds;
- Estimated expenditures for remainder of year;
- Estimated expenditures for remainder of project;
- Estimated fund support per province; and
- Total obligated funds expended by main line items to date.

E. PROGRAM INCOME

No program income is anticipated under this award.

F. FOREIGN GOVERNMENT DELEGATION TO INTERNATIONAL CONFERENCES

Funds in the agreement may not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a public international organization, except as provided in ADS Mandatory Reference "Guidance on Funding Foreign Government Delegations to International Conferences" at http://www.info.usaid.gov/pubs/ads/300/refindx3.htm or as approved by the Agreement Officer.

G. SALARY SUPPLEMENTS FOR HOST GOVERNMENT EMPLOYEES

Any payments by the Recipient to employees at any level of any foreign government shall be subject to the USAID policy on salary supplements (dated April 1988 or as amended). If this issue arises during the period of the Agreement, the Recipient shall consult with USAID on any questions regarding the applicability of the policy.

H. BRANDING STRATEGY AND MARKING PLAN

It is a federal statutory and regulatory requirement that all USAID programs, projects, activities, public communications, and commodities that USAID partially or fully funds under a USAID grant or cooperative agreement or other assistance award or sub-award, must be marked appropriately overseas with the USAID Identity. See Section 641, Foreign Assistance Act of 1961, as amended and 2 CFR 700.16.

Under the regulation, *USAID requires the submission of a Branding Strategy and a Marking Plan, but only by the "Apparent Successful Applicant,"* as defined in the regulation.

A Branding Strategy and Marking Plan must be in accordance with USAID Branding and Marking Plan as required per ADS 320 at the following link: https://www.usaid.gov/ads/policy/300/320.

The Apparent Successful Applicant's proposed Branding Strategy and Marking Plan may include a request for approval of one or more exceptions to marking requirements established in 2 CFR 700.16. The Agreement Officer is responsible for evaluating and approving the Branding Strategy and a Marking Plan (including any request for exceptions) of the Apparently Successful Applicant, consistent with the provisions "Branding Strategy," "Marking Plan," and "Marking of USAID-funded Assistance Awards" contained in AAPD 05-11 and in 2 CFR 700.16. Please note that in contrast to "exceptions" to marking requirements, waivers based on circumstances in the host country must be approved by the Mission Director or other USAID Principal Officers, see 2 CFR 700.16(j).

END OF SECTION VI

SECTION VII: AGENCY CONTACTS

USAID/Philippines contact for this RFA is:

Name:	Ms. Sandra Jansen
Title:	Agreement Officer
Email Address:	sjansen@usaid.gov
Postal Address:	Regional Office of Acquisition & Assistance USAID/Philippines Annex 2 Building U.S. Embassy 1201 Roxas Boulevard 1000 Ermita, Manila

Please note that only the abovementioned Agreement Officer is authorized to make commitments in behalf of USAID/Philippines.

Any questions on the information contained in this RFA should be sent to:

Name:	Grace M. Laspiñas
Title:	Acquisition and Assistance Specialist
Email Address:	manila-roaa-rfp@usaid.gov With subject line: “Questions on TB Innovations RFA submitted by [Name of Organization]”

END OF SECTION VII

SECTION VIII: OTHER INFORMATION

1. USAID RIGHTS

The Applicant is reminded that USAID reserves the right to fund any one or none of the applications received.

Issuance of this RFA does not constitute an award commitment on the part of USAID nor does it commit USAID to pay for costs incurred in the preparation and submission of questions/comments or application.

2. ANNEXES

Annex A – Health Project 2017-2022 Implementation Activities

Annex B – Tuberculosis Data

Annex C – Health Project 2017-2022 Results Framework

Annex D – Distribution of Interventions– Department of Health, Global Fund and USAID

Annex E – Gender Considerations

Annex F – Initial Environmental Examination

Annex G – List of Reference Documents

ANNEX A - Health Project 2017-2022 Implementation Activities

USAID/Philippines will implement the 2017-2022 Health Project through a combination of state-of-the-art field platforms, roll-out of innovations and system strengthening activities, along with monitoring, evaluation, learning and adapting. The suite of project activities related to tuberculosis will include:

- Five tuberculosis technical activities that transfer state-of-the-art experience in behavior change, quality improvement and equitable access to services, as well as working with the Department of Health and other stakeholders to develop and help roll out innovations in partnering, service delivery and technologies.

- Four systems strengthening activities designed to make local ownership a reality by fortifying regional health governance, central and regional health financing and resource management, supply chain management and human resources, while institutionalizing leadership and technical training, supply chain management and policy development, currently being buttressed by USAID and other donors, into the Department of Health.

- A Collaborating, Learning and Adapting activity that will assist USAID to define and report on the quantitative and qualitative progress, define a strategic research and analysis agenda in cooperation with stakeholders, evaluate data quality, conduct impact and program evaluations and develop tools and opportunities for dissemination and adaptation.

Health Activity Descriptions are below:

Tuberculosis Activities

- **"Patient-Centered TB Care"** - The "Patient-Centered TB Care" activity will collaborate with the Government of the Philippines to expand, scale-up and institutionalize prevention, detection, and treatment of tuberculosis and multidrug-resistant (MDR) TB. Through partnerships with regional, provincial and local governments and communities, the activity will build capacity to reduce the tuberculosis burden in selected regions, reinforcing the responsiveness of the health care delivery system, and develop approaches to reduce the catastrophic costs associated with tuberculosis treatment. The activity will focus on encouraging families and communities to adopt and foster healthy behaviors to prevent, detect and treat TB, uphold implementation at scale in regions with the highest TB burden and bolster key health systems necessary for efficient and optimal delivery of quality TB services. The activity will collaborate closely with partners to provide wrap-around technical assistance and scale-up new approaches and models developed by the "TB Innovations and Health Systems Strengthening" activity. Expected results include: improved TB health care-seeking, treatment adherence, and enrollment on treatment; robust service delivery networks with qualified health providers that offer comprehensive TB prevention, care and treatment services; and fortified systems that support governance, financing, laboratory services and data management and monitoring.

- **"TB Innovations and Health Systems Strengthening" -** The "TB Innovations and Health Systems Strengthening" activity to be awarded under this NFO is designed to strengthen national and regional level implementation of the National TB Strategic Plan by providing state-of-the-art

capacity building and approaches to scale-up TB and MDR-TB prevention, detection and treatment. The activity will fortify policies and build the capacity of the Department of Health and regions to implement a world-class national TB program, institutionalize and sustain partnerships with the private sector for TB prevention, detection and treatment, pilot and test innovative approaches to improve the quality of care for patients with DR-TB and bolster the TB diagnostic network system. The activity will also implement activities to address human resource and supply chain barriers that prevent quality TB service delivery. The activity will collaborate closely with the DOH, the Global Fund principal recipients and subrecipients, and other USAID partners to maximize contributions and investments to the TB program. Expected results include: improved, evidence-based approaches for engaging the private sector to diagnose and treat TB patients; more comprehensive and rapid high-quality TB laboratory diagnostics systems; accelerated development and dissemination of national TB policies and guidelines that are aligned with international standards; analysis and introduction of new treatment regimens, medications and approaches for DR-TB; and consistent supply of quality health service providers and TB drugs and commodities.

- **TREAT TB -** TREAT TB will provide interim capacity-building and expertise to bolster scaling up the shortened TB regimen (STR) with Bedaquiline, including integration of pharmacovigilance monitoring, support operations research (OR) and other analyses for the shortened treatment regimen, develop and implement OR training courses and develop initial strategies for engaging the private sector. This activity lays the groundwork for and will complement activities conducted under the "TB Innovations and Health Systems Strengthening" mechanism. Expected results include: enhanced quality of care and pharmacovigilance for patients under the STR, realistic and focused scale up of the STR to assure quality of services, accurate and improved analysis of the STR and bedaquiline data from the OR phase, and DOH staff trained to conduct operations research.

- **World Health Organization Technical Advisory Services -** The World Health Organization (WHO) TB technical advisor is to provides in-house international expertise in TB to the National TB Program to assist ending the global TB epidemic by 2035. To reinforce the National TB Elimination Plan (PhilSTEP1), the technical advisor will provide state-of-the-art technical expertise to improve the patient-centered care approach, enhance private sector engagement, integrate and mainstream TB and DR-TB care and treatment with other programs and improve quality of the TB program using data, evidence-based approaches and monitoring.

- **Technical Assistance and Support Contract (TASC) -** The Technical Assistance and Support Contract (TASC) provides in-house TB expertise and guidance on the expansion of prevention, diagnosis and programmatic management of drug-resistant TB in the context of Global Fund grant implementation. The technical advisor to the National TB Program identifies bottlenecks and facilitates solutions through coordinated capacity building, provides assistance to the Global Fund principal recipient to implement Global Fund grants, and assists the country to leverage resources for TB control and elimination.

Systems Strengthening Activities

- **Health Leadership and Governance (HLGP) -** The Health Leadership and Governance activity aims to institutionalize leadership and governance capacity building in central and regional health management systems. The activity bolsters the Department of Health's (DOH) capacity to manage HLGP by integrating leadership and governance capabilities into the DOH's performance competency-based framework. The activity will fortify the leadership capabilities of the DOH's Regional Offices to influence and affect health systems strengthening at the regional and local levels. Illustrative interventions include: developing and buttressing local health systems; co-developing leadership competency standards; collaborating with DOH Regional Offices to coach and mentor chief executives in provinces, cities, and municipalities; and integrating leadership modules for different levels of local government to address adaptive leadership challenges within a service delivery network. Expected results include: enhanced leadership and management capacities of the Bureau of Local Health Systems Development to implement the Health Leadership and Governance Program; leadership and governance competencies integrated into the DOH Competency Framework; and DOH Regional Offices, local government units, civil society, and the private sector established as convergence mechanisms to bolster HLGP implementation.

- **Expanding Universal Health Care** - The goal of the "Expanding Universal Health Care" Activity is to work with national, regional and local level institutions (Department of Health (DOH), PhilHealth and local government units (LGU)) to plan for adequate and sustained financing for health programs and services. The activity aims to institutionalize policy development, monitoring and oversight within the DOH and PhilHealth; build management, analytical and financial capacity at the central and regional levels of the DOH and PhilHealth; and assist regional governments to establish trust funds and other similar mechanisms for health financing at the LGU level. Illustrative interventions include: building fiscal and financial management capacities at the national, regional and local levels; developing a monitoring mechanism to track optimal utilization of funds for health; supporting the DOH and PhilHealth to streamline accreditation and claim processes; and rationalizing zero balance billing to support implementation at the national, regional, and local levels. Expected results include: increased demand for and utilization of PhilHealth benefits and reduced out-of-pocket expenses by underserved populations; DOH and PhilHealth financing policies and guidelines translated and systematically implemented at the regional and local levels; establishment of trust funds and similar mechanisms for health financing by LGUs; and increased and effective utilization of health budgets.

- **Supply Chain Management -** The goal of the "Supply Chain Management" Activity is to provide state-of-the-art capacity-building to the Department of Health (DOH) to establish a fully functional TB supply chain management system, including but not limited to forecasting, procurement, warehousing, inventory management, distribution and use at the point of care. Illustrative interventions include: establishing procedures, training, and monitoring systems for supply chain operations at the regional, local, and facility/provider levels; assisting the DOH and other Government of Philippines Agencies with pharmacovigilance and antimicrobial resistance monitoring. The activity will collaborate closely with the DOH, the Global Fund principal recipients and subrecipients, and other USAID partners to maximize contributions and

investments to the supply chain management program. Expected results include: an established functional supply chain system at the DOH that provides adequate and timely access to a regular supply of quality commodities at the point of care and supported by an enabling policy, legal and governance framework; and a strengthened pharmacovigilance and antimicrobial resistance monitoring system.

- **Human Resources for Health** - The goal of the "Human Resources for Health" Activity is to provide capacity-building to the Department of Health (DOH), at all levels, to strengthen the deployment, training, and management of a qualified health workforce to improve access to and quality of family planning (FP), maternal and child health (MCH) and TB services for vulnerable populations. Illustrative interventions include: assisting the DOH to develop a staffing plan that delineates requirements and competencies at all levels of care; supporting the DOH to conduct training needs assessments, develop a health workforce database, and institutionalize health service provider training courses; and building the capacity of the DOH to develop HRH policies and guidelines. Expected results include: an institutionalized training system; an improved workforce deployment system for competent and qualified health providers; and the development and implementation of relevant HRH policies and guidelines.

- **Collaboration, Learning and Adapting** - The "Collaboration, Learning and Adapting" Activity (CLA) will serve as the primary monitoring, evaluation, and learning instrument for the USAID/Philippines Office of Health's Health Project 2017-2022. The activity will provide technical assistance, advisory services and relevant logistical support to monitor project performance, design and implement performance evaluations, conduct select implementation research and impact evaluations, conduct secondary analyses of research data, and facilitate continuous collaboration, learning and adapting for all Health Project activities. Information generated by this activity will be used to inform policy recommendations and programmatic decision-making throughout the life of the Health Project. Expected results include: completion of analyses of USAID's contributions to support achievement of select indicators of the Philippine Health Agenda which may include, reductions in TB, reductions in unmet need for FP, and reductions in teen pregnancies and neonatal deaths; collection and analysis of baseline data for required and high-level project indicators; monitoring project level performance; completion of a project performance evaluation; completion of select impact and implementation research studies; and organization of innovative learning opportunities for adaptive management.

ANNEX B – TB Data

2015 NTP Report 3a. Case Finding of DS-TB Cases and IPT

Region	P						EP						All TB Cases	IPT		
	New		Relapse		Prev Treated		New		Relapse		Prev Treated			0-4	PLHIV	Total
	BC	CD	BC	CD	BC	CD	BC	CD	BC	CD	BC	CD				
NCR	11,154	28,371	1,464	1,701	1,140	1,319	110	891	6	46	7	36	46,245	1,302	6	1,308
CAR	856	2,471	27	37	26	29	19	143	1	3	0	2	3,614	5	0	5
I_Ilocos	4,250	10,545	219	292	76	76	13	353	0	7	1	6	15,838	330	1	331
II_Cagayan_Valley	2,458	6,102	99	261	38	134	12	168	3	7	0	3	9,285	162	0	162
III_Central_Luzon	9,443	21,010	630	1,385	279	570	102	312	5	5	7	15	33,763	383	2	385
IVA_CaLaBaRZon	12,084	25,979	1,026	1,782	587	1,035	19	516	0	14	0	20	43,062	370	4	374
IVB_MiMaRoPa	2,725	5,430	262	813	93	171	4	138	2	2	0	4	9,644	71	0	71
V_Bicol	6,321	12,140	489	1,333	163	454	28	334	2	11	1	5	21,281	291	0	291
VI_Western_Visayas	8,827	15,617	792	1,128	305	461	11	487	0	22	0	16	27,666	0	0	0
VII_Central_Visayas	7,068	10,299	386	570	70	62	12	391	0	6	1	3	18,868	667	274	941
VIII_Eastern_Visayas	4,726	5,912	240	461	122	177	17	342	0	3	0	3	12,003	197	0	197
IX_Zamboanga_Peninsula	3,865	5,071	206	641	117	209	9	151	0	2	0	2	10,273	421	6	427
X_Northern_Mindanao	4,073	7,609	188	498	45	150	8	446	2	5	0	4	13,028	513	9	522
XI_Davao	5,231	6,313	275	401	117	145	109	212	4	4	7	5	12,823	202	34	236
XII_SoCCSKSarGen	5,067	9,395	209	603	85	264	5	275	0	2	0	6	15,911	504	24	528
XIII_CARAGA	3,169	5,107	193	341	47	147	8	187	1	10	0	3	9,213	353	5	358
ARMM	3,310	4,470	103	296	74	138	6	67	6	3	1	6	8,480	78	6	84
Philippines	**94,627**	**181,841**	**6,808**	**12,543**	**3,384**	**5,541**	**492**	**5,413**	**32**	**152**	**25**	**139**	**310,997**	**5,849**	**371**	**6,220**

Registration Group	All Forms (New + Relapse)										Prev Treated
Sex	0-4	5-14	15-24	25-34	35-44	45-54	55-64	>=65	Unknown	Total	
M	8,523	11,484	26,008	28,791	29,560	31,707	28,677	24,170	6,233	195,153	6,384
F	7,204	9,505	15,674	15,357	13,568	13,992	13,512	14,721	3,222	106,755	2,705
Total	15,727	20,989	41,682	44,148	43,128	45,699	42,189	38,891	9,455	301,908	9,089

Public HC	195,655
Other Public	43,498
Private	41,977
Community	20,009
Unknown	769
All Forms	301,908

2015 NTP Report 3a. Case Finding of DS-TB Cases and IPT v2017

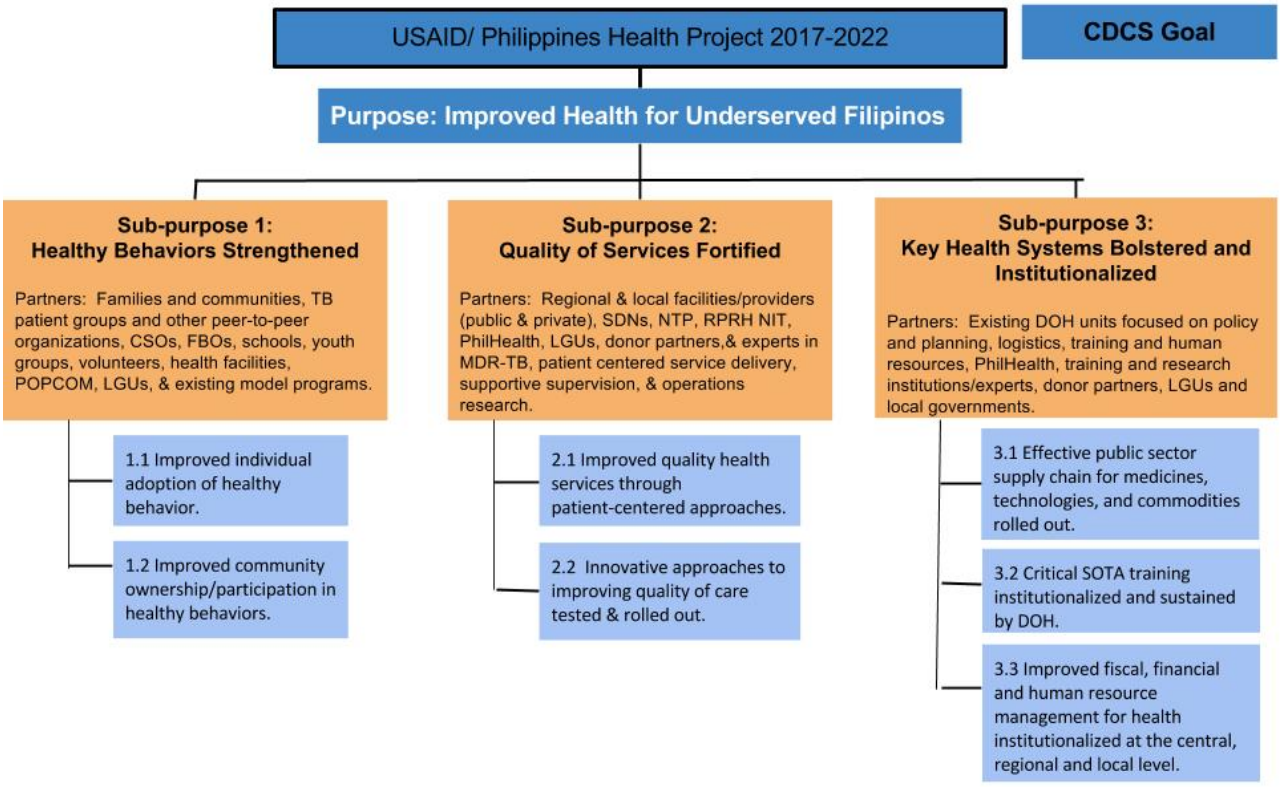
Region	Population	Presumptive TB Examined	DSSM Positive	Positivity Rate	Total								Estimate	CDR	CNR
					Children	EP	P	New	Retreatment	BC	CD	All TB	Incidence Rate:	322		
													All Forms (New + Relapse)			
NCR	12,977,075	138,309	15,351	11%	6,657	1,096	45,149	40,526	5,719	13,881	32,364	46,245	43,743	41,786	105%	337
CAR	1,762,502	13,599	786	6%	992	168	3,446	3,489	125	929	2,685	3,614	3,557	5,675	63%	202
I_Ilocos	5,052,994	39,267	4,774	12%	2,520	380	15,458	15,161	677	4,559	11,279	15,838	15,679	16,271	96%	310
II_Cagayan_Valley	3,463,674	22,117	2,212	10%	1,710	193	9,092	8,740	545	2,610	6,675	9,285	9,110	11,153	82%	263
III_Central_Luzon	11,295,742	72,150	10,843	15%	7,535	446	33,317	30,867	2,896	10,466	23,297	33,763	32,892	36,372	90%	291
IVA_CaLaBaRZon	14,724,550	67,085	9,656	14%	5,342	569	42,493	38,598	4,464	13,716	29,346	43,062	41,420	47,413	87%	281
IVB_MiMaRoPa	3,004,208	26,189	3,130	12%	1,285	150	9,494	8,297	1,347	3,086	6,558	9,644	9,376	9,674	97%	312
V_Bicol	5,836,655	57,075	7,441	13%	1,881	381	20,900	18,823	2,458	7,004	14,277	21,281	20,658	18,794	110%	354
VI_Western_Visayas	7,603,147	55,294	7,429	13%	2,484	536	27,130	24,942	2,724	9,935	17,731	27,666	26,884	24,482	110%	354
VII_Central_Visayas	7,436,253	65,714	8,031	12%	832	413	18,455	17,770	1,098	7,537	11,331	18,868	18,732	23,945	78%	252
VIII_Eastern_Visayas	4,375,473	31,918	4,390	14%	877	365	11,638	10,997	1,006	5,105	6,898	12,003	11,701	14,089	83%	267
IX_Zamboanga_Peninsul	3,745,198	34,835	4,205	12%	355	164	10,109	9,096	1,177	4,197	6,076	10,273	9,945	12,060	82%	266
X_Northern_Mindanao	4,768,630	40,554	4,128	10%	756	465	12,563	12,136	892	4,316	8,712	13,028	12,829	15,355	84%	269
XI_Davao	4,937,195	52,433	6,908	13%	590	341	12,482	11,865	958	5,743	7,080	12,823	12,549	15,898	79%	254
XII_SoCCSKSarGen	4,654,971	43,319	7,916	18%	2,182	288	15,623	14,742	1,169	5,366	10,545	15,911	15,556	14,989	104%	334
XIII_CARAGA	2,619,098	29,316	3,426	12%	865	209	9,004	8,471	742	3,418	5,795	9,213	9,016	8,433	107%	344
ARMM	3,514,588	25,147	3,386	13%	701	89	8,391	7,853	627	3,500	4,980	8,480	8,261	11,317	73%	235
Philippines	**101,771,953**	**814,321**	**104,012**	**13%**	**37,564**	**6,253**	**304,744**	**282,373**	**28,624**	**105,368**	**205,629**	**310,997**	**301,908**	**327,706**	**92%**	**297**

Source: http://ntp.doh.gov.ph/downloads/ntp_data/2015_ntp_conso_report_3a_and_5a_v011517.pdf

Region	All TB Cases Reported in 2014	% Over/ Under Reporting	All Forms (New + Relapse)								Prev Treated (except Relapse)							Excluded
			Cured	Completed	Failed	Died	Not Eval.	LTFU	Total	Success Rate	Cured	Completed	Failed	Died	Not Eval.	LTFU	Total	
NCR	40,301	-12%	9,932	21,797	171	454	1,557	1,598	35,509	89%	77	16	2	3	5	14	117	
CAR	3,123	-5%	757	1,943			277		2,977	91%	0	0	0	0	0	0	0	
I_Ilocos	13,440	0%	4,170	8,506	67	267	88	183	13,281	95%	29	78	2	8	3	10	130	13
II_Cagayan_V	7,602	0%	2,201	4,737	37	174	62	189	7,400	94%	60	10	2	14	6	7	189	0
III_Central_Lu	26,092	11%	8,114	17,790	231	519	342	1,059	28,055	92%	171	67	17	27	22	93	1,007	13
IVA_CaLaBaRZ	37,171	-4%	9,142	21,701	284	723	464	1,669	33,983	91%	305	80	9	63	28	122	1,331	201
IVB_MiMaRoP	9,018	-9%	1,929	5,288	37	242	79	375	7,950	91%	40	15	4	13	10	20	245	24
V_Bicol	18,087	-2%	5,280	10,354	96	374	192	575	16,871	93%	95	56	8	43	11	56	782	68
VI_Western_V	27,706	2%	8,085	18,187	67	516	255	938	28,048	94%	62	50	4	10	7	12	145	0
VII_Central_Vi	16,010	-58%	2,367	3,915	29	192	13	132	6,648	94%	16	11	0	1	0	2	30	23
VIII_Eastern_	9,981	0%	3,457	5,225	44	282	115	396	9,519	91%	81	28	10	21	12	35	447	6
IX_Zamboang	9,521	-2%	3,271	4,653	75	275	97	312	8,683	91%	218	28	10	17	3	27	564	41
X_Northern_	9,951	-3%	3,627	5,371	54	233	119	261	9,665	93%	3	4	1	2	0	0	10	0
XI_Davao	12,124	-11%	4,282	5,122	65	282	88	398	10,237	92%	116	37	13	22	5	30	560	1
XII_SoCCSKSar	12,243	5%	4,470	7,110	52	270	99	577	12,578	92%	33	16	4	9	2	12	226	1
XIII_CARAGA	9,356	-7%	2,855	4,777	52	239	95	279	8,297	92%	60	24	3	23	8	19	362	36
ARMM	7,109	-6%	2,492	3,174	35	141	98	509	6,449	88%	27	12	2	6	24	55	240	0
Philippines	**268,835**	**-6%**	**76,431**	**149,650**	**1,396**	**5,183**	**4,040**	**9,450**	**246,150**	**92%**	**1,393**	**3,95**	**91**	**282**	**146**	**514**	**6,385**	**427**

Source: http://ntp.doh.gov.ph/downloads/ntp_data/2015_ntp_conso_report_3a_and_5a_v011517.pdf

ANNEX C - Health Project 2017-2022 Results Framework



ANNEX D - Distribution of interventions - DOH, Global Fund and USAID

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Total Funding	$132 million over 5 years (assuming no increase in budget allocation)	$20 million over 5 years (2017 - 2022)	$30 million over 5 years (2017-2022)	$88 million over 3 years (2018-2020)
Procurement	Procurement of 100% of DS-TB drugs/laboratory supplies for targeted 1,480,900 TB cases in 5 years Currently no allocation for DR TB drugs but aims to procure SLD for 30% of enrolled cases by 2018, 60% by 2019 and 100% by 2020	No procurement planned	No procurement planned	Second-line TB drugs, laboratory tests and 584 (plus 280 from Catalytic Funding) GeneXpert machines.
Case finding	Testing of __% of estimated 5 million presumptive TB cases in 5 years	Support to engage individuals and communities to foster health care-seeking and treatment adherence including interventions for stigma reduction and increased detection of new TB cases through community approaches	Pilot and evaluate new approaches to detect TB cases	Testing of 900,000 presumptive TB cases Detection and Treatment of 34,935 patients through systematic screening of high risk groups among urban poor (in Reg 3, 4A, NCR, 6 and 11) and in 18 jails/prisons.

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Diagnosis	Develop and disseminate guidelines for scale up and expanded use of Xpert	Improve access to TB laboratory systems that provide rapid test results for TB at decentralized levels	Support to develop comprehensive strategic approach for diagnostic network, expand new diagnostic tools, improve quality assurance of diagnostics	Introduction of Xpert (OMNI-Organizing Medical Network Information/Single Module) as primary diagnostic tool available at point of care. Establishment of 2 LPA centers Improve systems for sputum collection/transport Improve QA for laboratory services
Service Delivery	Update NTP manual of procedures Capacity building of healthcare workers at all levels	Capacity-building to improve quality of mainstreaming DR-TB services in target regions. This includes: supportive supervision, infection control strengthening, respectful care	Capacity-building to develop private sector strategy for increased engagement	Improving infrastructure, systems, protocols and capacity building of healthcare providers Interrupter tracing, reduce LTFUs and improve treatment outcomes

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Private Sector	Develops strategic plan and establishes policies, guidelines and procedures	Roll-out policies, procedures and guidelines in select regions	Develops, tests and measures new strategies and approaches Supports DOH to develop strategy, policies, guidelines and procedures to increase private sector engagement	54,000 patients contributed by engagement of private sector Private sector engagement - standalone physicians, private providers, pharmacies Contract staff for program implementation and management, including 150 private sector "mobilizers"
DR TB	Programmatic implementation of SSTR Adopt and expand the use of new drugs Capacity building of all healthcare workers on PMDT	Strengthen and improve service delivery networks, engage health care providers to deliver quality patient-centered DR TB services	Testing of new approaches for DR TB detection, prevention and treatment	Detection and enrollment of 22,620 patients DRTB Cases 30% of the 2,600 RHUs will be upgraded as iDOTS and Xpert Centers by 2019. The rest of the RHUs will provide community-based care for directly observed treatment for the MDR/RR TB patients in their

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
				areas.
TB-HIV	Expand TB/HIV collaboration to cover 100% coverage by 2020 80% of adult TB cases provided with PICT.	Some assistance to foster healthy behaviors of vulnerable populations including co-infected PLHIV	New approaches for TB-HIV	Full coverage of TB-HIV collaborative services in full implementation in the National Capital Region, Region 3 and Region 4A 396,918 TB patients tested on HIV
Policies, Guidelines and Research	Leads development and roll-out of policies and guidelines	Implementation and roll-out of policies and guidelines in target regions	Assistance to develop national policies and guidelines	Support research such as the 2018 Inventory Study, Drug Resistance Survey, 2019 JPR and Catastrophic Cost Study and Implementation Research for TB free areas/islands

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Health information Systems	Overall management of ITIS through KMITS Conduct of Data Quality Checks Development of tools for recording, reporting and monitoring Implement policy and mechanisms for notifying TB cases by non-NTP providers	Improving collection, analysis and use of data at regional to facility levels	Testing new approaches to data collection, analysis and use of data	ITIS and support to improve the information system Provides hardware and internet access Hires programmers, system analyst and data managers

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Governance and Finance	Leads negotiations to improve governance and financing of TB programs Works with counterparts to develop PhilHealth benefit package for DR TB	Build capacity of decentralized levels (LGUs and providers) to manage, finance and oversee TB programs	Build capacity of NTP and regional levels to manage, finance and oversee TB programs Assistance to document and analyze administrative, human resource and financial needs for TB program Advocacy and capacity building to transition and sustain Global Fund investments	

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Supply Chain	Procurement, storage, distribution and management of NTP logistics	Support to roll-out supply chain policies and guidelines	USAID TB Supply chain management activity (separate activity) - technical assistance	Development of a national strategic plan to strengthen the current pharmaceutical management system of the DOH. Support engagement of technical assistance providers to assist in the development of a functional data management system for Procurement and Supply Chain Management (PSCM) Supply planning at facility, provincial/regional, central levels Integrating procurement mechanisms at regional/central levels through procurement framework contracts

Technical Area	DOH	USAID Patient-Centered TB Care	USAID TB Innovations & Health Systems Strengthening	Global Fund
Human Resources for Health	Develop and implement comprehensive HRD plan for Training activities of human resources at all levels Deployment of human resources for health/ rural-based health workers	Support to roll-out human resource policies and guidelines	Technical assistance to strengthen TB human resources Pilot test new approaches for HRH	

ANNEX E - Gender Considerations

USAID's Gender Equality and Female Empowerment Policy

Gender equality and women's empowerment are essential for achieving USAID's development goals. The USAID Gender Policy advances equality between women and men, boys and girls, and empowers women and girls to participate fully in and benefit from development activities, through the integration of gender in the entire project cycle -- from project design and implementation to monitoring and evaluation. This integrated approach focuses on achieving three overarching outcomes: 1) Reducing gender disparities in access to, control over and benefit from resources, wealth, opportunities, and services – economic, social, political, and cultural; 2) Reducing gender based violence and mitigate its harmful effects on individuals and communities, so that all people can live healthy and productive lives; and 3) Increasing the capability of women and girls to realize their rights, determine their life outcomes, and influence decision making in households, communities, and societies.

The "Patient-Centered TB Care" activity is expected to contribute to the first listed outcome by reducing gender disparities in access to and benefit from tuberculosis care and treatment services. It is also encouraged to contribute to the third listed outcome by increasing the capability of women and girls to realize their right to seek healthcare services and to influence decision-making regarding health care. Furthermore, as gender barriers often prevent men and boys from seeking services, the activity will work to transform negative masculinities that prevent men and boys from taking care of their own health as well.

Activity interventions will be implemented in a manner that promotes fair, equitable, and meaningful inclusion of both men and women in all activity interventions.

To provide greater focus on gender equality and women's empowerment in this activity, the Activity will prepare a Gender Action Plan that will include the following considerations:

- Conduct of training for the activity staff, partners and cooperators on gender awareness, gender analysis and gender-responsive planning.
- Collection of sex-disaggregated data for use of gender analysis tools to identify potential gender gaps and constraints.
- Conduct gender-responsive consultations to encourage the active participation of women and men and guarantee that the baselines and monitoring of all people-level indicators and voices of TB patients are heard and reflected in activity plans and activities.

The preparation of the Gender Plan of Action should be guided by the USAID gender policy (https://www.usaid.gov/sites/default/files/documents/1865/GenderEqualityPolicy_0.pdf) and compliant with GPH's Harmonized Gender and Development Guidelines in http://neda.gov.ph/hgdg/homepage.html.

Integration of Gender Considerations to Strengthen the TB Response

The Government of the Philippines has shown tremendous dedication and success regarding gender equality and women's empowerment. According to the 2016 World Economic Forum's Global Gender Gap Report, the Philippines ranks seventh of 144 countries worldwide on gender parity, higher than any other country in Asia. It is also one of four countries in the East Asia and Pacific region to close the Health and Survival gender gap and one of only two to close the Educational Attainment gap. While acknowledging these very impressive achievements, it is also necessary to remember the variation that exists among geographic regions and cultural groups. For example, the 2013 DHS found that, nationwide, 9.2 percent of women cited getting permission as a barrier to accessing health care, this ranged from 4.1 percent in CALABARZON to 30.3 percent in ARMM. Almost 48 percent of women nationwide cited money as a barrier, ranging from 31.4 percent in Davao to 90.7 percent in ARMM. Assessing and addressing the specific needs of these less-advantaged women will be necessary to achieve full gender equality.

Gender impacts how tuberculosis is experienced; to be most effective, TB programs need to take this into consideration at all stages of programming -- planning, implementation, monitoring and evaluation -- and at all points along the health/illness continuum -- risk factors, exposure, knowledge, access to services, diagnosis, treatment, support and recovery. The "Patient-Centered TB Care" activity is expected to analyze these differences and design gender-sensitive or gender-transformative activities. The activity shall also assert and uphold the right of all individuals -- men, women, and transgender people -- to access quality healthcare services. Due to lack of data regarding TB and transgender individuals, this section will focus on differences between men and women.

In the Philippines, 65 percent of incident cases in 2015 were among males and 35 percent were among females, close to the global averages of 62 percent among males and 38 percent among females (WHO, Global TB Report, 2016). The 2007 Nationwide TB Prevalence Survey reports a similar disparity in prevalence: 65 percent of smear positive cases are among males and 35 percent among females, and 73 percent of culture positive cases are among males and 27 percent among females (p. 58). The National TB policy (2010–2016) reports similar findings, stating that TB cases are more than two times more common among males than females. Consequently, successful TB activities will serve approximately two times more men than women. To be effective and most efficient in bringing the TB epidemic under control, men will need to be specifically targeted by TB interventions.

Interviews conducted as part of a USAID Evaluation of the Tuberculosis Portfolio (2012) revealed that the National Tuberculosis Program and other organizations involved in TB control and prevention disaggregate patient data by gender, but have not considered gender in the planning process and resulting documents. (The Updated 2010-2016 Philippine Plan of Action to Control TB does not mention any differences in TB rates, case notification, treatment or outcome by gender or sex.) Neither gender inequality nor lack of women's empowerment by themselves are considered a barrier to diagnosis and treatment, and the evaluation recommended that simple operational studies could be undertaken to further analyze gender issues and possible barriers to TB care.

Men and women may also experience different risk factors and exposures to TB. For example, men may be more likely to smoke or drink alcohol, increasing risk of tuberculosis. Occupational exposures can also vary. For example, men engaged in mining activities are at much higher risk; other studies have shown that women taking care of sick relatives may be at elevated risk.

Men and women may experience stigma related to TB in different ways and may have differing levels of knowledge of the disease and treatment options -- both factors that influence an individual's health seeking behavior. For example, results from the 2007 Prevalence Survey show that fewer men (84.3 percent) than women (89.1 percent) had heard of TB (p. 74), and men were slightly less likely to identify bacteria as the cause for TB (7.2 percent) than women (9.3 percent) (p. 75). Men were also less likely than women to identify each of seven symptoms as associated with TB (p. 77).

Once an individual does decide to seek care, subsequent barriers to care also differ: women may lack the financial resources or autonomy to visit a clinic; men may be unable to miss work to attend a clinic during regular hours. Stakeholders familiar with the health system report that men do not regularly access health care because the hours of health clinics usually overlap with their work schedules. Earlier research has also documented these gender-related and service provision factors that influence men's access to healthcare (Lee, 1999; Clark et al., 2007 as mentioned in Kiesel, et. al., 2014). More recently, the 2012 USAID Program Evaluation showed that men have difficulty accessing TB services since most facilities' operating hours overlap with their working hours. This hinders the men from going to the facilities, since they are daily-wage earners and having check-ups has an opportunity cost. Stigma surrounding TB by communities and potential employers, as well as potential and actual patients themselves, exacerbates the problem (USAID Philippines, 2012). The Prevalence Survey found that more men took no action regarding their TB symptoms (31 percent) than women (18.5 percent) (p. 78).

Differences in preference of health care providers and in treatment completion and success also exist. When seeking care, 19.6 percent of men vs. 32.1 percent of women consulted public health care workers at a DOTS Center; 32.4 percent of men and 22 percent of women reported to a hospital or clinic (Prevalence Survey, pg. 80). A study by Tupasi et al. (2006) found that women are more likely than men to be cured following TB treatment, but the researchers could not identify any clinical variable that predicted cure. However, in the Philippine cultural norms, women are perceived to be more compliant (to treatment regimen) than men which could be the reason for higher treatment completion and cure rates.

The success of tuberculosis programs and progress toward the elimination of tuberculosis require gender-sensitive programming. USAID expects the applicant to delve into the gender-based differences related to TB in order to thoughtfully design, implement and monitor activities that most effectively reach the targeted group while contributing to equitable access to quality care.

ANNEX F – Initial Environmental Examination

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INITIAL ENVIRONMENTAL EXAMINATION (IEE)

PROGRAM/ACTIVITY DATA:

Program/Activity Title:	USAID/Philippines Health Project
Development Objective:	Improved Health for Underserved Filipinos
Country/Region:	Philippines/Asia
Foreign Assistance Objective:	Investing in People
Program Area:	3.1. Health
Program Elements:	3.1.2. Tuberculosis 3.1.6. Maternal and Child Health 3.1.7. Family Planning and Reproductive Health
Period Covered:	4/01/2017 – 12/31/2023
Life of Project (LOP) Amount:	$128,250,000
IEE Prepared By:	Maria Teresa Carpio, USAID/Philippines Office of Health
IEE Amendment (Y/N):	No
Current Date:	March 02, 2017
Expiration Date:	December 31, 2023

ENVIRONMENTAL ACTION RECOMMENDED:

Categorical Exclusion:	[X]	Negative Determination with Conditions:	[X]
Positive Determination:	[ ]	Deferral:	[ ]

SUMMARY OF FINDINGS:

Scope: This document provides the first review of the reasonably foreseeable effects on the environment and recommends threshold decisions and conditions for proposed activities under the USAID/Philippines Health Project. In addition, this IEE sets out activity-level procedures intended to ensure that potential environmental impacts are mitigated and conditions are implemented.

Outline and Recommended Threshold Decisions:

This document consists of the following sections:

I – Purpose and Scope
II – Background and Description of the Health Project and Activities
III – Country and Environmental Information
IV - Analysis of Potential Environmental Impact
V – Recommended Threshold Decisions
VI – Climate Risk Management
VII – Monitoring and Implementation

This IEE recommends the threshold decisions summarized in the following table.

Implementing Mechanism (IM)	Categorical Exclusion	Negative Determination with Conditions
Health Leadership & Governance Program	✓	
Collaboration, Learning & Adapting	✓	
Universal Health Care (PhilHealth/Policy)	✓	
Tuberculosis (TB) Platforms	✓	✓
TB Innovations	✓	✓
Family Planning (FP) Innovations & Strengthening Service Platforms	✓	✓
Family Planning/Maternal and Child Health (FP/MCH) Service Delivery in the Autonomous Region in Muslim Mindanao (ARMM)	✓	✓

Limitations: The Program will not undertake any activities determined to pose a significant effect on the environment under 22 CFR 216.2(d)(1). This IEE does not cover activities involving:

- indoor residual spraying of pesticides for malaria control;
- procurement, transport, use, storage, or disposal of pesticides or toxic materials;
- procurement or use and/or disposal of other hazardous/toxic materials for construction projects;
- procurement, use and/or disposal of equipment containing and/or generating low-level radioactive materials and wastes; and
- construction (other than small-scale – e.g. rehabilitation).

General Implementation and Monitoring Conditions: In addition to the specific conditions listed in Section V, the negative determinations recommended in this IEE are contingent on full implementation of a set of general monitoring and implementation requirements specified in Section VII. These include the following:

- briefings for implementing partners on environmental compliance responsibilities;
- development, integration, and implementation of an Environmental Mitigation and Monitoring Plan (EMMP) by each implementing partner;

- EMMPs for activities deemed moderate or high risk, will include appropriate measures to mitigate the impact of climate change, as discussed in Section VI;
- integration of environmental compliance responsibilities in prime and sub-contracts and grant agreements;
- assurance of sub-grantee and sub-contractor environmental compliance;
- environmental monitoring responsibility of the USAID/Philippines Office of Health; and
- amending this IEE to reflect new or substantially modified activities.

APPROVAL OF INITIAL ENVIRONMENTAL EXAMINATION

Development Objective: Improved Health for Underserved Filipinos

Acting Office Chief, Clearance	cleared Bryn Sakagawa	3/2/2017 Date
Mission Environmental Officer/ Climate Integration Lead Clearance	cleared Marian Cruz Navata	3/2/2017 Date
Regional Environmental Advisor Clearance	cleared by email Aaron Brownell	3/2/2017 Date

APPROVAL:

Acting Mission Director

Clay Epperson — Date 3/8/2017

CONCURRENCE:

Bureau Environmental Officer

William Gibson — Date March 8, 2017

INITIAL ENVIRONMENTAL EXAMINATION (IEE)

PROJECT/ACTIVITY DATA:

Activity Name: USAID/Philippines Health Project
Country/region: Philippines/Asia
Start Date: 04/01/2017 **End Date:** 12/31/2023
Life of Project Amount ($): 128.25 million
IEE Prepared by: Maria Teresa Carpio **Date:** 2/28/2017
Amendment: no

ENVIRONMENTAL ACTION RECOMMENDED: (Place X where applicable)

Categorical Exclusion:	[X]	Negative Determination with Conditions:	[X]
Positive Determination:	[ ]	Deferral:	[ ]

I. Purpose and Scope

The purpose of this document, in accordance with Title 22, Code of Federal Regulations, Part 216 (22CFR216), is to provide a preliminary review of the reasonably foreseeable effects on the environment, as well as recommended Threshold Decisions, for the activities detailed below. This document provides a brief statement of the factual basis for Threshold Decisions as to whether an Environmental Assessment or an Environmental Impact Statement is required for the activities managed under the scope of this document. In addition, this IEE presents activity-level implementation procedures intended to ensure that conditions in this IEE are translated into activity-specific mitigation measures, and to ensure systematic compliance with this IEE during Health Project implementation. The activities under review are recommended for the threshold decisions indicated in Table 1 below:

Table 1: Health Project Activities Covered in This IEE, 2017-2023

Implementing Mechanism (IM)	Projected Life of Project Amount	Projected Start and End Dates	Recommended Determination
Health Leadership & Governance Program	$2.0 million	Apr 2017 – Mar 2020	CE*
Collaboration, Learning & Adapting	$7.8 million	Aug 2017 – Jul 2022	CE
Universal Health Care (PhilHealth/Policy)	$11.5 million	Feb 2018 – Jan 2023	CE
Tuberculosis (TB) Platforms	$25 million	Oct 2017 - Sep 2012	CE; NDC**
TB Innovations	$17 million	Dec 2017 – Nov 2022	CE; NDC
Family Planning (FP) Innovations & Strengthening Service Platforms	$49 million	Feb 2018 – Jan 2023	CE; NDC

Family Planning/Maternal and Child Health (FP/MCH) Service Delivery in the Autonomous Region of Muslim Mindanao (ARMM)	$15.95 million	Feb 2018 – Jan 2023	CE; NDC

*Categorical Exclusion
**Negative Determination with Conditions

II. Background and Description of Activities

A. Background

The Philippines has made significant strides to address inequities and inefficiencies in health financing, service delivery, regulation, and demand generation. The Department of Health budget continues to rise and social insurance continues to expand to cover the indigent. Local government units fund approximately 13 percent of the total health budget. The Department of Health's social insurance arm, PhilHealth, had reached 92 percent coverage of the projected 45 million households in 2015, of which 49 percent or 15.3 million are indigent households as of 2015. The number of PhilHealth accredited outpatient clinics providing primary care benefits, maternity care and the DOTS package for tuberculosis continued to increase with 83 percent of facilities in the local government units providing primary care benefits, maternity care and the DOTS package for tuberculosis.

Yet gaps in the continuum of care are still evident, particularly in addressing maternal and neonatal mortality, reproductive health, tuberculosis, HIV, emerging pandemic threats, malnutrition and illegal drug use. Underserved populations, especially those from the lowest income quintiles and from geographically isolated and depressed areas, continue to suffer from a high prevalence of tuberculosis, including multidrug-resistant TB (MDR-TB), and preventable maternal and newborn deaths, due to limited adoption of healthy behaviors, weak health systems and governance and inadequate service delivery. Health sector performance suffers as a result of weak logistics and pharmaceutical management, shortages of qualified health professionals in underserved areas, inadequate public sector capacity in policy development, finance and engagement of the private sector. Significant variations exist in the quality of health services and in supervision and mentoring at the national and local levels.

In 2016, the Department of Health embarked on its new Philippine Health Agenda, which focuses on financial risk protection, better health outcomes and a health system that is responsive and provides access to services. The Health Agenda will require bureaucratic systems to be effective and agile, strategic approaches to engender better health outcomes and stakeholder vigilance over policies, budgets and systems. The Health Agenda provides a platform for USAID to have an impact on the broad range of critical health problems and the underlying systems issues facing the country.

The USAID/Philippines Health Project prioritizes detecting and treating tuberculosis, especially multidrug-resistant tuberculosis and improving family planning and maternal and neonatal health. Priorities for systems strengthening include areas that demonstrate critical challenges for

the new Health Agenda and include fortifying public sector supply chain and pharmaceutical management, institutionalizing policy development and finance and technical training programs and sharpening capacity to manage and oversee human and financial resources. At the same time the Health Project will remain flexible to changing priorities within the U.S. government and the Government of the Philippines as well as new opportunities in the health sector, should additional funds become available.

B. Description of the Health Project and Activities

Project Purpose and Vision

The purpose of the Health Project is Improved Health for Underserved Filipinos. The vision is that individuals, particularly underserved populations, will gain control of their own health and will have continuous access to evidence-based information and to affordable, quality services and commodities. This translates into a focus towards fortification and institutionalization of healthy behaviors, services and systems. For the underserved, it means engaging a host of providers of information and support relevant to their age, social and cultural mores and immediate needs. For service providers it means adopting state-of-the-art approaches and technology to improve their effectiveness and reach. For systems strengthening it means deeper engagement with the local actors and the local systems that are crucial to continued achievement and sustainability of overall health outcomes.

The new Health Project is relevant to the existing Mission Strategy. USAID/Philippines' Country Development Cooperation Strategy (CDCS) for 2012-2016, with its goal of a More Stable, Prosperous, and Well-Governed Nation, includes Development Objective 1, "Broad-Based Growth Accelerated and Sustained" with Intermediate Result (IR) 1.3: "Improving health to create a healthier workforce."[1] The CDCS also includes health in Development Objective 2, "Peace and Stability in Conflict-Affected Areas in Mindanao Improved" and Intermediate Result 2.1: "Local Governance Strengthened, sub IR 2.1.2: Service Delivery by Local Governments." The CDCS makes a direct strategic link between this Development Objective and the Health Portfolio work with local government. In addition, the strategy calls for a focus on the most vulnerable, youth and male-friendly services.[2] Consistent with the inclusive, broad-based, economic growth goal of USAID/Philippines' Cities Development Initiative, the Health Project will adopt the urban health equity approach in selected cities with significant burden of disease and high-risk adolescent populations. Additionally, the Project's more specific focus on targeted underserved populations will be integrated into the new Country Development Cooperation Strategy to be developed in 2018.

Sub-Purposes

Embedded in the Project purpose is a three-pronged set of sub purposes designed to: 1) strengthen individual healthy behavior; 2) fortify the quality of health services to push for more patient-centered approaches; and 3) bolster and institutionalize the key public health systems needed to support these behaviors and services.

[1] USAID Philippines Country Development Strategy Statement 2012-2016, p.1; 14.
[2] Ibid., p. 25-26.

Sub-purpose 1: Healthy behaviors strengthened
1.1 Improved individual adoption of healthy behavior.
1.2 Improved community ownership/participation in health behaviors.

Healthy behaviors strengthened will be achieved through providing information, activities and new local partnerships that allow individuals to make informed choices about how to protect their health, sustain the practice of healthy behavior and access health services when needed. A project emphasis will be to engage relevant community partners, (e.g., NGOs, youth groups, tuberculosis patient groups and schools) to better meet these needs.

Sub-purpose 2: Quality of service delivery fortified
2.1 Improved quality of health services through patient-centered approaches.
2.2 Innovative approaches to improving quality of care tested and rolled out.

The quality of services will be fortified through the use of patient-centered approaches for diagnosis, care, treatment, follow-up and mentoring, as well as through facility-based supportive supervision to ensure all aspects of quality are met. The Project will also contribute to the identification, development and roll out of innovations in the provision of quality services.

Sub-purpose 3: Key health systems bolstered and institutionalized
3.1 Effective public sector supply chain for medicine, technologies, and commodities rolled out.
3.2 Critical state-of-the-art training institutionalized and sustained by the Department of Health.
3.3 Improved fiscal, financial and human resource management for health institutionalized at central, regional and local levels.

Under this sub-purpose, selected functions of the health system – training, provision of commodities, regional and local governance and financial risk planning and budgeting – that are considered critical by the Department of Health, USAID and other stakeholders will be fortified, institutionalized and sustained.

For sub-purpose 3, many activities will need to work at the central, regional and local levels of government and, at times with appropriate government agencies e.g., Food and Drug Administration for pharmaceutical management and PhilHealth for work on finance. A wide variety of public and private individuals and entities will be involved in implementation. Partners range from private sector suppliers and distributors to certified trainers in state-of-the-art technical areas from universities, civil society organizations and other donor's projects.

Project Activities will each contain unique work plans designed to meeting some or all of the three Sub-Purposes of the Project. Activities fall into four major categories: 1) Tuberculosis and Multidrug-resistant Tuberculosis; 2) Reproductive Health and Maternal and Child Health; 3) System Strengthening; 4) Other Health Issues; and 5) Collaboration, Learning and Adaptation. As additional funding becomes available, the Health Project will take on nutrition, non-communicable diseases, community drug rehabilitation and HIV treatment and prevention.

Activities covered in this IEE by sub-purposes supported are listed in Table 2 below.

Table 2: Health Activities by Sub-Purposes 2017-2023

Implementing Mechanism (IM)	Pursues Sub-Purpose			Recommended Threshold Decision
	1	2	3	
Health Leadership & Governance Program			✓	CE*
Collaboration, Learning & Adapting	✓	✓	✓	CE
Universal Health Care (PhilHealth/Policy)			✓	CE
TB Platforms	✓	✓	✓	CE; NDC**
TB Innovations	✓	✓	✓	CE; NDC
FP Innovations & Strengthening Service Platforms	✓	✓	✓	CE; NDC
FP/MCH Service Delivery in ARMM	✓	✓	✓	CE; NDC

*Categorical Exclusion
**Negative Determination with Conditions

The Health Project's geographic focus will be in areas where the health burden is the greatest. Specifically for tuberculosis, concentration will be in areas where the TB disease burden is the highest, and for family planning, in areas with the highest unmet need for family planning and where there are high teenage pregnancy rates. Maternal and child health priority will be areas where the nexus for high unmet need and high teenage pregnancy rates meets with high neonatal deaths. Health systems strengthening activities will be national in nature. All funding streams will support work at the national level to develop policies and guidelines and assist the Department of Health with systematic implementation of policies and guidelines at the regional and local government unit levels. Priority among City Development Initiative cities will be where health burden is high in the technical areas that the Health Project covers.

Specific actions by sub-purpose and recommended threshold decision are listed in Table 3.

Table 3: Planned Health Actions by Sub-Purpose and Recommended Threshold Decision

Sub-Purpose 1: Healthy Behavior Strengthened	Recommended Threshold Decision*
• Engagement with new partners to reach community members, empower and reinforce adoption of (a) TB healthy behaviors and (b) healthy behaviors with family planning, age appropriate reproductive health and maternal and neonatal health messages	• CatEx: 216.2(c)(2)i
• Raise awareness about TB and provide skills for healthy behavior, recognizing symptoms and seeking care	• CatEx: 216.2(c)(2)i
• Strengthen adoption of healthy behavior/lifestyle and infection control measures among the communities and families	• CatEx: 216.2(c)(2)i

• Address stigma and discrimination surrounding TB in workplace and schools	• CatEx: 216.2(c)(2)i
• Develop information and skill building activities, events, materials and products for diagnosis, treatment completion and infection control	• CatEx: 216.2(c)(2)iii
• Expand the establishment and availability of local TB patient support groups	• CatEx: 216.2(c)(2)i, iii, viii
• Support FP and TB service outreach to hard-to-reach communities	• CatEx: 216.2(c)(2)I; NDC
• Work with civil society organizations, community groups, non-governmental organizations, government entities and the private sector to (a) develop approaches to detect, prevent and treat TB and MDR-TB and (b) to develop state-of-the-art age-appropriate, culturally respectful and evidence-based sexuality and healthy lifestyle education and initiatives at the regional or sub-regional level	• CatEx: 216.2(c)(2)i; NDC
• Conduct operations research on new behavior change approaches for adolescents and youth, women of reproductive age groups and FP "influencers"	• CatEx: 216.2(c)(2)ii, viii •
• Identify and test new approaches to (a) increase enrollment in treatment, reduce default rates, and reduce stigma and discrimination for MDR-TB; (b) mobilize communities to identify TB suspects, refer for treatment and support patients to complete treatment; (c) create TB patient support groups and work with political leaders and other civil society organizations; and (d) reduce teen pregnancies and increase access to and utilization of family planning services, including involving men in reproductive and family health	• CatEx: 216.2(c)(2)ii, iii, viii
Sub-Purpose 2: Quality of Service Delivery Fortified	**Recommended Threshold Decision**
• Support TB Law implementation and development and implementation of policies on TB, family planning and maternal and neonatal health	• CatEx: 216.2(c)(2)i, iii, viii; NDC
• Support National TB Program to scale up MDR-TB diagnosis, prevention and treatment and roll out of TB innovations	• NDC
• Strengthen patient-centered approaches to provide TB diagnosis and treatment and family planning, maternal and neonatal health service delivery with a particular focus on respectful care	• CatEx: 216.2(c)(2)viii; NDC
• Improve and develop interpersonal communication and counseling for patient-centered care among midwives	• CatEx: 216.2(c)(2)i
• Improve patient skill-sets for infection safety for families and communities	• CatEx: 216.2(c)(2)i; NDC
• Improve quality of care by (a) training public and private providers on high-impact reproductive health and critical neo-natal procedures; (b) strengthening facility-based supportive supervision, follow-up and mentoring for both the public and private sectors; (c) mentoring and monitoring midwives to improve the quality of reproductive health and maternal and newborn care; and (d) strengthening adolescent friendly care with age-appropriate information	• CatEx: 216.2(c)(2)i; NDC

• Encourage the DOH and other agencies, including private providers, to introduce innovative and state-of-the-art approaches to improve the quality of reproductive, maternal and neonatal health services	• CatEx: 216.2(c)(2)i, iii, viii; NDC
• Provide assistance to accelerate DOH licensing and PhilHealth accreditation of facilities for TB, family planning and maternal and neonatal health services	• CatEx: 216.2(c)(2)i, iii, viii; NDC
• Support the DOH, regional offices and local government units in the establishment of appropriate Service Delivery Networks (SDN) to address the health needs of affected populations, in particular (a) support development and strengthening of functional TB referral networks (and document and apply lessons learned); (b) intensify participation of private midwives and provincial hospitals in SDNs or similar community efforts; and (c) support implementation research to document lessons learned for functional service delivery networks	• CatEx: 216.2(c)(2)iii, viii, xiv; NDC
• Bolster the quality of practice of midwives through adoption of standards for complete pre-natal care, safe attendance of deliveries and post-partum and newborn care	• CatEx: 216.2(c)(2)i, viii; NDC
• Support, test and document new approaches and innovations, including through operations research, for shorter TB treatment regimens and improved family planning, maternal and neonatal health services delivery and test and support national scale-up of strategic and targeted high-impact family planning, maternal and neonatal health interventions	• CatEx: 216.2(c)(2)ii, viii, xiv; NDC
• Catalyze civil societies, non-government organizations and academia though innovation grants to demonstrate state-of-the-art local solutions to increase health service utilization among underserved population groups	• CatEx: 216.2(c)(2)i, viii, xiv; NDC
• Strengthen communication to inform public and private providers of PhilHealth TB, family planning, maternal and child health requirements and procedures and other health policies	• CatEx: 216.2(c)(2)i
• Fill service delivery gaps of DOH-ARMM and the local government, including the provision of adolescent and reproductive health services	• CatEx: 216.2(c)(2) viii; NDC
• Establish approaches and support service outreach to hard-to-reach communities for FP and TB interventions	• CatEx: 216.2(c)(2)i; NDC
Sub-Purpose 3: Key Health Systems Bolstered and Institutionalized	**Recommended Threshold Decision**
• Support system strengthening activities to institutionalize facility-based and health provider training programs, including follow-up and mentoring	• CatEx: 216.2(c)(2)i, iii, v, viii
• Support policy development to add TB patient support group costs to normal facility-based operational expenses	• CatEx: 216.2(c)(2) xiv
• Assist with TB, FP/MCH and related health systems strengthening policy development and implementation	• CatEx: 216.2(c)(2)ii, iii, viii, xiv
• Work with PhilHealth, the National TB Program, and local government units to implement and roll-out key TB guidance and reforms	• CatEx: 216.2(c)(2)i, iii, viii; NDC
• Build capacity of regional offices and local government units to assist with flow-down and implementation of key TB policies	• CatEx: 216.2(c)(2)i, iii, viii; NDC

• Participate in working groups such as the National TB Program Technical Working Group and the National Implementation Team for the Responsible Parenthood and Reproductive Health Law	• CatEx: 216.2(c)(2)iii, viii
• Collect and document evidence and data to update and change MDR-TB prevention, care and treatment policies	• CatEx: 216.2(c)(2)i, iii, v
• Work with PopCom, PhilHealth, the DOH Family Health Office, the Department of Education and local government units to implement and roll-out reproductive health guidance and reforms	• CatEx: 216.2(c)(2)i, ii, v, viii
• Provide information and evidence to inform program and policy decisions and support processes that facilitate the use of the best information and evidence in program and policy development surrounding the Responsible Parenthood and Reproductive Health Act	• CatEx: 216.2(c)(2)i, iii, v, viii; NDC
• Strengthen and build capacity of local health systems to manage and use information, logistics and commodities and human resource	• CatEx: 216.2(c)(2)i, iii, v

* Reg 216 section reference corresponds with the classes of actions identified in section V.A. below.

III. Country and Environmental Information

The Government of the Philippines (GPH) is a signatory to several international environmental agreements such as the Agenda 21 (on Sustainable Development), the Rio Declaration on Environment and Development, the United Nations Framework Convention on Climate Change, the Hyogo Framework of Action, the 1987 Montreal Protocol, the Basel Convention, and the Stockholm Convention. As a signatory to these agreements, the Philippines commits itself to the principles of sustainable development, climate change adaptation, disaster risk reduction and management, protection of human health and the environment. International commitments are supported by national efforts to enact environmental laws and policies. Foremost of these is the Climate Change Act (CCA) of 2009, which promotes the principles of subsidiarity local government units (LGUs) to serve as frontline agencies to address climate change at the local level) and multi-stakeholder participation and partnerships.

Several Philippine statutes provide guidelines on proper waste management. The 1965 Republic Act (RA) 4226 or the *Hospital Licensure Act* (HLA), as enunciated in the Department of Health's AO 1965-01 Rules and Regulations Implementing RA 4226[3], provides that healthcare facilities shall provide for the "maintenance of sanitary standards, including approved water supply and sewage disposal systems…throughout hospital buildings and premises for the purpose of ensuring cleanliness and as a protection against the spread of infectious and contagious diseases". It further provides that hospitals and other health facilities shall provide approved methods for the disposal of contaminated dressings, surgical and obstetrical wastes and other similar materials.

Republic Act (RA) 6969 or the *Toxic Substances and Hazardous and Nuclear Waste Act* of

[3] http://hfsrb.doh.gov.ph/images/issuances/Mandates/ra4226.pdf

1990[4] and RA 9003 or the *Ecological Solid Waste Management Act* of 2001[5] provides the over-all framework for managing hazardous and infectious waste. RA 6969 provides guidance on managing hazardous and infectious wastes in such a manner as not to cause or potentially cause: (a) pollution; (b) state of danger to public health, welfare and safety; (b) harm to animals, birds, wildlife, fish or other aquatic life, plants and vegetation; and (d) limitation in the beneficial use of a segment of the environment. RA 6969 further provides that the waste generator shall be responsible for the proper management and disposal of the hazardous waste, and shall bear the costs for the proper storage, treatment and disposal of their hazardous wastes. RA 9003 identifies the short-term and long-term adverse impacts of improper use and management of toxic substances on people and on the environment[6], and emphasizes recycling, re-use and composting as methods to minimize and eventually manage the waste problem. The law assigns to LGUs the responsibility to collect waste at 100% efficiency, and encourages collaboration between LGUs and waste generators to reduce and efficiently manage waste.

Other Philippine laws, policies and specific administrative requirements related to health care waste management provide for any or a combination of the following: (a) regulation of the sale and use of equipment and devices in treating sharps, pathological and infectious waste; (b) promotion of environmentally sound and safe non-burn technologies for the handling, treatment, thermal destruction, utilization and disposal of biomedical and hazardous wastes; (c) waste segregation; (d) phase-out the use of mercury containing devices and equipment such as mercury thermometers and sphygmomanometers in the healthcare facility; (e) patient safety; and (f) health care facilities should have a health care waste management policy, plan, and written procedures for the proper disposal of healthcare waste and other hazardous substances and required written policy guidelines on bio-safety and bio-security.

While no comprehensive baseline environmental information is available for the Philippine health sector, guidelines on medical waste management and infection prevention protocols exist in the Philippines. Among the most relevant policies and regulations governing health care waste management are the joint issuance of the Department of Environment and Natural Resources (DENR) and the Department of Health governing health care waste management and the Department of Health Healthcare Waste Management Manual.

The DOH-DENR Joint Administrative Order No. 02 series of 2005 *Policies and Guidelines on Effective and Proper Handling, Collection, Transport, Treatment, Storage and Disposal of Healthcare Wastes*[7] aims to: (a) provide guidelines to generators, transporters and operators/owners on proper handling, collection, transport, storage, treatment and disposal of healthcare waste; (b) clarify the jurisdiction, authority and responsibility of the DENR and DOH

[4] http://www.gov.ph/1990/10/26/republic-act-no-6969/
[5] http://www.lawphil.net/statutes/repacts/ra2001/ra_9003_2001.html *
[6] RA 9003 identifies `Short-term acute hazards include acute toxicity by ingestion, inhalation or skin absorption, corrosivity or other skin or eye contact hazards or the risk of fire or explosion, and 'Long-term hazards, including chronic toxicity upon repeated exposure, carcinogenicity (from acute exposure but with a long latent period), resistance to detoxification process such as biodegradation, the potential to pollute underground or surface waters, or aesthetically objectionable properties such as offensive odors.'
[7] http://denr.gov.ph/policy/2005/dao/joint_dao2005-02.pdf

with regard to healthcare waste management; and (c) harmonize the efforts of the DENR and the DOH on healthcare waste management.

The DOH "Healthcare Waste Management Manual" of 2004, 2nd edition[8] aims to: (a) improve regulatory compliance; (b) protect human health by reducing the exposure of workers, patients, watchers, and entire community to hazardous HCW in the work environment; (c) enhance community relations by demonstrating a commitment to environmental protection; (d) gain economic benefits resulting from pollution prevention, products that reduce and recycle waste; (e) avoid long-term liability; and (f) increase workers' morale resulting from a healthier and safer work environment. The Healthcare Waste Management Manual 3rd edition[9] aims to make the guidelines, practices and techniques compliant with policies and legislation enacted in the last seven years and be at par with international best practices. A national roadmap that defines medium-term strategic directions and a training module to keep health workers informed are two other complementary efforts of the DOH to enhance national capacities in managing healthcare waste. The Manual emphasizes the need for every healthcare facility to minimize, properly segregate, treat and dispose of the waste generated to prevent the spread of disease, occurrence of accidents and environmental degradation.

Health care facilities as generators of health care waste are responsible for the collection, handling, segregation, transport, treatment and disposal of the wastes they produce. The DOH AO 2012-0012[10] updates the RA 4226 classification of hospitals and other health facilities to consider differences in ownership, scope of services and specialization. This is aimed to upgrade the services offered in health facilities and come up with a more homogeneous category for health facilities with similar services. The new classification of health facilities will simplify licensing systems and processes and make the regulatory scheme more effective and efficient.

The DOH[11] licensing requirements ensure that health care facilities comply with minimum standards for environmental protection, proper waste disposal and infection prevention. The DOH license qualifies health facilities for PhilHealth[12] accreditation. Most LGUs, which are decentralized, have their own local regulations on waste disposal. However compliance monitoring is not conducted uniformly or regularly.

In general, Government of the Philippines guidelines are consistent with USAID guidance on environmental compliance regarding matters such as medical waste management and infection prevention. General guidelines and best practices can be found at *Environmental Guidelines for Small-Scale Activities* at http://www.usaidgems.org/sectorGuidelines.htm and *ENCAP Visual Field Guide: Healthcare Waste* at http://www.encapafrica.org/sectors/medwaste.htm and http://www.usaidgems.org/Documents/VisualFieldGuides/medwastJan2010.pdf.

[8] http://www.pcij.org/blog/wpdocs/ hcwm.pdf
[9] http://www.wpro.who.int/philippines/publications/health_care_waste_ management_manual_3rd_ed.pdf
[10] http://hfsrb.doh.gov.ph/images/Hospital/issuances/ao2012-0012.pdf
[11] Ibid, DOH AO 2012-0012 Annex C
[12] PhilHealth or the Philippine Health Insurance Corporation is a national government owned- and controlled health insurance corporation (GOCC). The law mandates universal coverage with PhilHealth. Accreditation by PhilHealth allows facilities and health providers to charge or reimburse for services provided to members.

IV. Analysis of Potential Environmental Impact

While development activities are intended to provide benefits for targeted recipients, when managed ineffectively they may cause adverse impacts that can offset or eliminate these intended benefits. Impacts can be direct, indirect, or cumulative. They can also be beneficial or negative. The USAID Sector environmental guidelines at http://www.usaidgems.org/sectorGuidelines.htm are good resources for finding more information on potential impacts for various sectors.

Healthcare waste generation is inevitable in the provision of health services. If not managed appropriately, healthcare waste can have hazardous impacts on the environment and the general public. 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 agent such as 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.

Chemical and pharmaceutical waste, especially in large quantities, can be a threat to the environment and human health. Since hazardous chemical waste may be toxic, corrosive, flammable, reactive and/or explosive, they can harm people who touch, inhale or are in close proximity to them. If burned, they may explode or produce toxic fumes. Some pharmaceuticals are toxic as well.

Some Health Project activities involve actions that may generate healthcare waste, or in other ways, indirectly or indirectly affect the community and the environment adversely, such as:

1. Procurement, use, storage, management and disposal of public health commodities used for delivery of services in family planning, tuberculosis treatment and prevention, maternal and neonatal health, such as the following:
   - medical supplies, pharmaceuticals, including over-the-counter and prescription drugs and medications; and
   - catheters, bandages, sutures, syringes, scalpels, sharps and other health supplies.

2. Clinical training in health facilities and communities that directly or indirectly result in the generation, storage, handling and disposal of hazardous medical waste or in techniques that have a direct or indirect environmental impact such as:
   - training and application of essential intrapartum and neonatal care, including neonatal resuscitation, as necessary;
   - training of midwives on emergency obstetric care and essential newborn care;
   - training on family planning methods such as administration of injectable contraceptives, intra-uterine device (IUD) insertion and removal of intra-uterine devices, removal of implant and permanent methods (bilateral tubal ligation and non-scalpel vasectomy);
   - support for deployment of itinerant teams that provide family planning services particularly short, long-acting and permanent methods; and

- training of health care workers as part of strategies to intensify TB case finding and treatment in indigenous populations, plantation and mining populations, geographically isolated and depressed areas, congregate settings of the urban poor, and population groups at risk for TB or multi-drug resistant TB (MDR-TB).

3. Improper use of equipment may reduce its useful life and the disposal of electronic waste might negatively impact the environment if not properly handled. Health activities may involve the use and disposal of healthcare equipment such as:
   - general medical equipment, infant monitors, breastmilk pumps, and other equipment and fixtures used for FP/MCH service delivery;
   - cartridges to be used with GeneXpert, the technology for rapid diagnosis of drug resistant TB; and
   - minor laboratory equipment support for expanding access to TB diagnostic services.

4. Improper use of electric and electronic equipment may reduce its useful life and the disposal of electronic waste might negatively impact the environment if not properly handled. Health activities may involve limited procurement and distribution of small electric and electronic equipment, such as cellular phones, netbooks and tablets, in support of the following:
   - FP/MCH health services monitoring, logistics management, health information systems management and other related purposes;
   - strengthening TB logistics management tracking and scaling up TB case-holding and treatment at the community level to reduce rates of drop-outs of TB patients and other related purposes

V. Recommended Threshold Decisions

A. Justification for Categorical Exclusion Request

Implementing mechanisms covered in this IEE for which all the actions are recommended for Categorical Exclusion are listed in Table 4.

Table 4: Health Activities Recommended for Categorical Exclusion

Activity Name	Goals
Health Leadership & Governance Program	Institutionalize leadership and governance training and lessons learned into central and selected regional government systems. The leadership and governance training program strengthens the knowledge and skills of government leaders at the provincial, city, and municipal levels to improve and manage the health programs under their jurisdiction.
Collaboration, Learning & Adapting	Serve as the primary monitoring, evaluation and learning instrument of the Office of Health. Provides the Office of Health with technical assistance and expertise to convene stakeholders to define how best to monitor, evaluate and adapt the Project in an evidence-based, participatory manner. This activity will focus on support to Office of Health monitoring, evaluation and learning activities.

Universal Health Care (PhilHealth/ Policy)	Enable national, regional and local level institutions to ensure adequate and sustained financing for health programs and activities. The major objectives of this activity are to: 1) institutionalize policy development, monitoring and support within Department of Health; and PhilHealth; 2) build capacity for financial and resource analysis and management at the central and regional levels of the Department of Health and PhilHealth; and 3) assist regional governments to establish trust funds and other similar mechanisms for health financing at the LGU level.

All planned actions in the above health implementing mechanisms and certain actions in all implementing mechanisms covered in this IEE do not have foreseeable direct adverse environmental impacts. Specifically, pursuant to 22 CFR 216.2 (c)(1) and (2), the activities that fall into the following classes of action are recommended for Categorical Exclusion:

- education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.), per 22 CFR 216.2 (c)(2)(i);
- controlled experimentation exclusively for the purpose of research and field evaluation which are confined to small areas and carefully monitored per 22 CFR 216.2 (c)(2)ii;
- analyses, studies, academic or research workshops and meetings per 22 CFR 216.2 (c)(2)iii;
- document and information transfers per 22 CFR 216.2(c)(2)v;
- 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), per 22 CFR 216.2(c)(2)viii; and
- studies, projects or programs intended to develop the capability of recipient countries to engage in development planning, except to the extent designed to result in activities directly affecting the environment (such as construction of facilities, etc.) 22 CFR 216.2(c)(2)xiv.

The actions under review that justify Categorical Exclusion are detailed in Table 3. In general, they are technical assistance and capacity-building activities that involve education, training, workshops, research, studies and transfer of information.

B. Negative Determination with Conditions

Implementing mechanisms in Table 5 below are ones that (in addition to categorically excluded actions) have actions that are recommended for Negative Determination with Conditions per 22 CFR 216.3(2) (iii).

Table 5: Health Activities that include actions **Recommended for Negative Determination with Conditions**

Activity Name and Goal/s
TB Platforms will support the Government of the Philippines to expand and scale up prevention, detection, and treatment of tuberculosis and multidrug-resistant TB. The Platforms project will aim to increase TB case detection rates, decrease default rates, increase treatment success and cure rates. The

activity will fortify local platforms to support the expansion of TB activities at the regional and provincial levels.
TB Innovations will support the Department of Health and other partners to significantly reduce cases of multidrug-resistant TB through the introduction of state-of-the-art technologies and approaches to scale up MDR-TB diagnosis, prevention and treatment.
FP Innovations and Strengthening Service Platforms will endeavor, in close collaboration with key counterparts, to: (a) strengthen adoption of FP and MCH healthy behaviors among youth, women and men; (b) fortify the quality of reproductive health services with a focus on patient-friendly service delivery and improved supervision and mentoring for public and private sector providers; (c) build capacity to test and introduce state-of-the-art technologies and new approaches to strengthen reproductive health and maternal and newborn care; and (d) enhance local platforms to support scale-up of FP/MCH services.
FP/MCH Service Delivery in Autonomous Region of Muslim Mindanao will improve and support family planning and maternal and child health service delivery in ARMM.

Planned actions recommended for Negative Determination with Conditions in the health activities listed in Table 3 are assessed to have the potential for directly or indirectly affecting the environment and fall under the following classes of actions:

1. Activities involving treatment in health facilities and in communities that directly or indirectly result in the generation and disposal of hazardous medical waste or in techniques that have a direct or indirect environmental impact.
2. Activities that directly or indirectly cause the procurement, storage, management and disposal of public health commodities,
3. Limited procurement and distribution of small electric and electronic equipment in support of FP/MCH and TB health services and commodities, monitoring, and health information systems management and other related purposes.

The following are specific conditions to mitigate the potential negative impacts discussed in Section IV.

Conditions for (a) the procurement, use, storage, management and disposal of public health commodities used for delivery of services; and (b) training in health facilities and in communities that directly or indirectly result in the generation, storage, handling and disposal of hazardous medical waste, or in techniques that have a direct or indirect environmental impact:

USAID must work with implementing partners to ensure that:

- when training professionals or community health workers in service delivery procedures that result in the generation and disposal of potentially hazardous medical waste, the curricula should cover best management practices concerning the proper handling, use, and disposal of medical waste, as applicable, and that it is consistent with current DOH protocols; and
- the medical facilities have procedures in place to properly handle, label, treat, store, transport and properly dispose of blood, placenta, sharps and other medical waste such as used sputum cups, slides, applicator sticks, syringes and cartridges for GeneXpert as well as sputum specimens, based on standards of DOH and USAID or based on guidelines developed from these standards.

At the start of each activity, the implementing partner, in consultation with the Assistance Officer's Representative (AOR) or Contracting Officer's Representative (COR) will formulate an Environmental Monitoring and Mitigation Plan. The IP will validate the plan's consistency with DOH and USAID guidelines as well as with internationally accepted standards for medical waste disposal. As appropriate, the implementing partner 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. The management of potential health and environmental hazards from health service delivery and health systems management may include ensuring LGUs are aware of and adhere to local standards of medical waste disposal.

Implementing partners may require selected medical facilities to complete a Healthcare Waste Management Minimum Program Checklist and Action Plan (Annex 1) as part of monitoring.

Conditions on the use/disposal of medical equipment and supplies:

Implementing partner(s) should ensure and provide the AOR/COR with evidence that equipment is procured from certified retailers and include environmental safety and quality certificates that conform to national and/or international standards. The recipient of the equipment should be provided with information on the proper use of and instructions on proper disposal of electronic waste. The recipient should also be provided with a list of Government of the Philippines-accredited recyclers for proper disposal of the equipment after its useful life.

Conditions on the use and disposal of small electric and electronic equipment, such as cellular phones, netbooks and tablets:

No special mitigation measures are needed. Normal good practices will be used. The proposed action is that the implementer should provide evidence that equipment is procured from certified retailers and include environmental safety and quality certificates that conform to national and/or international standards. The recipient of the equipment should follow all applicable national and international laws to ensure that it is used in an environmentally sound and safe manner. Equipment should be properly disposed of (when applicable) at the end of its useful life in a manner consistent with best management practices according to USG, European Union or equivalent standards acceptable to USAID.

Conditions and best practices for general classes of activities involving healthcare waste:

- All activities shall be conducted following principles for environmentally sound development, as provided in the USAID Sector Environmental Guidelines – Healthcare Waste. This document can be found at: http://www.usaidgems.org/Sectors/healthcareWaste.htm.
- An Environmental Monitoring and Mitigation Plan shall be developed that includes the principles of the guidelines.
- Each activity that has healthcare waste should have a sound healthcare waste

management plan and system to minimize adverse health and environmental impacts caused by their wastes. A program to manage healthcare waste includes the minimum elements: (1) written plan; (2) clear responsibilities; (3) written internal rules; (4) staff training; (5) protective clothing; (6) good hygiene practices; (7) vaccinated workers; (8) designated storage locations; (9) waste minimization; (10) waste segregation; (11) waste treatment; (12) final disposal site; and (13) periodic reviews. The format and guidance of this report will be provided by the AOR/COR and should include the qualities of the Minimal Program Checklist And Action Plan in Annex 1, from the above mentioned environmental guidelines.

- With activities involving health commodities, the implementing partner should have a written plan to ensure appropriate procurement, storage, management and/or disposal of public health commodities, including pharmaceutical drugs and nutritional supplements such as established adequate procedures and capacities in place to properly manage and dispose of such commodities.
- The checklist found at the following website should be used for monitoring: http://www.usaidgems.org/Documents/VisualFieldGuides/medwastJan2010.pdf

Conditions and best practices for general classes of activities involving Healthcare Facilities:

- All activities shall be conducted following the principles for environmentally sound development, as provided in the USAID Sector Environmental Guidelines – Health Facilities. This document can be found at: http://www.usaidgems.org/Sectors/healthcareFacilities.htm.
- Design for waste management.
- Ensure sufficient water supply and sanitary management capacity.
- Support to activities that include healthcare waste should have a sound healthcare waste management plan and system to minimize adverse health and environmental impacts caused by their waste. See healthcare waste management guidelines found at: http://www.usaidgems.org/Sectors/healthcareWaste.htm.
- An Environmental Monitoring and Mitigation Plan shall be developed that includes the principles of the aforementioned guidelines.
- The checklist found at the following website can be used for monitoring: http://www.usaidgems.org/Documents/VisualFieldGuides/medwastJan2010.pdf

Contingency Provision. Construction is not among the current planned actions of the Health Project. Should the need for construction arise during the period covered by this IEE, USAID will take into consideration the conditions listed below.

Conditions and best practices for general classes of activities involving Small-Scale Health Facility Construction:

- All construction activities shall be conducted following the principles for environmentally sound construction, as provided in the USAID Sector Environmental Guidelines - Small Scale Construction, which can be found at: http://www.usaidgems.org/Sectors/construction.htm.
- For the rehabilitation of existing facilities and for construction of facilities in which the total surface area disturbed is less than 10,000 square feet, the implementing partner shall

conduct and prepare a supplemental Environmental Review Checklist (ERC) documenting a site specific environmental review. A link to the ERC template is below. The ERC should include an Environmental Monitoring and Mitigation Plan. Construction will not begin until such a review and report is completed and approved by the AOR/COR in consultation with Mission Environment Officer.

- For the construction of any facilities in which the total surface area disturbed exceeds 10,000 square feet (1,000 square meters) or is considered to have a significant effect on the environment, the IEE must be amended and may need an Environmental Analysis.
- The implementing partner should design activities to minimize vulnerability of facilities to climate change.
- A USAID Engineer is available to review all construction designs.
- A template for the ERC can be found under the Asia section at the following website: http://www.usaidgems.org/compliance.htm. The checklist at http://www.usaidgems.org/Documents/VisualFieldGuides/ ENCAP_VslFldGuide--Construction_22Dec2011.pdf should be used to monitor activities.

VI. Climate Risk Management

To comply with the new Agency guidance for implementing the Executive Order on Climate Resilient International Development, as defined in the ADS 201 Mandatory Reference,[13] the climate risk-screening tool was used to identify the activities and interventions most at risk from climate change and to propose measures for mitigating those risks as appropriate. The design team also used existing climate change vulnerability assessments and risk analyses, previously conducted by USAID, other donors, the Philippine government and local institutions. Overall, climate change impacts in the Philippines are expected to cause warmer temperatures in the summer months, reduce rainfall in the dry season and produce heavier rainfall in the wet season. The Philippines is also expected to be subjected to more flooding, droughts, and intense typhoons, as well as sea level rise in coastal areas.

These climate risks may exacerbate existing health challenges in the country -- deaths from extreme weather events, cardiovascular and respiratory diseases, infectious diseases, and malnutrition -- while undermining water and food supplies, infrastructure, health systems, and social protection systems[14]. Many of these impacts and their consequences are discussed further in Table 5 below, "Project-Level Climate Risk Management Summary Table." The climate risk rating for activities and interventions proposed as part of this Project are generally "low," but some activities, particularly those related to service delivery, are classified as "moderate" risk. From ADS 201, "low risk indicates that climate change is unlikely to materially impact achievement or sustainability of project or activity outcomes." Also from ADS 201, "moderate risk indicates that climate change is likely to materially impact achievement of development outcomes." Because of this determination, some activities under this project will address the potential climate risk as part of activity design and implementation so that climate impacts are mitigated and USAID investments are sustainable.

The ability of the health system to manage climate risks reflects the system's overall capacity and resilience. Many activities under this project, such as supply chain management, human resources for health, and expanded access to universal health care, aim to fortify the overall health system, which will in turn bolster the system's ability to respond to adverse events, including climate-related shocks. In addition, climate risk considerations will be included in future procurement documents for activities under this project. Using the USAID Climate Risk Screening and Management Tool for Project Design, the Health Team has detailed in Table 5 how these impacts will be addressed in the Health Project.

Table 5: Output Matrix: Climate Risks, Opportunities, and Actions

1.1: Defined Project Element	**Sub-purpose 1: Healthy Behaviors Strengthened**

[13] https://www.usaid.gov/sites/default/files/documents/1876/201mat.pdf

[14] WHO 2015. Philippines Climate and Health Country Profile. http://drustage.unep.org/system/files/RFEHDocs/phe-country-profile-philippines.pdf

1.2: Time-frame	● 5-10 years
1.3: Geography	● National, Regional, Municipal and Village (Barangay) levels
2: Climate Risks	● Increased extreme weather events disrupt communication channels that encourage adoption of healthy behaviors. ● Increased flooding disrupts implementation of research activities. ● Flooding/increased extreme weather events inhibit ability of trainers and participants to travel to training/workshops.
3: Adaptive Capacity	● Philippines developed a national health strategy and has been implementing projects to ensure health adaptation strategies are adopted across the country. ● A national Climate Change Adaptation for Health Strategic Plan 2014-16 is being implemented in 20 provinces directed towards designing and implementing responsive adaptation measures and interventions in the country's health care delivery system.
4: Climate Risk Rating	● Low
5: Opportunities	● Health Promotion, Research and Surveillance is one of the strategies of the National Climate Change Adaptation in Health Strategic Plan which is currently under implementation. ● Explore opportunities to expand successful approaches to PhilHealth, the Population Commission and other stakeholders.
6.1: Climate Risk Management Options	● Utilize communication channels that are less sensitive to extreme weather events. ● Use climate data and information in strategic planning and management of research and training activities. ● Consider targeted family planning and tuberculosis interventions in high-risk areas with the greatest need or highest burden of disease.
6.2: How Climate Risks Are Addressed	● Encourage the Department of Health, PhilHealth, PopCom and other entities to incorporate climate change data and information in policy development, program implementation, research, and knowledge management activities.
7: Next Steps for Activity Design	● Include specific language on climate risk assessment and management in Project Descriptions, Scopes of Work, Requests for Applications, and Requests for Interest. ● Encourage activities to use climate data and information in strategic planning, management and budgeting.
8: Accepted Climate Risks*	● None

1.1: Defined Project Elements	**Sub-purpose 2 : Quality of Services Fortified**
1.2: Time-frame	• 5-10 years
1.3: Geography	• National, Regional, Municipal and Village (Barangay) levels.
2: Climate Risks	• Extreme weather effects and increased flooding may lead to interruptions in service delivery as a result of patients/clients who are unable to physically access facilities or service providers lose track of patients for follow-up for TB and FP/MCH supplies/services due to destruction of records. • Increased flooding may lead to population displacement and increased migration to urban centers which may lead to overcrowded conditions and a possible increase in TB cases. • Increased flooding may exacerbate food insecurity, malnutrition, and water and vector borne illnesses, all of which will result in increased demand for health services. • Wet and dry seasons beyond normal ranges are associated with increased incidence of waterborne, foodborne or vector-borne diseases such as pneumonia or malaria.
3: Adaptive Capacity	• Philippines developed a national health strategy and has been implementing projects to ensure health adaptation strategies are adopted across the country. • A national Climate Change Adaptation for Health Strategic Plan 2014-16 is being implemented in 20 provinces directed towards designing and implementing responsive adaptation measures and interventions in the country's health care delivery system.
4: Climate Risk Rating	• Moderate.
5: Opportunities	• Consider implementing some interventions in the 20 provinces where DOH has been implementing the CCAH Strategic Plan. • In provinces outside of the 20 focus provinces, consider analyzing and adopting similar approaches to improving resilience which the DoH could use as a comparison. • Where appropriate, align service provision and capacity enhancement to the CCAH Strategic Plan. • Incorporate climate information into an integrated disease surveillance and response system, with an early warning system for climate-sensitive health risks. • Conduct a review with the DOH and other stakeholders to understand opportunities and lessons from the CCAH Plan.
6.1: Climate Risk Management Options	• Ensure that planned capacity-building to the Department of Health, PhilHealth, PopCom and other entities encourages incorporation of climate change data and information in supply chain management, information systems and high impact practices for service delivery.
6.2: How Climate Risks Are	• Encourage the Department of Health, PhilHealth, PopCom and other entities to incorporate climate change data and information in policy development,

Addressed	program implementation, research and knowledge management activities.
7: Next Steps for Activity Design*	• Meet with the Department of Health to gather information about their plans to develop a new Climate Change Adaptation for Health Strategic Plan and identify opportunities to leverage climate risk management within the scope of the project. • Include specific language on climate risk assessment and management in Project Descriptions, Scopes of Work, Requests for Applications, and Requests for Interest.
8: Accepted Climate Risks*	• None.
1.1: Defined Project Elements*	**Sub-purpose 3: Key Health Systems Bolstered and Institutionalized**
1.2: Time-frame	• 5-10 years.
1.3: Geography	• National, Regional, Municipal and Village (Barangay) levels.
2: Climate Risks*	• Increased flooding and extreme weather events inhibit ability of trainers and participants to travel to training/workshops. • Increased flooding and extreme weather events ability to disrupt training, monitoring, supervision and other activities associated with policy development, knowledge management, data utilization, and general organizational development.
3: Adaptive Capacity	• Philippines developed a national health strategy and been implementing projects to ensure health adaptation strategies are adopted across the country. • A national CCAH Strategic Plan 2014-16 is being implemented in 20 provinces directed towards designing and implementing responsive adaptation measures and interventions in the country's health care delivery system.
4: Climate Risk Rating	• Low.
5: Opportunities	• Build upon the DOH's work implementing the Climate Change Adaptation for Health Strategic Plan and conduct a systematic review of the existing program's policies and guidelines to identify specific components that need to be modified to become climate change responsive.
6.1: Climate Risk Management Options	• Ensure that planned capacity-building to the Department of Health, PhilHealth, PopCom and other entities encourages the incorporation of climate change data and information in supply chain management, information systems and high impact practices for service delivery.

6.2: How Climate Risks Are Addressed	• Encourage the DOH and other stakeholders to use climate data and related information to inform policy development, financial risk protection, local health governance, supply chain management and human resource management of health providers.
7: Next Steps for Activity Design*	• Include specific language on climate risk assessment and management in Project Descriptions, Scopes of Work, Requests for Applications, and Requests for Interest. • Encourage activities to use climate data and information in strategic planning, management and budgeting.
8: Accepted Climate Risks*	• None.

VII. Monitoring and Implementation

In addition to the specific conditions enumerated in the Negative with Conditions section, the threshold determinations recommended are contingent on full implementation of the following general monitoring and implementation requirements:

A. USAID Requirements

1. **Environmental compliance actions and results in USAID solicitations and awards.** The Contract/Agreement Officer will include language and reference to this IEE as appropriate in Health Project solicitations and awards. Suggested language for use in solicitation and awards can be found at the following link: http://www.usaid.gov/ads/policy/200/204sac.
2. **Implementing partner and AOR/COR briefings and trainings on environmental compliance responsibilities**. The AOR/COR will ensure and provide the implementing partner with a copy of the relevant IEE. The implementing partner shall be briefed on their environmental compliance responsibilities by their AOR/COR. During this briefing, the IEE conditions (if any) that are applicable to the activities will be identified. The Mission or Bureau Environment Officer will provide training to AOR/CORs and implementing partners on environmental compliance.
3. **Project team compliance monitoring responsibility**. As required by ADS 204.3.4, USAID will actively monitor and evaluate whether there are new or unforeseen consequences that arise during implementation that were not identified and reviewed in accordance with 22 CFR 216. USAID will also monitor the need for additional review. If additional activities not described in this document are added to this program, an amendment to this analysis will be included as part of the PAD amendment process. Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID. This includes activities that were previously within the scope of the IEE, but were substantively modified in such a way that they move outside of the scope. The Health Team will closely monitor compliance of implementing partners with stated monitoring plans.

B. Implementing Partner Requirements

1. **Development of environmental mitigation and monitoring plans**. For activities with an NDC threshold decision, or with planned actions that are subject to one or more conditions set out in the "Recommended Threshold Decision" section of this IEE, the implementing partner (IP) shall develop and submit an EMMP for USAID AOR/COR review and approval that documents how their project will mitigate and reduce potential environmental impacts. The IPs will integrate into their EMMP actions to address climate risks as identified in Table 5, as relevant. The EMMP shall also identify how the IP shall assure that IEE conditions that apply to activities supported under subcontracts and sub-grants are implemented. The Health Office will develop a standard monitoring tool that will be provided to all implementing partners. This will also apply to any subcontracts or sub-grants.
2. **Integration of climate risk management.** In compliance with the new Climate Risk Management for USAID Projects and Activities: A Mandatory Reference for ADS Chapter 201, this IEE includes climate risk management. EMMPs for activities deemed ***moderate*** or high risk will include appropriate measures to mitigate the impacts of climate change on specific interventions. Implementing partners shall refer to Table 5 of this IEE for actions relevant to their activity to consider in their strategy and/or workplan.
3. **Integration and implementation of the EMMP**. If applicable, the implementing partners shall integrate the EMMP into their project work plan and budgets, implement the EMMP, and report on its implementation as an element of regular project performance reporting. The IP will assure that subcontractors and sub-grantees also implement the IEE conditions, where applicable, into their own project work plans and budgets and report on their implementation as an element of subcontract or grant performance reporting. The implementing partners will include annual monitoring targets in the EMMP, share environmental monitoring findings with relevant stakeholders, such as the Department of Health, local government units, and PhilHealth, and integrate monitoring findings into subsequent annual implementation plans.
4. **Assurance of sub-grantee and subcontractor capacity and compliance**. The implementing partner shall assure that sub-grantees and subcontractors have the capability to implement the relevant IEE requirements. The implementing partner will, if appropriate, provide training to sub-grantees and subcontractors in their environmental compliance responsibilities and in environmentally sound design and management of their activities.
5. **New or modified interventions**. As part of initial work plans and all annual work plans thereafter, the implementing partner, in collaboration with the respective AOR/COR, shall review all planned and ongoing interventions to determine if they are within the scope of the approved IEE. Any interventions outside the scope of the approved IEE will require an IEE amendment. No new interventions may be undertaken without prior formal approval of the amendment. Additionally, other than an extension of less than 6 months or a funding increase of less than $250,000, all other changes to an activity's implementation period and budget would require an IEE amendment.
6. **Compliance with Host Country Requirements.** Nothing in this IEE substitutes for or supersedes implementing partner, sub-grantee and subcontractor responsibility for compliance with all applicable host country laws and regulations for all host countries in which activities will be conducted under the USAID activity. The implementing partners, sub-grantees and subcontractor must comply with each host country's environmental regulations unless otherwise directed in writing by USAID. However, in case of conflict between host country and USAID regulations, the latter shall govern.

7. **Compliance Reporting.** Implementing partners will report on environmental compliance requirements as part of their routine project reporting to USAID.

C. Revisions

If during implementation, project activities are considered outside of those described in this document, an amendment shall be submitted. Pursuant to 22CFR216.3(a)(9), if new activities are added and/or information becomes available which indicates that activities to be funded by the project might be "major" and the project's effect "significant," this determination will be reviewed and revised by USAID or the implementing partner, in collaboration with the C/AOR of the project, and submitted to the Mission Environmental Officer and Bureau Environmental Officer for approval and, if appropriate, an environmental assessment will be prepared. It is the responsibility of the C/AOR to keep the Mission Environmental Officer and the BEO informed of any new information or changes in the activity that might require revision of the IEE.

D. Limitations

The Program will not undertake any activities determined to pose a significant effect on the environment under 22 CFR 216.2(d)(1). This IEE does not cover activities involving:

- indoor residual spraying of pesticides for malaria control;
- procurement, transport, use, storage, or disposal of pesticides or toxic materials;
- procurement or use and/or disposal of Asbestos Containing Materials (ACM) (i.e. piping, roofing, etc.), Polychlorinated Biphenyl's (PCB) or other hazardous/toxic materials for construction projects;
- procurement, use and/or disposal of equipment containing and/or generating low-level radioactive materials and wastes; or
- construction (other than smallscale – ex. rehabilitation).

Any of these actions would require an IEE amendment to be approved by the Mission Director and concurred by the Bureau Environmental Officer (BEO).

List of Acronyms

ADS	Automated Directives System
AO	Agreement Officer
AOR	Agreement Officer Representative
ARMM	Autonomous Region in Muslim Mindanao
CCAH	Climate Change Adaptation for Health
CDCS	Country Development Cooperation Strategy
CDI	Cities Development Initiative
CHWs	Community Health Workers
CLA	Collaboration, Learning and Adapting
CFR	Code of Federal Regulations
CSOs	civil society organizations
DOH	Department of Health
DOTS	Directly Observed Treatment Short-course
DQA	Data Quality Analysis
EINC	Essential intra-partum and neonatal care
EMMP	Environmental Mitigation and Monitoring Plan
FP	Family Planning
GPH	Government of the Philippines
HLGP	Health Leadership and Governance Project
IEE	Initial Environmental Examination
IPs	Implementing Partners
IPC/C	interpersonal counseling and communications
IUD	Intrauterine device
LAPM	Long-acting and permanent methods (of contraception)
LGU	Local Government Unit
MCH	Maternal and Child Health
MDR-TB	Multidrug-resistant TB
MMR	Maternal mortality ratio
MNCHN	Maternal Neonatal, Child Health and Nutrition
NDHS	National Demographic and Health Survey
NGO	Non-governmental organization
NTP	National TB Control Program
OH	Office of Health
PhilHealth	Philippine Health Insurance Corporation (Expanded National Health Insurance Program)
PHOs	Provincial Health Officers/Offices
PopCom	Commission on Population
RPRH	Responsible Parenthood and Reproductive Health
SDN	Service Delivery Network

SOTA	State of the Art
TB	Tuberculosis
TREAT-TB	Technology, Research, Education and Technical Assistance for Tuberculosis
UHC	Universal Health Care (also known as Universal Health Coverage)
USAID	United States Agency for International Development
USG	United States Government

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 G –List of Reference Documents

- USAID/Philippines Office of Health Redacted Concept Paper (https://www.usaid.gov/documents/1861/usaidphilippines-health-concept-paper)

- USAID/Philippines Office of Health Redacted Project Appraisal Document (https://www.usaid.gov/documents/1861/redacted-health-project-appraisal-document-2017-2022)

- USAID/Philippines Notice of Funding Opportunity RFA No. 492-17-00001 "Patient-Centered TB Care" (Search in www.grants.gov by typing "RFA-492-17-00001" in the "Opportunity Number" box. Before hitting "Search", in the "Opportunity Status" tick "Archived".)

- Systems for Improved Access to Pharmaceuticals and Services (SIAPS) - National TB Program Laboratory Network Assessment (https://www.usaid.gov/documents/1861/philippines-ntp-laboratory-network-assessment-draft)

- SIAPS - Assessment of Human Resource Needs of the Philippines' TB Laboratory Network and the Programmatic Management of Drug Resistant TB (PMDT) (https://www.usaid.gov/documents/1861/philippines-assessment-hr-needs-philippines-tb-draft)

END OF SECTION VIII