USAID
FROM THE AMERICAN PEOPLE

September 28, 2012

Program for Appropriate Technology in Health (PATH)
2201 Westlake Avenue, Suite 200
Seattle, WA 98127

Reference: Achieving Universal Diagnosis and Appropriate Case Management for Malaria (hereinafter Malaria Diagnosis and Treatment)

Subject: Cooperative Agreement No. AID-OAA-A-12-00057

Dear Mr. [redacted],

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Program for Appropriate Technology in Health (PATH), hereinafter referred to as the "Recipient", the sum of [redacted] to provide support for a program as described in the Schedule of this award and in Attachment B, entitled "Achieving Universal Diagnosis and Appropriate Case Management for Malaria (hereinafter Malaria Diagnosis and Treatment)".

This Cooperative Agreement is effective and obligation is made as of the date of this letter and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning September 30, 2012 and ending September 29, 2017. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to the Recipient, PATH, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (Detailed Program Description), Attachment C (Branding Strategy and Marking Plan), Attachment D (Standard Provisions), and Attachment E (Initial Environmental Examination), all of which have been agreed to by your organization.

Please sign this original to acknowledge your receipt of the Cooperative Agreement and return it to the Agreement Officer (AO).

Sincerely,

Bruce Baltas
Agreement Officer
USAID

Attachments:

A. Schedule
B. Detailed Program Description
C. Branding Strategy & Marking Plan
D. Standard Provisions
E. Initial Environmental Examination

ACKNOWLEDGED:

BY: [redacted]
TITLE:
DATE:

A. GENERAL

1. Amount Obligated this Action: [redacted]
2. Total Estimated USAID Amount:
3. Total Obligated USAID Amount:
4. Amount Remaining to be Obligated:
5. Cost-Sharing Amount (Non-Federal):
6. Activity Title: Malaria Diagnosis and Treatment
7. USAID Technical Office: GH/HIDN
8. TIN: 911157127
9. DUNS No.: 103713624

B. SPECIFIC

BBFY	2012
EBFY	2013
Fund	GH-C
OP	GH/HIDN
Prog Area	A11
Dist Code	936-3100
Prog Elem	A049
BGA	997
SOC	4100201
Amount	[redacted]

BBFY	2012
EBFY	2013
Fund	GH-C
OP	DROC
Prog Area	A11
Dist Code	660-W
Prog Elem	A049
BGA	660
SOC	4100301
Amount	[redacted]

BBFY	2012
EBFY	2013
Fund	GH-C
OP	LIBERIA
Prog Area	A11
Dist Code	669-W

Prog Elem	A049
BGA	669
SOC	4100301
Amount	[redacted]

BBFY	2012
EBFY	2013
Fund	GH-C
OP	ZAMBIA
Prog Area	A11
Dist Code	611-W
Prog Elem	A049
BGA	611
SOC	4100301
Amount	[redacted]

Total obligated with award: [redacted]

C. PAYMENT OFFICE

The USAID M/FM office prefers to receive invoices via email. When submitting invoices to USAID FM, in addition to the required submission to the Agreement Officer Representative (AOR), please send to:

Vendor invoices: loc@usaid.gov
Point of Contact: Mr. Gary Jacobs
Telephone: 202-712-5162
Letter of Credit # HHS-70A7P

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ATTACHMENT A – SCHEDULE

A.1 PURPOSE OF COOPERATIVE AGREEMENT

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled, Malaria Diagnosis and Treatment.

A.2 PERIOD OF COOPERATIVE AGREEMENT

1. The effective date of this Cooperative Agreement is September 30, 2012. The estimated completion date of this Cooperative Agreement is September 29, 2017.

2. Funds obligated hereunder are available for program expenditures for the estimated period beginning the effective date of the Agreement through completion date as shown in the Agreement budget A.4.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Cooperative Agreement for the period shown in A.2 above is [redacted] not including required cost share of not less than [redacted] of the total obligated amount of the Agreement as described in A.9.

2. USAID hereby obligates the amount of [redacted] for program expenditures. The Recipient will be given written notice by the AO if additional funds will be added. USAID is not obligated to reimburse the Recipient for the expenditure of amounts in excess of the total obligated amount.

3. Payment will be made to the Recipient in accordance with procedures set forth in 22 CFR 226.22.

4. Additional funds up to the total amount of the Cooperative Agreement stated in A.3.1, above may be obligated by USAID subject to the availability of funds, satisfactory progress of the project, and continued relevance to USAID programs.

A.4 COOPERATIVE AGREEMENT BUDGET

The following is the Agreement Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 22 CFR 226.25.

Total Budget – Budget Summary
September 30, 2012 – September 29, 2017

Cost Element	USD
Direct Costs	[redacted]
Indirect Costs	
Total Federal	[redacted]
Cost Share ([redacted])	
Total Program	[redacted]

A.5 REPORTING AND EVALUATION

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

1. **Financial Reporting**

The recipient shall submit Financial Reports which shall be in accordance with 22 CFR 226 as described below.

(1) The recipient must submit the Federal Financial Report (FFR) Form (SF-425) on a quarterly basis via electronic format to the AOR and to U.S. Department of Health and Human Services (HHS) at (http://www.dpm.psc.gov).

(2) The recipient must submit all final financial reports to USAID/Washington, M/CFO/CMPLOC Unit, the AO, and the AOR. The recipient must submit an electronic version of the final FFR to HHS in accordance with paragraph (1) above.

(3) Additional financial reporting may be required by the AOR.

2. **Program Reporting**

Throughout the life of the cooperative agreement, the Recipient will be required to submit two reports each year. Each report is to be six (6) months apart. The first report is the semi-annual performance monitoring report. This will cover activities carried out in the first six months of the fiscal year. This is due to the AOR every year by February 15 (45 days before the end of the first six months). The next report is due six (6) months later. This is the annual performance monitoring report. It will cover the activities carried out during the entire fiscal year. It is due within 45 days of the end of the fiscal year (which is August 15).

The Recipient shall submit the following documents to the AOR electronically within the time period specified by the AOR. Guidelines and a schedule will provided by the AOR post award. All reporting shall conform with 22 CFR 226.50 through 22 CFR 226.53.

Semi-Annual Performance Monitoring Reports
Reports should briefly document actual accomplishments toward the program objectives, intermediate results, and milestones. The performance monitoring report at the end of the year should be a summation of the results and progress toward results made during that year and should be directly linked to the annual work plan. This will include information on activities in all countries and regions. The reports must include the following:

- Description of quantifiable output of the programs including accomplishments, lessons learned, and indicators;
- Description of the obstacles and their effect of meeting established goals, if appropriate, and remedies or actions undertaken or planned to address these obstacles;
- Analysis and explanation of costs including any overspending or high unit costs;
- Six month pipeline analysis; and,
- Outline the next steps for the next reporting period.

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

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

The Recipient(s) shall submit the final report to the AOR and the USAID Development Experience Clearinghouse at docsubmit@dec.cdie.org.

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

A.6 INDIRECT COST RATE

The NICRA rates established for the recipient are listed below.

PATH Current USAID NICRA
Rates effective for the period of January 1, 2011 – Until amended

Description	Rate	Base
Staff Leave	[redacted]	a/
Fringe	[redacted]	b/
Facilities	[redacted]	c/
Overhead	[redacted]	d/

Base of Application

a. Total labor dollars excluding temporary staff labor dollars
b. Total labor dollars including temporary staff labor dollars and applicable staff leave
c. Total labor dollars (excluding temporary staff labor dollars) plus applicable staff leave for PATH staff occupying PATH facilities
d. Total costs excluding overhead, project equipment, commodities and associated costs, in-kind contributions, insurance costs associated with clinical studies, participant support costs, sub-agreement costs in excess of [redacted] per sub-agreement are excluded, sub-agreements with total costs of [redacted] or less per sub-agreement are excluded in their entirety, and sub-contract costs in excess of [redacted] per subcontract are excluded. (Effective January 1, 2011 sub-agreement/contract costs in excess of [redacted] per sub-agreement/contract are excluded and sub agreements with total cost of [redacted] or less per sub-agreement are excluded in their entirety)

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 22 CFR 226.30 through 37, until such time as USAID issues disposition instructions.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of services and commodities under this Agreement Malaria Diagnosis and Treatment is 937.

A.9 COST SHARING

The Recipient agrees to expend cost share in an amount not less than [redacted] of the total obligated amount of the agreement. All cost sharing contributions shall be in accordance with 22 CFR.226.23 and Standard Provisions on Cost Sharing or Matching and are subject to audit.

A.10 SUBSTANTIAL INVOLVEMENT

USAID shall be substantially involved during the implementation of this agreement as follows:

a. Approval of Recipients annual implementation, work plans, and budget: Within 60 days of signing the Cooperative Agreement, the Recipient will be required to submit an annual work plan and budget for core and field support funds, including federal and cost share funds for each cost category. The final draft work plan for subsequent years will be due to the AOR for approval 30 days prior to the start of the new fiscal year. This may include a guide to program implementation, a demonstration of links between activities, strategic direction, outcomes and intended results, a basis for budget estimates, annual reports, international travel plans, planned expenditures, event planning and management, research studies/protocols, and changes to any activity to be carried out under the Cooperative Agreement. The work plans should be organized to clearly link activities to the expected results, with delineation of core versus field support funded activities. The work plan is negotiated with the AOR in consultation with program managers and Mission staff. Substantial changes may require a formal modification by the Agreement officer.

b. Approval of specified key personnel assigned to the positions listed:
   Technical Director
   Project Director

c. Agency and recipient collaboration or joint participation and coordination.

d. Approval of quarterly, annual and final reporting format and content.

e. Approval of sub-awards: USAID approval is required for all sub-awards and all sub-tier subawards, in accordance with 22 CFR 226. The term "sub-awards" includes both sub-agreements and contracts under this agreement. All sub-awards not included and approved in the original Cooperative Agreement require approval as per 22 CFR 226.25. The following subawards are approved per the Program Description: Medical Care Development International (MCDI), Population Services International (PSI), and Save the Children (STC).

f. Approval of yearly monitoring and evaluation plan.

A.11 USAID MANAGEMENT OF THE ACTIVITIES

An AOR shall be appointed upon award of this agreement. The AOR shall serve as the primary contact between USAID and the Recipient. The AOR shall be based in GH/HIDN/ID and assist the project in linking with other GH projects, Mission bilaterals, and other donors/foundations. In addition, technical and management input shall be provided by Missions for management of activities supported by field support funds.

For U.S. organizations, 22 CFR 226, OMB Circulars, and the Standard Provisions for U.S. Nongovernmental Recipients are applicable, detailed in Attachment D.

A.12 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 22 CFR 226.24. Program income is not anticipated under this Program; but, if accrued, shall be added to the Program.

A.13 KEY PERSONNEL

Technical Director
Project Director

A.14 SPECIAL PROVISIONS

A.14.1 NON-FEDERAL AUDITS

In accordance with 22 C.F.R. Part 226.26 Recipients and subrecipients are subject to the audit requirements contained in the Single Audit Act Amendments of 1996 (31 U.S.C. 7501–7507) and revised OMB Circular A–133, "Audits of States, Local Governments, and Non-Profit Organizations." Recipients and subrecipients must use an independent, non-Federal auditor or audit organization which meets the general standards specified in Generally Accepted Government Auditing Standards (GAGAS) to fulfill these requirements.

A.14.2 ENVIRONMENTAL CONCERNS

During the life of the Agreement, the Recipient will follow the approved environmental mitigation measures described in the Initial Environmental Examination, included as ATTACHMENT E.

A.14.3 SALARIES and WAGES

a) During the period of this agreement as stated in A.2, annual salary increases given to employees or consultants must be reasonable under the standards of OMB Circular A-122 applicable to personal compensation and shall conform to the established policy of the Recipient consistently applied to both Federal and non-Federal activities. The annual salary increase for all employees and annual wage increase for any consultant may not exceed [redacted] in the aggregate within any 12 month period of satisfactory services **under this agreement unless approved in advance and in writing by the Agreement Officer, after concurrence by the AOR**. Salary increases include cost of living adjustments, inflation, and merit increases.

b) Promotions given under the Malaria Diagnosis and Treatment Cooperative Agreement must be in accordance with the Recipient's established policy on

promotions. Any salary increase due to a promotion must meet the standards of reasonableness in OMB Circular A-122.

c) Pursuant to 22 CFR 226.81 Prohibition against profit, No funds shall be paid as profit to any recipient that is a commercial organization. Profit is any amount in excess of allowable direct and indirect costs.

END OF ATTACHMENT A

ACRONYM LIST

ACT	Artemisinin-based Combination Therapy
AOR	USAID Agreement Officer's Representative
APHIA	AIDS, Population, and Health Integrated Assistance in Kenya
BCC/IEC	Behavior Change Communication/Information, Education, Communication
BIRT	Business Intelligence Reporting Tools
CCM	Community Case Management
FIND	Foundation for Innovative Diagnostics
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GH	USAID Bureau for Global Health
HIDN	USAID Infectious Diseases and Nutrition Office
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
ICC	In-Country Coordinator
iCCM	Integrated Community Case Management
IMaD	Improving Malaria Diagnostics project
IMCI	Integrated Management of Childhood Illness
IPTp	Intermittent Preventative Treatment in Pregnancy
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Nets
LLIN	Long-lasting Insecticide-treated Nets
K4H	Knowledge for Health
M&E	Monitoring and Evaluation
MACEPA	Malaria Control and Evaluation Partnership in Africa
MCDI	Medical Care Development International
MCHIP	Maternal and Child Health Integrated Program
MOH	Ministry of Health
NAMS	National Archive of Malaria Slides
NGO	Nongovernmental Organization
NMCP	National Malaria Control Program
PATH	Program for Appropriate Technology in Health
PMI	President's Malaria Initiative
PMP	Performance Monitoring Plan
PSI	Population Services International
SC	Save the Children
SMT	Senior Management Team
RBM	Roll Back Malaria
QA/QC	Quality Assurance/Quality Control
RDT	Rapid Diagnostic Test
TA	Technical Assistance
TB	Tuberculosis
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization
WHO GMP	WHO Global Malaria Program

ATTACHMENT B – DETAILED PROGRAM DESCRIPTION

1. Technical U Understanding, Approach, and Implementation

1.1 Understanding the issues and current response to malaria

Malaria is a leading public health problem, with an estimated 216 million episodes in 2010 and approximately 81 percent of the infections in Africa. In the same year there were an estimated 655,000 deaths from malaria of which 86 percent were African children under the age of five years. Long-lasting insecticide treated nets (LLINs) have been distributed on a massive scale and IRS has been deployed in many countries and has achieved 85 to 95 percent coverage in targeted populations. Malaria infections and deaths have been reduced by approximately 25 percent overall and by 50 percent in more than 10 countries where these interventions have been scaled up, [i] saving more than 735,000 lives in 34 African countries over the past decade. This success has been due in large part to major support from the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), PMI, the World Bank, and other multi- and bi-lateral initiatives. See [redacted] for works cited references.

Prior to the availability of Artemisinin-based treatment, the first line was inexpensive drugs (such as chloroquine and sulfadoxine-pyrimethamine) and presumptive treatment of all febrile patients was thought to be cost-effective. However, the arrival of quality affordable diagnostics that could be deployed at scale, increasing drug resistance, the higher cost of alternative medications, and the need to more accurately quantify malaria burden has led to an increased focus on malaria diagnosis. The standard of malaria diagnosis has long been the use of Giemsa-stain blood smear examination under light microscopy. The deployment of microscopy for diagnosis has been problematic in both the establishment and management of adequate reference laboratories and at peripheral levels of the health system. In resource-poor settings, the challenges of procuring and maintaining quality equipment, laboratory supplies, and of training and retaining skilled microscopists are substantial. Because of these barriers, as well as the time from which the specimen is collected and when the diagnosis is made (requiring patients to return for test results), the introduction of RDTs offered a simple, accurate diagnostic test that could be performed in health facilities without other diagnostic capacity. In late 2009, WHO recommended that parasitological diagnosis (using RDTs or microscopy) be compulsory for all cases of suspected malaria illness prior to prescribing ACTs. The recent shift to promoting diagnostic confirmation of malaria comes with the much improved performance and quality of RDTs based on collaborative standardized assessment of test performance by WHO, USAID, Centers for Disease Control and Prevention (CDC), and the Foundation for Innovative Diagnostics (FIND). Modern RDTs typically allow for point of care testing with results in roughly 15 to 20 minutes, allowing for prompt treatment based on test findings.

It is increasingly recognized that for malaria, as well as HIV and other diseases, quality assurance of the test performance in the field is critical to maintain the accuracy of the test through. This is done through early identification of poor performance that results from either through spoiling of the test itself or through poor user practices. RDTs fare better than microscopy in the field, but identifying and implementing effective and sustainable quality assurance systems is critical for both. The use of quality RDTs, administered in all facilities and communities, has changed the management of suspected-malaria infections dramatically. Recent evaluations suggest that progress can be made, but much work remains to improve the management of suspected malaria, particularly in Africa. Much work is also

necessary to address non-malaria, life-threatening childhood illnesses such as pneumonia, diarrhea, meningitis, sepsis, and other infectious diseases. Improved and integrated approaches to diagnosis and case management will be critical to effectively manage sick children with negative malaria diagnostic tests.

Acknowledging this global policy shift and the available global guidance, many countries have already moved to update their national policies and practices. Investments in national laboratory capacity, including microscopy and RDTs, have increased dramatically in the past several years. However, estimates for diagnostic use is only available in a few countries and still shows slow progress with most reporting countries not exceeding 25 percent coverage. Overtreatment with ACTs has become a significant concern, not just because of the potential mistreatment of other life-threatening febrile illnesses, but also because it exposes artemisinin to increased risk of resistance development, leads to global stresses on ACT production, and wastes resources. In 2010 in Africa, most ACTs still were given to patients with un-confirmed "suspect malaria." A broad, global effort to actively promote the new paradigms and policies in countries is needed, particularly in peripheral health facilities and communities. In most high mortality countries, facility-based services alone do not provide adequate access to treatment, and most importantly not within the crucial window of 24 hours after onset of symptoms. Community Case Management (CCM), a strategy that enables assessment, classification, treatment, and referral of certain health conditions in communities as a compliment to fixed or scheduled facility based services, is being adopted and scaled up in many PMI countries. Supporting countries to introduce, scale-up and strengthen the quality of CCM of malaria is a global priority of malaria control efforts. The team will address the overlapping clinical presentation of malaria and pneumonia, because pneumonia remains a leading killer of children under five years of age in all high mortality settings, including those with endemic falciparum malaria. Most children ill with pneumonia will present with fever. In many settings, most children referred to a higher level of care never make it to the referral site. Thus, an approach to case management in which frontline health workers are supported in case management of malaria and referral of RDT-negative children will not adequately address the need for prompt standard case management of children ill with pneumonia. We thus propose to support all frontline health workers to assess, classify, and treat children for malaria and pneumonia (as well as diarrhea) in settings where the policy environment allows this kind of approach. In settings where the policy environment is not conducive, we will work with partners to promote policy change to allow frontline health workers to do case management of both malaria and pneumonia.

Another priority is to reach private sector providers, over which the Ministry of Health (MOH) often has little authority. A significant portion of patients (40 to 60 percent) in many malaria-endemic countries seek medical treatment from private clinics, pharmacies, and other retail outlets. To achieve national success in diagnostic strategies and patient safety, improvements in malaria diagnosis and case management must be realized in the public *and* private sectors. Ideally, all vulnerable populations would have access within 24 hours of the onset of symptoms, to providers who use microscopy or RDTs for diagnosis, who prescribe ACTs for those who test positive for malaria, and who provide appropriate differential diagnosis, treatment, or referral for other febrile illnesses. Finally, the health information system reporting of malaria cases and the opportunity to understand malaria epidemiology in communities has changed with the advent of local confirmation of malaria (especially with RDTs) and more and more countries are reporting morbidity and mortality based on malaria confirmation—though yet again, there is much room for improvement. Without confirmatory diagnosis of suspected

malaria cases, it is difficult to accurately track progress in malaria, to appropriately treat whatever disease is causing the fever, and to manage ACT use.

Challenges and best practices

Despite the updated global policy and guidance on malaria diagnosis prior to treatment, a variety of factors must be addressed in order to resolve the pervasive lack of adequate diagnostic services and consequent inappropriate use of anti-malarial drugs. Based on the five-year implementation of IMaD, [redacted] shows how the partnership will address common challenges with best practices. Despite the challenges, there is evidence that progress is being made in Ethiopia, Senegal and Zambia. To assure provider response based on test results, all providers must be confident in the test used and that the results are credible and worthy of action. Many health care providers, who have for years been presumptively diagnosing malaria, resist using RDTs and mistrust results; trainings must present compelling and data-driven evidence on their accuracy. Current evidence suggests that clear diagnostic and treatment algorithms can result in effective action at all health care levels, and that community health workers will adhere to training and use new algorithms to guide decision-making. Even in light of the substantial policy and guidance for universal use of diagnostics, the translation from the global guidance to national policy and planning has been imperfect. Credible approaches to the quantification of diagnostic equipment, tests, and supplies, as well as treatment doses, must inform applications and/or requests for reprogramming of financial support from national budgets, GFATM, the World Bank, PMI, and other donors. Table 1 below shows actions and events required for impact at scale.

Success story: RDT introduction reduces ACT use and commodity costs

In IMaD-supported countries implementing quality assurance programs with outreach training and support supervision (OTSS), a significant increase was observed in the proportion of fever cases with a negative malaria test for which malarial treatment was withheld: Benin from 36% to 72%; Liberia from 58% to 78%; Malawi from 48% to 58%; Mali from 42% to 52%; Zambia from 61% to 84%. Use of RDT's in these countries has resulted in higher percentages of confirmed malaria diagnoses and the ability to have clear data on malaria burden and enabled district action regarding inventory and stockouts.

*For more detail on OTSS, please see PATH's response to clarification question 2a, date July 26, 2010.

1.2 Technical approach and implementation support

We propose a five-year project, the **goal of which is to support PMI focus or non-focus countries to scale up high-quality malaria diagnosis and case management services**. Through the provision of timely technical assistance (TA), training, capacity-building, and management support, we will support participating countries to achieve:

- Greater than 90 percent accuracy of diagnostic testing in the public sector.
- Increased percentage of suspected malaria patients who received a diagnostic test for malaria.
- Increased percentage of patients who receive appropriate treatment for malaria or other related illness, consistent with the diagnostic test.
- Strengthened lab systems at country level for the diagnosis of malaria and other infectious diseases.

Similar to efforts that effectively led to national scale-up of other malaria interventions (ITNs, IRS, prevention in pregnancy), we will utilize the Roll Back Malaria (RBM)-adopted *scale-up for impact* approach involving an intensive, coordinated partner effort focusing on rapidly achieving high nationwide coverage of diagnosis and case management. This approach embraces the PRIME cycle of optimizing program performance through multi-partner consensus Planning, alignment of financial and

human Resources, well-coordinated Implementation, and Monitoring and Evaluation. The results framework [redacted] further illustrates the linkage of critical indicators to ensure alignment to our intermediate results, project objectives, project goal, and, where appropriate, PMI's goal. National scale-up efforts for diagnostics will benefit greatly from the recent availability of quality assured RDTs that can be deployed to all levels of the health system and the wide availability of ACTs and policies that facilitate their use at local levels. We will emphasize strengthening of reference laboratory capacity where: (1) malaria microscopy can serve as a basic diagnostic and as a method for quality assessment of other diagnostics, and (2) other test technologies (e.g., nucleic acid detection, serology, etc.) can allow for further exploration of field and research activities. And, we will emphasize the actions required to achieve impact at scale (see Table 1).

Table 1. Actions and events required for impact at scale

Actions to reach universal diagnosis of suspected malaria cases	Actions to achieve diagnostic results-directed treatment of all cases
• **Quantify lab supplies and tests needed at all sites.** • **Secure financing (national budget and/or donor resources).** • **Procure tests that are quality assured based on global standards.** • **Strengthen supply chain management systems to ensure no stock-outs occur.** • **Maintain the quality of the tests once in-country.** • **Ensure sustained high skill level among test users in both public and private sector.**	• Quantify treatment drugs needed at all sites. • Secure financing for treatment drugs. • Procure drugs that are quality assured based on global standards. • Strengthen supply chain management systems to ensure no stock-outs occur. • Diagnostic tests and test results are available (per above). • Ensure high, sustained health worker commitment to using RDTs and skill level in management of malaria and non-malaria illnesses in public and private sector.

To improve access to diagnostics and increase appropriate case management, we will build on the training and supervision model refined [redacted]. A competency framework will be developed to address core competencies for each cadre within the health system and target training and supervisory models appropriate to achieve objectives. Training may include pre-service, in-service, regional workshops, technology-assisted training, and mentoring. Implementation at local levels will emphasize systematic building of decision-making and management skills while ongoing supervision will emphasize quality of care and patient outcomes. Performance monitoring and feedback loops will inform decision-makers and establish best practices. Program evaluation and strengthening the integration of data collection and reporting systems are critical to ensuring timely access to information to drive national priority-setting. Table 2 shows actions proposed by the partnership to achieve the overall goal of the project, providing illustrative activities for each objective area. Upon award, we will conduct a needs assessment and, in partnership with USAID/PMI, develop a work plan responsive to country malaria operational plans and aligned with national strategies. In addition, we will plan to coordinate closely with the UNITAID project to identify synergies and share best practices and relevant tools between the public and private sectors. Illustrative scenarios for likely country support needs are provided [redacted]. Please [redacted] for team capabilities that demonstrate the ability to implement the work described. We will lead global efforts by engaging in key malaria policy and advocacy groups, participating in conferences and meetings, leading online discussions, and developing

publications and multimedia materials to provide a means to establish and share our technical contributions and to promote the adoption of the innovations and best practices that we establish. We will reach out and participate in technical working groups with partners such as WHO, the United Nations Children's Fund (UNICEF), GFATM, RBM, World Bank, and African regional networks.

Table 2. Illustrative project activities for achieving universal diagnosis and appropriate case management for malaria

Objective 1: The accuracy of diagnostic testing for malaria is improved to greater than 90 percent. The activities described in this section relate to addressing the laboratory technician and health care provider competency related to providing quality diagnostic services and appropriate treatment.	
Technical assistance (TA)	We will provide support to clarify policies and develop guidelines, tools, standard operating procedures, training and supervision materials, quality assurance, and M&E-based on gaps in current country programs; provide TA on quantification of diagnostic test needs (RDT and microscopy); deliver training in microscopy and RDT use as appropriate along with updated job aids, treatment guidelines, and algorithms for the treatment of febrile illnesses; provide TA on design, establishment, and evaluation of sustainable proficiency and quality assurance systems for point-of-care testing.
Implementation support	We will provide support to national programs to implement policy change, disseminate guidelines, and implement training programs (may include pre-service) in collaboration with other partners; may procure equipment and supplies as directed by the mission to address urgent bottlenecks; support may include partner coordination, priority-setting based on performance data, and training and supervision support to reference lab staff to manage the quality assurance of lab testing.
Building technical and managerial capacity	We will engage key clinicians and laboratory staff to review and adapt diagnostics and case management guidance to achieve agreement on clinical use of diagnostics to optimize their accuracy at the user level; work with the National Malaria Control Program (NMCP) and national laboratory staff to assess gaps and develop a plan for capacity building over time for diagnostics and case management including: tools, meetings to review diagnostic, Integrated Management of Childhood Illness (IMCI), and referral guidelines and practices with NMCP, clinicians, public/private sectors, & provincial/district leadership, and health procurement & supply chain and logistics staff in country.
Global technical leadership and policy development	We will ensure that new diagnostic and treatment paradigms are clearly and extensively communicated throughout target countries; analyze, document, and publicize country-level interventions that contribute to improved accuracy of test results; share these lessons with global, regional, and national audiences--in-country partners, USAID-PMI, the RBM Case Management Working Group, WHO Global Malaria Program (GMP), and other relevant organizations; summarize findings annually for national reporting and PMI reporting.

M&E of project activities	We will train staff in case definitions required for accurate reporting; improve compliance with Health Management Information System (HMIS) reporting, and, where applicable, more frequent reporting systems; train staff in analysis of performance data and assessment of areas of improvement. Cell phone technology/mHealth is a cost effective way to improve supervision and reporting. In Zambia, PATH introduced this system for rapid reporting of malaria cases.
Objective 2: Increased percentage of patients suspected to have malaria or febrile illness who receive a diagnostic test for malaria. These activities relate to addressing health care provider performance in the use of diagnostic tools after appropriate training. Emphasis is on supervision and use of performance monitoring tools.	
Technical assistance	We will provide TA in the development and/or implementation of supportive supervision structures to encourage compliance with testing policies and to provide ongoing coaching and mentoring to staff as required based on gaps in the current country program model; provide TA in support of linkage of public and private sector activities including all guidance, tools, and training and supervisory material.
Implementation support	We will provide support for the training of supervisors and development/production of supervision tools; as requested, provide logistics support to supervisors to ensure facility and/or community visits and compliance with reporting framework; coordinate with other groups providing care at the community level to align messaging for prompt and effective case management; increase patient acceptance of test results.
Building technical and managerial capacity	We will schedule regional meetings with supervisors to continue to build their skills in supportive supervision; assess opportunities to improve pre-service training across disciplines; work with partners involved in strengthening case management and/or child health to integrate approaches and improve referral systems; identify needs for training in laboratory supplies inventory management, ordering, and/or reporting; coordinate with partners to provide supportive supervision.
Global technical leadership and policy development	Based on the work noted above, we will identify best practices at global, regional, national leadership and local service provider levels; document these and identify and use mechanisms for sharing (malaria newsletters, regional publications with RBM Sub-Regional Networks, global publications, webinars, and scientific literature).
M&E of project activities	In each country, we will develop appropriate performance indicators through engagement with health care providers, laboratory technicians, and policy leaders; ensure reporting mechanisms to each level of health system with adequate information for decision-making and prioritizing action.
Objective 3: Increased percentage of patients who receive appropriate treatment for malaria or other febrile illnesses—consistent with the result of the diagnostic test. The activities described in this section relate to addressing health care provider performance in delivering appropriate treatment after training has occurred. Emphasis is on supervision and ongoing use of performance monitoring tools.	

Technical assistance	We will provide TA in the development and/or implementation of supportive supervision structures to encourage compliance with treatment protocols and to provide ongoing coaching and mentoring to staff as required based on gaps in the current country program model to achieve diagnosis result-driven treatments; provide TA in support of linkage of public and private sector activities including all guidance, tools, and training and supervisory material.
Implementation support	We will provide support for the training of supervisors and development/production of supervision tools; as requested, provide logistics support to supervisors to ensure facility and/or community visits and compliance with reporting framework; coordinate with other groups providing care at the community level to align messaging for prompt and effective case management; increase patient acceptance of test results; liaise with PMI and other organizations procuring antimalarial and other drugs to treat febrile illnesses to assure that capacity strengthening and training and supervision is aligned to availability of drug supplies; based on guidelines, tools, and materials for training (noted above), provide timely training, supervision, and quality assurance and work directly with MOH staff in sharing responsibilities and building capacity; support meetings/trainings as appropriate to span the work from diagnostic result to proper treatment at peripheral health facilities and into the community.
Building technical and managerial capacity	We will schedule regional meetings with supervisors to continue to build their skills in mentoring and coaching; assess opportunities to improve pre-service training across disciplines; work with partners involved in strengthening malaria case management and/or child health to integrate approaches and improve referral systems; provide TA to countries for quantifying ACT needs based on pattern and evolution of RDT and microscopy results; identify needs for training in laboratory supplies inventory management, ordering, and/or reporting and coordinate with partners to address.
Global technical leadership and policy development	Based on the work above, we will identify ongoing gaps and bottlenecks to progress in universal appropriate treatment of suspected malaria cases based on accurate diagnosis of malaria; share information directly with RBM (via the RBM Case Management Working Group) and WHO Regional Offices, and WHO-GMP; summarize progress in the annual report in each country.
M&E of project activities	We will develop performance indicators through engagement with health care providers, laboratory technicians, and policy leaders; indicators to include differential diagnosis and treatment of non-malaria febrile illness and current malaria-specific indicators; develop a consensus plan for aligning indicators to the HMIS but generating results frequently for timely assessment of progress; ensure reporting mechanisms to each level of health system with adequate information for decision-making and prioritizing action; assess national evidence base for non-malaria causes of febrile illness, advocate for operations research or etiology studies if needed.

Objective 4: Strengthened laboratory systems at the country level for detecting malaria and other infectious diseases. These activities relate to addressing the health systems issues that are a barrier to achieving universal access to malaria diagnostics and appropriate case management practices such as physical health facilities, human and financial resources, and support systems required to deliver quality diagnosis and treatment services—including procurement and supply chain management, regulatory structures, and statutory bodies.

Technical assistance	We will provide TA on the design, implementation, and evaluation of quality assurance programs for monitoring the performance of malaria diagnostics through the country; review available relevant information on laboratory testing and reference capabilities for malaria and non-malaria febrile illnesses that are common in these countries—this information will be used to provide TA on guidelines, tools, training, and supervision of relevant lab strengthening work; provide TA on quality assessment of relevant malaria and non-malaria infectious disease testing in country.
Implementation support	We will provide direct assistance in the establishment and/or strengthening of national reference laboratories to assess diagnostic test performance (for non-malaria work, assistance will be focused on other life-threatening infectious diseases [pneumonia, bacterial sepsis, meningitis, TB, lymphatic filariasis, schistosomiasis, and others]); liaise with PMI and other organizations procuring diagnostic supplies (RDTs, microscopes, etc.) to assure that capacity strengthening and training and supervision is aligned to availability of supplies and equipment; based on guidelines, provide tools and materials for training, supervision, and quality assurance and work directly with MOH staff in sharing responsibilities and building capacity.
Building technical and managerial capacity	We will strengthen reporting to policymakers to inform national strategies, applications for donor funding, and prioritization of policy issues; develop a consensus plan for aligning indicators to HMIS but generating results frequently for timely assessment of progress; support countries in applications to national government and external partners (e.g., Global Fund, World Bank, PMI, and others) to resource the required amount of antimalarial drugs, lab supplies, and RDTs, based on continuous estimates from diagnostic test results.
Global technical leadership and policy development	We will work with global policymakers to inform a standard set of capacities required for a national reference lab and develop guidelines for implementations; WHO-FIND-CDC test performance evaluation of RDTs will be monitored regularly by project staff to inform country programs on test procurement planning; we will identify and document country action in improved lab systems, improved accuracy of test results and improved confidence in results and change in clinical care behaviors and share with global community through communications with in-country partners, USAID-PMI, RBM Case Management Working Group, WHO-GMP, and others; summarize progress in the annual report.
M&E of project activities	We will develop appropriate performance indicators through engagement with health care providers, laboratory technicians, and policy leaders. Indicators to include operational capacity of national and/or facility labs to inform prioritization of RDT rollout. We will ensure reporting mechanisms to each level of health system with adequate information for decision-making and prioritizing action.

2. Monitoring and Evaluation Plan

Developing and implementing the project M&E plan will be a crucial activity for our team. Under direction of the Project Director with technical leadership from the project M&E Officer, the performance monitoring plan (PMP) [redacted] will identify performance indicators to be measured and will establish an M&E system that complements annual work plans, measures results, and reports information in a timely manner. Upon a signed agreement and throughout the life of the project, the M&E team will actively engage USAID's Bureau for Global Health (GH), Infectious Diseases and Nutrition (HIDN) Office, PMI, USAID regional bureaus, and USAID missions to ensure that the intended results for this agreement are consistently measured, reported, and aligned with global and country aims. Adhering to the following principles, our PMP:

- **Measures and reports** on indicators critical to USAID, USAID missions, HIDN, and GH.
- **Adheres to a logic model** to track and measure expected outputs, short- and medium-term outcomes, and intended impacts through operational and performance indicators; measures and methods will seek to attribute health outcomes to interventions.
- **Uses a participatory and capacity building approach** that encourages engagement of counterparts at the national, provincial, and district levels in design and revision of key indicators as they pertain to specific national malaria control programs.
- **Reflects gender and equity issues** by using gender- and equity-sensitive indicators disaggregated at the national and sub-national levels, where appropriate.
- **Effectively communicates**—the PMP is a measurement and communication tool and its collaborative development **with partners and stakeholders** will set a common malaria control measurement agenda and will encourage mainstreaming of M&E.
- **Reduces redundancies and promotes transparency** by including clear methodology, quality control, information analysis, USAID reporting, and information-sharing. Whenever possible, the PMP will use in-country data collection and analysis and existing secondary resources and surveys, such as DHS, ACTwatch, Malaria Indicator Surveys, data from malaria surveillance systems and health management information systems, for baseline and annual follow-up data.
- **Aligns with USAID global/mission needs and initiatives** to ensure that the PMP harmonizes critical indicators across global bureaus and missions and translates national data into these formats.

State of the art M&E in Zambia

The National Malaria Control Center in Zambia has adopted up-to-date guidance on measuring the identification, testing, and treatment of malaria cases using a cell phone-based rapid reporting system aligned with existing HMIS systems. Seventeen indicators related to malaria testing and treatment—including test results and drug inventories--are reported via a cell-phone to a web-based database. This system demonstrates that increased quality and more precise data at district and facility levels can lead to better targeting of malaria cases and better allocation of prevention, testing, and treatment resources.

2.1 Approach to performance monitoring

Our results framework [redacted] illustrates how we will orient our measurement approach to measure progress towards the four project objectives. Our approach to performance monitoring will follow five phases:

Design and planning. Within [redacted], the M&E Officer will create an M&E plan/PMP and logical framework to help project leadership, partners, and USAID-articulate assumptions and risks related to each objective and set of activities. Using the framework to identify the critical inputs,

activities, outputs, outcomes, and impact will form a common understanding of the causal pathway that we are working to influence. Gender and equity considerations will be integrated to ensure that we can report on the differing effects of interventions on males and females, barriers to female participation, challenges to empowerment, equity, and rights to malaria testing and treatment. Our M&E system will have flexible arrangements for working with different countries and addressing Mission PMP needs, while remaining cognizant of USAID/HIDN and national needs and reporting requirements. Together with the USAID Agreement Officer's Technical Representative (AOTR), we will set preliminary geographic targets based on trends, evidence, timing of interventions, and long-term goals. We anticipate that some targets will require a baseline assessment or reviews of the most recent country-level data and other partner and agency reports. At the beginning of the program, a draft PMP will be presented to the AOTR for approval and finalized [redacted], subject to modification if agreed to by USAID/HIDN and project leadership. We will review and revise our PMP and country PMPs annually with USAID guidance, as annual work plans are developed. As stipulated in the RFA, we will be subject to a mid-term review (either organized by the partners or in collaboration with USAID) and the M&E data will be made available for the final external performance evaluation.

Data collection. During the first quarter, we will assess lessons learned from the [redacted] experience and update processes and systems to gather and analyze monitoring data in areas including country assessments, training, lab strengthening, and key indicators on testing and treatment. To ensure routine and efficient monitoring, we will collaborate with technical activity leads to devise reporting forms and protocols, using digital data collection tools where appropriate, for implementing partners and counterparts. Qualitative methods—unstructured interviews, focus group discussions, and direct observations with NMCP counterparts, district health management teams, laboratorians, and frontline providers—may be used to obtain data on processes and program outcomes. A relational open source database will track qualitative and quantitative indicators. We will also consider relevant research, such as that conducted through the ACTwatch project, including health facility audits.

Data analysis. In order to illustrate direct and indirect effects of the program, Path will conduct diverse analyses. Performance indicators will track trends at the national, provincial, and district levels, including service utilization rates and changes in coverage—as appropriate given country work plans. We will provide evaluation expertise or work directly with national counterparts to help demonstrate an intervention's effectiveness, strengthen existing evidence, or support policy or programmatic direction. We will use advanced statistical analysis and triangulation techniques to conduct a rigorous examination of the change that has occurred and to determine to what degree the change is attributable to program activities. Web-based platforms for business intelligence and reporting tools will be utilized to ensure accessibility and use for decision-makers (i.e. Tableau, or BIRT).

Data interpretation and reporting with USAID/HIDN and other agencies and partners. Accurate and timely M&E and reporting will enable the team to adapt to changing conditions and make course corrections. Quarterly reviews of performance data by program managers are the basis for direct feedback to staff, contributing to keeping the program on track, strengthening data quality, and generating periodic (quarterly or semi-annual) and annual reports, as needed. Through semi-annual meetings and results-sharing with USAID/HIDN and partners, we will identify issues, make course corrections, refine indicators, and improve monitoring. Under the leadership of our M&E officer and communications officer, and oversight by our project director, data gathered from project activities will be regularly communicated to USAID.

Translating lessons learned. The PMP ensures all results and implementation lessons are captured, analyzed, and shared regularly. We will transparently document how data will contribute to strengthening judgments and effectiveness, and/or inform decisions about current and future work with USAID and in-country partners. Project accomplishments as well as challenges will be used to continuously improve the support provided and effectiveness of training interventions. On an operational level, we will present results [redacted] as well as conduct results reviews [redacted], which will allow staff and stakeholders to reflect on results from in-country evaluations and findings from formative research, country assessments, and milestones. PATH will identify themes for further investigation, build consensus around results and lessons, and facilitate knowledge-sharing. These will be shared outwardly with USAID projects focused on knowledge sharing such as the Knowledge for Health (K4H) project. We will work with in-country partners and national counterparts to produce manuscripts and formal commentary on how to improve capacity and expand diagnostic testing for serious childhood diseases, inform scale-up of malaria diagnostic testing and diagnosis-directed treatment of childhood illnesses in key PMI countries, as well as provide annual updates on country progress and global changes in malaria testing and treatment. This process will create dual ownership of project results with national counterparts and demonstrate both successes and lessons to other countries looking to learn from these experiences. In each country, we will have a formal transfer process of data collected, trip reports, and final reports, including lessons learned, recommendations, and draft actions plans. Where we have opportunities to develop longer term TA and implementation relationships, we will co-sponsor national level disseminations with NMCP, MOH, and other national counterparts.

2.2 Understanding of M&E requirements

PATH has extensive experience developing and implementing M&E plans for work funded directly by USAID. Within [redacted] we will work with the AOTR and appropriate M&E personnel to ensure that our proposal's PMP is drafted into a working document for review. A final PMP will be submitted with our year one project work plan and will be organized around the four stated objectives of this project. As work with missions is developed our PMP indicators will be aligned and, where appropriate, expanded to include specific outputs and outcomes identified in mission results frameworks. Additionally, the AOTR will share PMPs as they are developed with the global AOTR to ensure transparency and alignment with the global project PMP. Results will be reported in accordance with USAID's annual reporting requirements, but it is expected that results will be finalized and made available on a quarterly basis for review with partners, USAID, and host country counterparts. M&E activities will adhere to USAID legal and policy requirements and USAID's 2010 Evaluation Policy. As appropriate, the PMP will include evaluations on performance and impact, ensuring data quality according to USAID ADS 203 precision, reliability, and timeliness standards.

3. Key Personnel Qualifications

3.1 Summary of key personnel qualifications

Project Director Summary Qualifications: [redacted] experience in managing and leading global, regional, and country programs and projects in public health. [redacted] has led projects from multiple donors and is comfortable collaborating with the wider donor and technical communities. He has extensive knowledge of health systems in Africa, Southeast Asia, and the Caribbean (Haiti), and his work has strongly focused on strengthening these systems in support of preventive and curative care for malaria, reproductive health and family planning, child survival, and

nutrition. [redacted] is extremely knowledgeable of USAID rules and regulations and has been responsible for annual budgets ranging from $1.5 million to $35 million. Currently, [redacted] he leads the expansion and improvement of preventive care and diagnostics for malaria [redacted], using both the public and private sectors for the distribution of LLINs, implementation of behavior change communication/ information, education, and communication (BCC/IEC) campaigns at community and district levels, and training of providers in the effective use and interpretation of RDTs for case management of childhood illnesses. He also guides his team in working closely with relevant government and NGO partners to strengthen commodity/pharmaceutical supply systems to ensure the availability of RDTs and drugs for treatment of positive cases at the district level. [redacted] led social marketing activities in support of malaria prevention, including the distribution of LLINs and the implementation of BCC/IEC campaigns. His management focus is on ensuring efficiency and cross-functional team work. [redacted] and speaks fluent [redacted].

Interim Technical Director Summary Qualifications: [redacted] of public health experience and is an internationally recognized expert in malaria. He spent [redacted] as an active duty member of the [redacted]; he spent [redacted] as a [redacted] and [redacted] he lived [redacted] evaluating the use of anti-malarial prevention programs in pregnancy and early childhood – including establishing a field team to perform quality assured diagnostics and a team managing childhood illness. Also during that interval, he worked closely with the WHO program developing the [redacted] component on malaria and fever management. Starting [redacted], he was the [redacted], managing a staff of [redacted] professionals engaged in malaria prevention and control efforts in [redacted]; this included oversight of the malaria diagnostics laboratory program [redacted]. Subsequently, [redacted] has worked as the [redacted] where he has supported field work for [redacted] on all aspects of malaria control including national-to-local work on malaria case management. He has worked closely with the Roll Back Malaria (RBM) Partnership and has participated on RBM working groups including the Monitoring and Evaluation Working Group, the Harmonization Working Group, the Malaria in Pregnancy Working Group and the Case Management Working Group. He has worked closely with [redacted] colleagues on diagnostic test development and with [redacted] in their work on innovative diagnostics and has many years of field experience that has included microscopy training for research and program activities in African countries.

Table 3. Project staffing plan (average LOE split Year 1)

Staff/Position	LOE Split Core/Field		Job Responsibilities and Qualifications
[redacted] Project Director PATH Contingent Hire Able to start within 30 days of award	90%	10%	Reports directly to [redacted], and will be the primary liaison to the AOTRs at USAID. Will liaise with USAID mission staff and other USG partners. Serves as team leader, charged with the development and execution of the overall project strategy, work plan, and achievement of project results. Oversees all TA and administrative support activities under the program. Ensures the timely and complete submission of all performance reports and responses to donor requests for performance, success stories, and financial information for the program. Ensures compliance with all donor-related, PATH, and program-specific policies. Oversees liaison between project partners, PMI, CDC, and other global institutions. With [redacted], [redacted] has [redacted] of leadership experience in managing public health and development projects, [redacted] he was based in Africa [redacted] and [redacted] he managed global programs, that included activities in Africa, from the US.
[redacted] Interim Technical Director *Able to start immediately upon award and remain until permanent technical director is found	[redacted]	0%	Liaises with partners, tracks progress towards benchmarks based on work plans, develops overall quality assurance framework. Identifies opportunities to leverage laboratory training to improve diagnostics for other diseases, coordinates presentations in technical conferences; budgeting; assigns country-specific responsibilities to partners; and coordinates development of technical scopes of work for consultants. Responsible for overseeing the development of progress reports and for providing guidance on the development of project work plans in each project country.

5. Management Approach

PATH brings 35 years of experience managing multiple, complex, partnerships, including large US government-funded programs. PATH's ability to successfully implement these multi-partner projects is evidence of its strong policies, practices, and culture of management. Our partnering strategy for this project is to have a small number of core organizations with broad capabilities in malaria diagnostics and case management and extensive field presence, complemented by carefully selected Resource Groups (RGs) offering additional country presence and specialized expertise. Having a small number

of core partners will simplify partner contracting and management requirements resulting in more efficient project operations. PATH is well-known for its strong partnerships and has documented successful approaches to partnering. We have a long history of establishing and maintaining productive and multi-faceted alliances with peer nongovernmental organizations (NGOs), nonprofit and for-profit organizations, public- and private-sector companies, host-country governments, donors, and international health organizations from which this project will benefit.

5.1 Management and administrative arrangements

Core partners. PATH, as project lead, will be responsible to USAID for all aspects of the project, including technical vision, project design, partner relations, program performance, and fiscal/resource management, and will provide technical leadership for the project. This core project team– [redacted] –will be supported by a select set of resource partners that add depth and breadth to our technical and geographic reach. With vast expertise in malaria diagnostics, case management, private sector engagement, and community-based approaches, the core team will provide global leadership and world class TA to increase the number and proportion of persons with suspected malaria who receive appropriate diagnosis and treatment services. Our relationships with key stakeholders in malaria prevention, diagnosis, treatment, and control at global, regional, and national levels are evidence of our ability to implement a collaborative approach that works across sectors and focuses on country priorities, community-based programming, and integration, while bringing programs to scale. Partner letters of commitment are [redacted] and letters of support and collaboration are [redacted]. PATH will complete sub-agreements [redacted] to confirm their participation in HQ staffing, short-term TA, home office support, and substantial support of country programs as they are identified and funded. We will complete sub-agreements with resource groups as activity plans are agreed upon with USAID and funding becomes available. We will provide modest core budget funding for some resource groups but most resource group funding will come from field budgets. It is understood by all partners, core and resource, that funding for field activities is dependent on mission buy-in and that all activities will be based on USAID and host country government priorities as well as the amount and source of available funds. PATH will establish a Senior Management Team (SMT) to ensure maximum engagement and coordination across all partners and efficient use of each organization's resources. The technical director will review field support requests received from USAID Missions and then consult with the project director and partners to develop a tailored response for the most appropriate programmatic and logistical response for USAID. The team will elaborate a technical and financial proposal and initial work plan in response to the requesting mission's objectives. The SMT will meet bi-monthly to review key technical and management issues and oversee progress against project goals. The SMT will monitor potentially duplicative efforts and opportunities for cost containment.

The project team advantage

- Current presence in all of PMI's focus countries, plus the three non-focus countries, including the Mekong Region. [redacted], the team offers USAID seamless continuity from the [redacted].
- Clear linkages with global malaria collaborators and donors such as UNITAID, the Global Fund, Roll Back Malaria.
- Significant reach to achieve results at scale.

5.2 Lines of authority for managing staff and partners

The organizational chart [redacted] illustrates the staffing plan at project start-up, with staff from each organization playing pivotal roles. The project director will be accountable for the project team, and for

ensuring that activities are high quality and cost-effective. All personnel will work flexibly to bring a blend of multidisciplinary skills to each task. The technical leadership teams, led by the technical director, will include three distinct technical teams: Diagnostics, Clinical Care and Quality Assurance, Policy and Advocacy, and those will be supported by cross cutting areas, including field, finance, procurement, and M&E, led by the project director. Within each team, a group of technical experts will be responsible for different technical areas at the core level and engage closely with field activities. PATH is committed to clear communication with USAID, including in-person reporting to support program implementation and identify potential problems and solutions. The project director will work with USAID through the AOTR and the Agreement Officer as appropriate. He will be the primary contact with USAID/Washington will liaise with missions.

Breadth, depth, and technical skills necessary for successful implementation. The core team will be supported by a set of strategically selected resource groups to enable missions to access a skilled and experienced group of malaria, diagnostics, and case management experts. In cases where the right person is not available within the core staff or partners, PATH will access its network of consultants and resource groups for specialized expertise. Several factors will influence the nature of our country engagement, such as USAID/PMI priorities, epidemiological profile, country size, and the capacity of the country program. For example, for countries with moderate malaria burden and reasonably well-developed diagnostic and treatment programs, the project implementation model will mainly rely on short-term TA, using its roster of employees, consultants, and resource groups covering the gamut of technical areas required. For countries with heavy burden and weak programs, PATH will employ full-time, locally-based staff (i.e., In-Country Coordinators [ICCs] to be supported by short-term TA from staff, consultants, and resource groups, all under the supervision of the core team). [redacted] currently employs six ICCs with experience in malaria diagnostics in Liberia, Ghana, Malawi, Zambia, Madagascar, and the DRC. These existing ICCs can implement the work in these localities or in neighboring countries per negotiations with the Technical Director and country missions. We will support local institutions, NGOs, and regional networks to increase and institutionalize capacity to plan, manage, implement, and support malaria diagnostics and case management improvements. Our plan for engaging local partners includes: a rapid audit of potential existing local partners, starting with referrals from our core partners and resource groups; a rapid assessment of the technical, financial and management capacities of the most highly recommended of these groups to identify a qualified pool for a competitive procurement process; TA to grantees in areas where capacity-strengthening is needed; and M&E of grantee performance and financial and procurement compliance.

5.3 Small, efficient, and cost-effective home-office operations

PATH will keep a full-time core team of management and technical staff at its office in Washington, DC to lead its activities for this project and for reporting to USAID/Washington. The team will focus efforts on providing global leadership to malaria diagnostics and case management and in attracting field support through close interaction with PMI. PATH's home office senior staff will ensure smooth "behind the scenes" functioning of operations and draw upon significant experience leading multi-country and multi partner projects. [redacted] will be the Officer-in-Charge (not charged direct to the project), responsible for oversight including regular management and technical reviews. PATH HQ's HR, Legal, Accounting, and Contracts Departments will provide additional guidance and input as needed (not charged direct). Given the partnership's global presence, PATH will use a nesting strategy, embedding field-supported activities into existing PATH and partner offices. In addition, PATH will support country teams through regional hubs in

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Charity Navigator has awarded PATH its highest possible rating for sound fiscal management for the eighth year in a row. Fewer than 2 percent of the rated charities have received four stars in eight consecutive years.

Kenya, South Africa, and Vietnam established for administrative functions, such as human resources, IT, and financial management. This presence allows PATH to minimize travel expenses and response time, and maximize corporate overhead support to deliver services around the world. PATH and its partners are able to access current full-time staff for on demand TA, thus leveraging other project work and reducing the need to have full-time staff for multiple technical domains.

Accountability and financial management. PATH has a longstanding reputation for financial stewardship and successfully managing USAID cooperative agreements and contracts. Since its inception, PATH has an unqualified audit opinion and seldom has findings. When findings have been reported, they have been of an administrative compliance nature and have been corrected in the following period. To ensure field accountability and regulatory compliance, and to combat fraud, PATH uses a three-tiered financial monitoring approach. Our financial systems are designed for effective but simple monitoring, with overlapping reviews to ensure expenditures are captured and any subagreements or grants are managed to high-performance standards. [redacted], will report directly to the project director and will sit on the senior management team. PATH implements activities for multiple donors—including USAID—in collaboration with a range of public- and private-sector partners, and has developed highly refined organizational and management practices, including robust systems for managing partners' sub-awards and staff. PATH monitors project budgets internally and staff produce monthly expense reports. PATH also provides training to local administrators and subs to ensure compliance with regulations.

Three-tiered financial monitoring

- Monthly review of field transactions by headquarters staff.
- Monthly expense, labor, and general ledger detail reports easily accessible to all program managers online.
- Field-based internal audit staff use a risk-based approach to determine what programs/projects should be audited.

Containing costs, minimizing duplication. PATH has processes, tools, and staffing arrangements to contain costs and maintains efficiencies:

- Consistently use low-cost web-based voice, video.
- Use existing partner organization mechanisms, including websites, offices, vehicles, established communities of practice, and annual conferences.
- Emphasize knowledge sharing across partners over time (ie. tools, resources, and lessons learned)
- Identify synergies with other programs and activities [redacted], and MCHIP to achieve maximum impact.
- Piggy-back on regularly scheduled meetings and facilitate batched travel.

5.4 Rapid start-up in first year

With [redacted] as a core partner and partnership offices in all of the RFA's focus countries, this project is poised for rapid start-up in the first year. Please [redacted] for a map showing partner presence in the focus countries. We will maximize use of existing infrastructure. Due to [redacted] involvement in FY13 planning, the team will be able to significantly contribute to the development of individual country work plans. Standard training

materials and methodologies have been established for refresher training in malaria diagnostics and standard checklists have been developed and field tested in eight of the twelve countries. Existing staff have good relationships with both MOH and PMI teams and, as needed, current in-country coordinators can continue to provide support to NMCPs and PMI missions, providing both with a level of familiarity and continuity. ICCs also provide in-depth knowledge of the needs of the diagnostics QA programs which will allow the program to continue uninterrupted during program start-up and planning phases. The project will design approaches with minimum disruption to the NMCP. Also, PATH is a member of RBM Partnerships in Ethiopia, Kenya, Mozambique, Senegal, Tanzania, and Zambia.

5.5 Plan for providing and managing country support

Country needs. During Year 1, team members will travel to potential field support countries to meet with stakeholders to assess needs, discuss the value of project services, and discuss potential scopes of work. The staffing model will be dependent upon the level of support requested from the participating country and could range for short-term TA to longer term in-country staff. The core management team will monitor overall country and headquarters linkages to ensure synergies and avoid duplication, and will collaborate with USAID/PMI. The SMT will develop criteria for identifying lead country partners. [redacted] relied on an in-country coordinator model that enabled rapid country start-up, provided embedded TA, and demonstrated added value to missions. PATH will aim to replicate this model where appropriate, but also utilize the team's well-established country presence and infrastructure to strengthen [redacted] previous approach. The structure of each field team will be shaped to specific in-country needs and will espouse the principles of country ownership and engagement.

6. Institutional Capacity

PATH presents an exceptional set of partners that collectively has presence in all PMI countries, includes the project's incumbent, and has unparalleled expertise in designing and implementing programs to improve malaria diagnosis and treatment across a range of national settings. PATH transforms global health through innovation. PATH currently works in more than 70 countries, focusing on health technologies, maternal and child health, reproductive health, vaccines and immunization, and emerging, infectious, and epidemic diseases. Our multidisciplinary staff includes public health experts with experience in diverse cultural contexts as well as policy and business strategists skilled in translating promising ideas into products and sustainable approaches. MACEPA, initiated in 2004, has provided leadership within the global community and partnership to national governments in sub-Saharan Africa to demonstrate the measurable impact that can occur when a package of malaria control interventions are rapidly scaled up to a national level. MACEPA works closely with MOHs and other key partners to develop and implement national strategies and action plans to control—and ultimately eliminate—malaria. Scaling up and strengthening access to use effective malaria diagnostics and treatment is a central priority of this work, and essential to success. [redacted] is leading three projects that are significantly increasing the number of people who receive an appropriate malaria diagnosis and treatment. [redacted] is currently implementing the USAID-funded [redacted] in 14 PMI countries, the

Impact at scale -MenAfrIVac
PATH leads this innovative global partnership that leverages funding, technical capacity, and existing technology to create a low-cost, effective vaccine to fight meningitis illness, disability, and deaths in Africa. Within weeks of the vaccine being launched, nearly 20 million people age 1 to 29 were vaccinated against meningitis in Burkina Faso, Mali, and Niger. Six months later, the three countries reported the lowest number of confirmed meningitis A cases ever recorded during an epidemic season.

[redacted] in Equatorial Guinea , and the [redacted] funded by the Global Fund (2006–2011). In addition, [redacted] was recently awarded the [redacted] by USAID/Benin to support government and private providers in improving their malaria program, including diagnostics and treatment. [redacted] is implementing malaria programs in more than 30 countries in Africa, Asia, and South America to rapidly achieve universal coverage targets and maintain high utilization rates over time. A recently awarded project from UNITAID to a consortium led by [redacted] and the Malaria Consortium, and FIND involved substantial work in the private sector to support universal use of confirmatory diagnosis for malaria and treatment based on these results. The five target countries are PMI-focus countries (Kenya, Madagascar, Nigeria, Tanzania, and Uganda). Between this proposed project and the UNITAID funded work, the shared development, refinement, and dissemination of findings, assessment tools, training materials, evaluation tools, etc. is planned. [redacted] maintains a global team of health professionals with expertise in community mobilization, child and newborn health, nutrition, maternal and RH, and HIV/AIDS. [redacted] focuses on strengthening facility-based diagnosis and case management. In addition, [redacted] supports MOHs in extending access to improved case management of malaria beyond facilities through the integrated community case management (iCCM) strategy in 12 countries. [redacted] works closely with MOH to develop policies, guidance, and curricula, and then train, supervise, support, and supply both facility and community health workers to treat children with malaria, diarrhea, pneumonia, and sometimes dysentery and newborn sepsis. In Mali, [redacted] current PMI project is supporting the MOH to scale up iCCM, including case management of malaria, in the Sikasso region (target population of 721,000). See Tables 4 and 5 for partners' roles:

Table 4. Core partners' roles

Org	Role
PATH	Overall management and technical oversight, M&E and operations research, advocacy/policy, procurement/supply chain (including quality testing of meds and RDTs), sharing global best practices, tools, and standard operating procedures, coordination with international partners.
[redacted]	Strengthen malaria diagnostics by assessing capacity and gaps in national laboratory systems, implementing trainings for group of microscopists and health care workers; support to the National Malaria Task Force and to the Ministry of Health, and integrated project activities.
[redacted]	Provide TA for community-based diagnostics and case management with CHWs and first line providers; support the development or revision of training packages, job aids; link with established community structures, NGOs and GFTAM CCMs; support documentation and dissemination of best practices; Provide access to multilateral consortia.
[redacted]	Link to project to introduce RDTs into private sector. Sharing of policies, tools, QA processes, job aids and ops research learning will accelerate progress in achieving project objectives. Extend access to RDTs beyond public sector; share results from ACTwatch that captures both antimalarials and RDTs.

Table 5. Resource partners' roles

Org	Role
[redacted]	Drug resistance, surveillance systems, policy and guideline development & dissemination.
	Health systems strengthening and TA for pharmaceutical, lab, IS, and clinical training
	Specific country TA, distance learning, epidemiology, operations research, policy, iCCM
	Applied research, malaria epidemiology, malaria surveillance, and impact evaluation
[redacted]	District and provincial-level health systems management capacities; strengthening data quality and utilization. Field offices in Mozambique, Ivory Coast, and E Timor
[redacted]	OR, training on national slide archive development, technology transfer and QA
[redacted]	WANMAT (West African Network on Malaria Treatment)

6.1 Team capabilities [redacted]

Technical assistance. PATH has a proven, successful track record of providing TA to Ministries of Health and other key partners on a range of program and policy areas critical to effective malaria control, including providing the most up-to-date guidance and training on malaria diagnosis, case management, and best practices for scaling up these activities. For example, MACEPA recently invested in strengthening Zambia's Health Management Information System (HMIS), piloting a weekly reporting protocol using mobile technology which enabled district, provincial, and national level officials to monitor case loads and make decisions about resource allocation. By the end of 2011 more than 350 health facilities in Zambia and 20 in Senegal were participating. In addition, PATH has provided key TA in the adoption of progressive new targets and methodologies for the use of RDTs, and distributing LLINs at the community level. [redacted] uses a TA approach that builds local capacity and promotes sustainability. [redacted] project routinely worked with the host country's NMCP to align national malaria policy guidelines with WHO standards.

Implementation support. Through MACEPA, PATH is involved at every level of malaria control implementation support in Ethiopia, Senegal, and Zambia. In Zambia, PATH has been a resident partner at the National Malaria Control Centre since 2005 and has focused on rapid scale-up of proven prevention and treatment interventions. The *scale-up for impact* approach, innovated by PATH, has had broad uptake by malaria partners and malaria-endemic African countries and is effective in delivering on results. PATH participates in national working groups to plan LLIN distribution, indoor residual spraying of households, advocacy, and awareness-raising. PATH's longstanding in-country procurement, logistics and systems-strengthening expertise has proven instrumental to helping countries identify and tackle bottlenecks, fluctuations in needs, and sudden gaps related to commodities. This team has established systems and practices for procuring malaria commodities in Zambia, Ethiopia, Senegal, Malawi, and Tanzania, has extensive expertise in laboratory strengthening, (Tanzanian TB labs under the USAID TB2015 project, for example). PATH has had an effective working relationship with USAID DELIVER for over 20 years which would continue through this project work. [redacted] deployed In-Country Coordinators (ICCs) for timely implementation of

supervision visits, management of M&E and reporting activities, responsiveness to the NCMP and MOH, and promotion of data system ownership. [redacted] has contributed to the global effort to increase access to appropriate case management, including diagnostic testing by providing more than 2.9 million RDTs since 2003. [redacted] implementing programs through provider networks in 24 countries, including expansion of services via social franchise networks and community health workers.

Building technical and managerial capacity. PATH strengthens in-country technical and managerial capacity as a mechanisms key to country ownership, sustainability and success. PATH's country partnerships are characterized by intensive collaboration with MOH to build proven systems, practices, and standards that are ultimately governed at the national level. In Kenya, PATH implemented the AIDS, Population, and Health Integrated Assistance Program II (APHIA II) Western project that worked closely with the MOH to improve, scale up, and expand facility-based HIV/AIDS, malaria, TB, maternal and child health, and reproductive health services. In partnership with provincial, district, and local government teams, APHIA II Western built the capacity of providers to increase integrated clinical services uptake and to develop and reinforce facility-community links. MACEPA is a collaborator with the follow-on project of APHIA II Western, APHIA+, to develop program strategies to reduce malaria transmission in Kenya. [redacted] emphasizes capacity building and systems approaches tailored to the specific country context. [redacted] Integrated Case Management interventions, being rolled out in Kenya, include training and supervision of community health workers.

Global technical leadership and policy development. PATH and our partners are leaders in disseminating evidence of best practices to national and global audiences and have productive relationships for policy development with WHO, the RBM Partnership, and national governments. Through MACEPA, PATH has played a central role in the development of global policies and guidelines for national actions, leveraging its unique breadth of technical expertise along with extensive country experience. MACEPA recently demonstrated critical leadership in informing new WHO guidelines on malaria diagnostics based on internal technical expertise and applied experience from Zambia and Senegal. [redacted] are part of the WHO's TA Group which helped elaborate the WHO's Universal Access Manual. [redacted] is developing a National Archive of Malaria Slides (NAMS) that will provide slides for training and has supported the attendance of local microscopists to WHO's regional malaria diagnostics certification course. The partnership has representation in major international malaria policy platforms including the Technical Research and Advisory Committee of the WHO GMP, the RBM board, six RBM technical working groups, the Special Committee of the Technical Review Panel of GFATM, the Independent Review Panel of GFATM, the Essential Medicines Initiative and the AMFM task force. [redacted] is a founding member of the global CCM Task Force, for which [redacted] serves as a Steering Committee member with WHO, UNICEF and USAID.

Monitoring and evaluation. As a leader in malaria control, PATH's has a strong commitment to monitor progress and measure impact. Development of the Malaria Indicator Survey tools and guidelines enabled PATH to help countries document national impact, identify gaps, and channel resources and commodities where they are needed. PATH has produced M&E guidelines for several of its projects and developed user-friendly tools and guidelines for partners. As the lead on the USAID-funded ProVIC project in the DRC, PATH established an extensive M&E system based on systematic data collection across 22 participating health facilities, as well as prevention activities in 40 communities. Further, with more than 70 donors with different reporting requirements, PATH is fluent

at adapting to donor reporting formats. [redacted] has a CCM implementation research portfolio which has yielded or planned 26 peer-reviewed publications since 2003.

Gender. PATH works to address gender-related issues at a variety of levels. We identify gender-based constraints, such as women's unequal socioeconomic status and decision-making power in relationships, and create strategies to address these constraints and maximize health. To achieve strides in global anemia prevention and control, MCHIP is working to promote and advocate for an integrated package of treatments to address multiple causes of anemia through malaria control programming and nutrition. As part of HealthTech, PATH aimed to address women's vulnerability to malaria related anemia by assessing the barriers of a point-of-collection tool that identifies whether the cause of anemia is iron deficiency, malaria, or both to help inform treatment in malaria-endemic areas. PATH has considerable breadth and depth of experience globally working on projects focusing on boys and men, girls and women, and gender norms. With malaria service delivery, PATH's experience shows that it is most important to address the broader equity issues, including equity across gender, but also geography (urban/rural) and socioeconomic conditions.

6.2 PATH leadership on multi-partner collaborations

PATH has an established track record of working in partnership on malaria and other public health issues, including providing leadership to multi-partner collaborations. Over the past five years, PATH has managed 950 sub-agreements totaling $126 million for activities in over 95 countries. Our robust systems ensure high-quality management of project finances, M&E, and reporting. PATH has managed and implemented many large US government-funded projects, working with the public and private sectors and multilateral institutions to design, implement, assess, and scale up health programs similar to the Malaria diagnosis and case management program. For example, PATH leads the USAID/Kenya-funded AIDS, Population, and Health Integrated Assistance Program II (APHIA II) with three subcontractors and 76 sub-recipients.

END OF ATTACHMENT B

ATTACHMENT C – BRANDING STRATEGY AND MARKING PLAN-

The plan is presented in two parts—Branding Strategy, responding to the guidance found in the AAPD 05-11, and Marking Plan, responding to guidance provided in AAPD 05-11 and 22 C.F.R. 226.

BRANDING STRATEGY

Positioning

What is the intended name of this program, project, or activity?

The current name of the program is Achieving Universal Diagnosis and Appropriate Case Management for Malaria. We propose to work in collaboration with USAID and PMI to determine a project name and appropriate branding. We recognize that the prior incumbent has an established project identity under the name of Improving Malaria Diagnosis (IMaD) and its related brand. Consultation with USAID/PMI can inform the relative value of maintaining a link to the prior name/brand or the importance of a new name/brand given the expanded scope of work.

Will a program logo be developed and used consistently to identify this program? If yes, please attach a copy of the proposed program logo.

No new program logo is proposed unless USAID/PMI advises us to do so.

Program Communications and Publicity

With the purpose of promoting USAID visibility and acknowledgment as a funding agency during the implementation of the Achieving Universal Diagnosis and Appropriate Case Management for Malaria project, PATH intends to mark program deliverables funded under the award as outlined in the marking plan below.

Who are the primary and secondary audiences for this project or program?

Type of Beneficiaries	
Primary	Health providers at various levels (national reference labs, health facilities, and in the community), Ministry of Health workers in charge of laboratories and training/ academic institutions, and community health workers.
Secondary	District and central government health departments, district administration, donors, other nongovernmental organizations, the international development community, research/academic institutions, and others.

What communications or program materials will be used to explain or market the program to beneficiaries?

The PATH team anticipates that the following list of communication materials will be created and utilized by the beneficiaries. Any additional materials will be developed in accordance with USAID branding and marking guidance.

Orientation and capacity-building materials:

- Clinical guidelines and protocols – adapted from existing pre-service and in-service materials.
- Job-aids – national reference labs, clinical facilities, and community-based health workers as appropriate.
- Capacity building tools for CBOs and civil society groups.
- Training manuals, curricula for use with health workers.

Communication materials:

- Newsletters, updates, website.

Reports, workshop or presentation materials:

- Signage – workshops, knowledge sharing events, and mini-conferences.
- PowerPoint presentations.
- Research and technical reports.
- Quarterly and annual reports.

What is the main program message(s)?

The messages of the project are focused on the following areas:

- Support PMI focus and select non-focus countries to scale up high-quality malaria diagnosis and case management services.
- Improve accuracy of diagnostic testing in the public sector.
- Increase percentage of suspected malaria patients who received a diagnostic test for malaria.
- Increase percentage of patients who receive appropriate treatment for malaria or other related illness, consistent with the diagnostic test.
- Strengthen lab systems at country level for the diagnosis of malaria and other infectious diseases.

Will the recipient announce and promote publicly this program or project to host country citizens? If yes, what press and promotional activities are planned?

Yes, the Achieving Universal Diagnosis and Appropriate Case Management for Malaria project will be publicly announced in the following ways:

- Announcement to the Ministry of Health and relevant local partners at stakeholder workshops during project start-up in the participating countries.
- Announcements to potential participating missions (i.e., PMI country missions).
- Posting on PATH website.
- Announcement of new program through normal PATH communication channels.

Please provide any additional ideas about how to increase awareness that the American people support this project or program.

We will work closely with USAID to identify additional opportunities to increase awareness that the American people support the Achieving Universal Diagnosis and Appropriate Case Management for Malaria project. In general, the project team will take advantage of all situations, including formal and informal meetings with partners and other organizations working in the malaria and health sector, to properly identify USAID and the American people as the supporter of the project. We will also use national and international forums to share information about the project as well as share materials, best practices, and lessons learned through implementation of this project.

Acknowledgements

Will there be any direct involvement from a host-country government ministry? If yes, please indicate which one or ones. Will the recipient acknowledge the ministry as an additional co-sponsor?

The Achieving Universal Diagnosis and Appropriate Case Management for Malaria project will work closely with the ministries of health of the cooperating countries, including the national malaria control programs in most cases. As the primary source of malaria diagnostic and drug treatment commodities, the MOH is a critical partner in this project effort. Where appropriate, participating government ministries will be acknowledged as collaborators in country-specific communications products.

Please indicate if there are any other groups whose logo or identity the recipient will use on program materials and related communications.

In addition to the USAID logo, the Achieving Universal Diagnosis and Appropriate Case Management for Malaria project team proposes to include the identities of the other implementing partners and appropriate collaborators for documents that encompass the full project. This would involve the PATH identity listed first, and the other implementing partners listed alphabetically, displayed on the inside secondary page and back cover of print materials. The team feels that including the relevant partner identities is important to provide clear and effective lines of accountability and communication to consumers of any communication materials.

The Achieving Universal Diagnosis and Appropriate Case Management for Malaria project team anticipates that other groups' logos or identities will be used on program materials or related communication. In situations where groups participate in the development and/or funding of specific program materials that may be targeting audiences specific to their purpose (e.g., private sector organizations, other ministries) the project team would co-brand materials with that group's identity.

In any of these situations, the project team will be sure to make marking decisions for any item in collaboration with USAID and in accordance with USAID identity and marking guidance.

Branding and Marking Costs:
We do not anticipate additional costs associated with marking program deliverables and communications materials. Costs associated with marking supplies and equipment are included in the amounts budgeted for these items in the project budget.

MARKING PLAN
The public communications, commodities, and program materials that the recipient will produce as a part of the cooperative agreement and which will visibly bear the USAID Identity.

(i) Technical assistance, studies, reports, papers, publications, audiovisual productions, public service announcements, and other promotional, informational, media, or communications products funded by USAID:
- Formative research reports.
- Technical research reports.
- Job aids.
- Training materials.
- Peer outreach materials.
- Press releases.

(ii) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences, and other public activities:
- Workshops, knowledge sharing events, brown bags, and mini-conferences.
- Trainings – clinical, community health worker outreach.

(iii) All commodities financed by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs, and all other equipment, supplies, and other materials funded by USAID, and their export packaging:
- Commodities purchased under this project will be marked with the USAID logo.

Marking Table

DELIVERABLE	REPRESENTING	MARKING	TIMING
Materials			
Reports – research, technical	USAID, Project, PATH, implementing partners, and other participating groups.	Front Cover: USAID, Project, other participating groups. Inside page: Text noting USAID funding and disclaimer of contents, project, implementers, collaborators inside front cover. Back cover: USAID, project, implementing	At time of publication.

DELIVERABLE	REPRESENTING	MARKING	TIMING
		partners participating other groups.	
Job-aids	USAID, Project, PATH, participating implementing partners, other participating groups.	If multiple pages - Front Cover: USAID, Project, other participating groups. Back cover: USAID, project, implementing partners other participating groups.	At time of publication.
Leaflets and banners promoting	USAID, Project, PATH, participating implementing partners, other participating groups.	Visible on front of all leaflets and banners.	At time of publication.
Events			
Trainings – Diagnostics and Case Management. Guidelines, protocols, and other materials.	USAID, Project, PATH, implementing partners, and participating other groups.	Front Cover: USAID, Project, other participating groups. Inside page: Text noting USAID funding and disclaimer of contents, project, implementers, collaborators inside front cover. Back cover: USAID, project, implementing partners participating other groups.	At time of publication.
Workshops, knowledge sharing events, and stakeholder meetings.	USAID, Project, PATH, participating implementing partners, other participating groups.	Signs, announcements, invitations, PowerPoint presentations, and all handouts and take-away materials.	At time of event and production of materials.

Presumptive Exceptions and Waivers

The Achieving Universal Diagnosis and Appropriate Case Management for Malaria team does not request any presumptive exceptions or waivers at this time but proposes the right to request exceptions and waivers during the project implementation period as necessary.

END OF ATTACHMENT C

ATTACHMENT D – REQUIRED MANDATORY AND AS APPLICABLE STANDARD

I. MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

1. APPLICABILITY OF 22 CFR PART 226 (MAY 2005)

a. All provisions of 22 CFR 226 and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients which meet the definition of "Recipient" in part 226, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.

b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable "Standard Provisions for Non-US Nongovernmental Organizations." Recipients are required to ensure compliance with monitoring procedures in accordance with OMB Circular A-133.

[END OF PROVISION]

2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran's status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.
In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive

nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

(1) To the USAID Agreement Officer, at the address specified in this award; or

(2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

6. SUBAGREEMENTS (JUNE 2012)

a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.

b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2003)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

Standard Provision	Burden Estimate
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5
Protection of the Individual as a Research Subject	1

22 CFR 226	Burden Estimate
22 CFR 226.40-.49, Procurement of Goods and Service	1
22 CFR 226.30 -.36, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523-7801 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (JUNE 2012)

a. This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

b. Ineligible and Restricted Commodities and Services:

(1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:

(i) Military equipment,
(ii) Surveillance equipment,
(iii) Commodities and services for support of police or other law enforcement activities,
(iv) Abortion equipment and services,
(v) Luxury goods and gambling equipment, or
(vi) Weather modification equipment.

(2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, "Debarment, Suspension and Other

Responsibility Matters" and Standard Provision, "Preventing Terrorist Financing" must not be used to provide any commodities or services funded under this award.

(3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:

(i) Agricultural commodities,
(ii) Motor vehicles,
(iii)Pharmaceuticals,
(iv) Pesticides,
(v) Used equipment,
(vi) U.S. Government-owned excess property, or
(vii) Fertilizer.

c. Source and Nationality:

Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at $250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: http://inside.usaid.gov/ADS/300/310.pdf.

d. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.

e. This provision must be included in all subagreements, including subawards and contracts, which include procurement of commodities or services.

[END OF PROVISION]

9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (JUNE 2012)

a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:

(1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;

(2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;

(3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and

(4) Have had one or more public transactions (Federal, State, or local) terminated for cause or default within the preceding three years.

b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subagreements or contracts under this award with a person or entity that is included on the Excluded Parties List System (www.epls.gov/). The recipient further agrees to include the following provision in any subagreements or contracts entered into under this award:

DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION (JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

*c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

10. DRUG-FREE WORKPLACE (JUNE 2012)

a. The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2012)

a. Faith-Based Organizations Encouraged.

Faith-based organizations are eligible to compete on an equal basis as any other organization to participate in USAID programs. Neither USAID nor entities that make and administer subawards of USAID funds will discriminate for or against an organization on the basis of the organization's religious character or affiliation. A faith-based organization may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, within the limits contained in this provision. More information can be found at the USAID Faith-Based and Community Initiatives Web site: http://transition.usaid.gov/our_work/global_partnerships/fbci/ and 22 CFR 205.1.

b. Inherently Religious Activities Prohibited.

(1) Inherently religious activities include, among other things, worship, religious instruction, prayer, or proselytization.

(2) The recipient must not engage in inherently religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in inherently religious activities, it must offer those services at a different time or location from any programs or services directly funded by this award, and participation by beneficiaries in any such inherently religious activities must be voluntary.

(3) These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.

(4) These restrictions do not apply to USAID-funded programs where chaplains work with inmates in prisons, detention facilities, or community correction centers, or where USAID funds are provided to religious or other organizations for programs in prisons, detention facilities, or community correction centers, in which such organizations assist chaplains in carrying out their duties.

(5) Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services

(i) Retains its independence and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support any inherently religious activities,

(ii) May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols, and

(iii) Retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.

c. Construction of Structures Used for Inherently Religious Activities Prohibited. The recipient must not use USAID funds for the acquisition, construction, or rehabilitation of structures to the extent that those structures are used for inherently religious activities, such as sanctuaries, chapels, or other rooms that the recipient uses as its principal place of worship. Except for a structure used as its principal place of worship, where a structure is used for both eligible and inherently religious activities, USAID funds may not exceed the cost of those portions of the acquisition, construction, or rehabilitation that are attributable to eligible activities.

d. Discrimination Based on Religion Prohibited. The recipient must not discriminate against any beneficiary or potential beneficiary on the basis of religion or religious belief as part of the programs or services directly funded with financial assistance from USAID.

e. A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of 1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.

[END OF PROVISION]

12. PREVENTING TERRORIST FINANCING -- IMPLEMENTATION OF E.O. 13224 (JUNE 2012)

a. The recipient is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. The recipient must not engage in transactions with, or provide resources or support to, individuals and organizations associated with terrorism. In addition, the recipient must verify that no support or resources are provided to individuals or entities that appear on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Treasury (online at: http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx) or the United Nations Security designation list (online at: http://www.un.org/sc/committees/1267/aq_sanctions_list.shtml).

b. This provision must be included in all subagreements, including contracts and subawards, issued under this award.

[END OF PROVISION]

13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (JUNE 2012)

a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and brandmark with the tagline "from the American people." The USAID Identity is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:

(1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;

(2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

(3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;

(4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and

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

b. When this award contains an approved Marking Plan, the recipient must implement the requirements of this provision following the approved Marking Plan.

c. If a "Marking Plan" is not included in this award, the recipient must propose and submit a plan for approval within the time specified by the Agreement Officer (AO).

d. The AO may require a preproduction review of program materials and "public communications" (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection

with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.

e. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer's Representative (AOR) and to USAID's Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

"The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide."

f. Any "public communication" in which the content has not been approved by USAID must contain the following disclaimer:

"This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government."

g. The recipient must provide the USAID AOR, with two copies of all program and communications materials produced under this award.

h. The recipient may request an exception from USAID marking requirements when USAID marking requirements would:

(1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;

(2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;

(3) Undercut host-country government "ownership" of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;

(4) Impair the functionality of an item;

(5) Incur substantial costs or be impractical;

(6) Offend local cultural or social norms, or be considered inappropriate; or

(7) Conflict with international law.

i. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.

(1) Approved waivers "flow down" to subagreements, including subawards and contracts, unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.

(2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.

j. The recipient must include the following marking provision in any subagreements entered into under this award:

"As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient's, subrecipient's, other donor's, or third party's is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity."

[END OF PROVISION]

14. REGULATIONS GOVERNING EMPLOYEES (AUGUST 1992)

(The following applies to the recipient's employees working in the cooperating country under the agreement who are not citizens of the cooperating country.)

a. The recipient's employees must maintain private status and may not rely on local U.S. Government offices or facilities for support while under this grant.

b. The sale of personal property or automobiles by recipient employees and their dependents in the foreign country to which they are assigned are subject to the same limitations and prohibitions which apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.

c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any

business, profession, or occupation in the foreign countries to which the individual is assigned.

d. The recipient's employees, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.

e. In the event the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's chief of party must consult with the USAID Mission Director and the employee involved, and must recommend to the recipient a course of action with regard to such employee.

f. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen or the discharge from this grant award of any third country national when, in the discretion of the Ambassador, the interests of the United States so require.

g. If it is determined, either under e. or f. above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or point of origin, as appropriate.

[END OF PROVISION]

15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY (NOVEMBER 1985)

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to

indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:

(1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.

(2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).

(3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.

(4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:

Name of individual or organization (followed by
letter symbol "G")
City Name of post (USAID/_____)
Agency for International Development
Washington, DC 20523-0001

(5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO). This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.

c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (JUNE 2012)

a. PRIOR BUDGET APPROVAL

Direct charges for travel costs for international air travel by individuals are allowable only when each international trip has received prior budget approval. Such approval is met when all of the following are met:

(1) The trip is identified by providing the following information: the number of trips, the number of individuals per trip, and the origin and destination countries or regions;

(2) All of the information noted at a.(1) above is incorporated in the Schedule of this award or amendments to this award; and

(3) The costs related to the travel are incorporated in the budget of this award.

The Agreement Officer (AO) may approve, in writing, international travel costs that have not been incorporated in this award. To obtain AO approval, the recipient must request approval at least three weeks before the international travel, or as far in advance as possible. The recipient must keep a copy of the AO's approval in its files. No other clearance (including country clearance) is required for employees of the recipient, its subrecipients or contractors. International travel by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee's benefits package, must be consistent with the recipient's personnel and travel policies and procedures and does not require approval.

b. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed charges normally allowed by the non-profit organization in its regular operations as the result of the non-profit organization's written travel policy.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

c. FLY AMERICA ACT RESTRICTIONS

(1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.

(2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the Standard Provision, "Accounting, Audit and Records." The documentation must use one of the following reasons or other exception under the Fly America Act:

(i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU "Open Skies" agreement (http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm).

(ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see http://apps.fas.gsa.gov/citypairs/search/):

a. Australia on an Australian airline,
b. Switzerland on a Swiss airline, or
c. Japan on a Japanese airline;

(iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;

(iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;

(v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or

(vi) If the US Flag Air Carrier does not offer direct service,

a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,

b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or

c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

d. DEFINITIONS

The terms used in this provision have the following meanings:

(1) "Travel costs'' means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. "Travel costs" do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee's benefits package that are consistent with the recipient's personnel and travel policies and procedures.

(2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.

(3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at http://ostpxweb.dot.gov/aviation/certific/certlist.htm. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.

(4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

e. SUBAGREEMENTS

This provision must be included in all subagreements, including all subawards and contracts, under which this award will finance international air transportation.

[END OF PROVISION]

18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523-7900

Email: oceantransportation@usaid.gov

b. This provision must be included in all subagreements, including subwards and contracts.

[END OF PROVISION]

19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

(1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

(1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term "motivate," as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

(2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

20. TRAFFICKING IN PERSONS (JUNE 2012)

a. USAID is authorized to terminate this award, without penalty, if the recipient or its employees, or any subrecipient or its employees, engage in any of the following conduct:

(1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of

this award;

(2) Procurement of a commercial sex act during the period of this award; or

(3) Use of forced labor in the performance of this award.

b. For purposes of this provision, "employee" means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.

c. The recipient must include in all subagreements, including subawards and contracts, a provision prohibiting the conduct described in a(1)-(3) by the subrecipient, contractor or any of their employees.

[END OF PROVISION]

21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

a. Submissions to the Development Experience Clearinghouse (DEC).

1) The recipient must provide the Agreement Officer's Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.

2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: http://dec.usaid.gov.

3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.

4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.

5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.

b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

[END OF MANDATORY PROVISIONS]

II. REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S. NONGOVERNMENTALORGANIZATIONS

RAA1. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (APRIL 1998)

APPLICABILITY: *This provision is applicable to educational or nonprofit institutions whose indirect cost rates under this award are on a predetermined basis.*

a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.

b. Within the earlier of 30 days after receipt of the A-133 audit report or nine months after the end of the audit period, the recipient must submit to the cognizant agency for audit the required OMB Circular A-133 audit report, proposed predetermined indirect cost rates, and supporting cost data. If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.

d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, (3) the fiscal year for which the rates apply, and (4) the specific items treated as direct costs. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.

e. Pending establishment of predetermined indirect costs rates for any fiscal year, the recipient must be reimbursed either at the rates fixed for the previous fiscal year or at billing rates acceptable to the USAID Agreement Officer, subject to appropriate adjustment when the final rates for the fiscal year or other period are established.

[END OF PROVISION]

RAA2. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (APRIL 1998)

APPLICABILITY: *This provision is applicable to any nonprofit organizations whose indirect cost rates under this award are on a provisional basis.*

a. Provisional indirect cost rates must be established for each of the recipient's accounting periods during the term of this award. Pending establishment of revised provisional or final rates, allowable indirect costs must be reimbursed at the rates, on the bases, and for the periods shown in the schedule of the award.

b. Within the earlier of 30 days after receipt of the A-133 audit report or nine months after the end of the audit period, the recipient must submit to the cognizant agency for audit the required OMB Circular A-133 audit report, proposed final indirect cost rates, and supporting cost data. If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, along with the proposed final indirect cost rates and supporting cost data, to the Overhead, Special Costs, and Closeout Branch, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of final indirect cost rates must begin soon after receipt of the recipient's proposal.

c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.

d. The results of each negotiation must be set forth in a written indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon final rates, (2) the bases to which the rates apply, (3) the fiscal year for which the rates apply, and (4) the items treated as direct costs. The agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.

e. Pending establishment of final indirect cost rate(s) for any fiscal year, the recipient must be reimbursed either at negotiated provisional rates or at billing rates acceptable to the Agreement Officer, subject to appropriate adjustment when the final rates for the fiscal year are established. To prevent substantial overpayment or underpayment, the provisional or billing rates may be prospectively or retroactively revised by mutual agreement.

f. Failure by the parties to agree on final rates is a 22 CFR 226.90 dispute.

[END OF PROVISION]

RAA3. NEGOTIATED INDIRECT COST RATE - PROVISIONAL (Profit) (APRIL 1998)

APPLICABILITY: *This provision applies to for-profit organizations whose indirect cost rates under this award are on a provisional basis.*

a. Provisional indirect cost rates must be established for the recipient's accounting periods during the term of this award. Pending establishment of revised provisional or final rates, allowable indirect costs must be reimbursed at the rates, on the bases, and for the periods

shown in the schedule of this award. Indirect cost rates and the appropriate bases must be established in accordance with FAR Subpart 42.7.

b. Within six months after the close of the recipient's fiscal year, the recipient must submit to the cognizant agency for audit the proposed final indirect cost rates and supporting cost data. If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit three copies of the proposed final indirect cost rates and supporting cost data, to the Overhead, Special Costs, and Closeout Branch, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of final indirect cost rates must begin soon after receipt of the recipient's proposal.

c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.

d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon final rates, (2) the bases to which the rates apply, (3) the fiscal year for which the rates apply, and (4) the items treated as direct costs. The agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.

e. Pending establishment of final indirect cost rates for any fiscal year, the recipient must be reimbursed either at negotiated provisional rates or at billing rates acceptable to the Agreement Officer, subject to appropriate adjustment when the final rates for the fiscal year are established. To prevent substantial overpayment or underpayment, the provisional or billing rates may be prospectively or retroactively revised by mutual agreement.

f. Failure by the parties to agree on final rates is a 22 CFR 226.90 dispute.

[END OF PROVISION]

RAA4. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

***APPLICABILITY**: This provision applies to awards that contain funding for any exchange visitor activities or participant training, as defined in ADS 252 and 253, respectively, conducted or paid for by the recipient with USAID funds under this award.*

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. **Definitions:**

(1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.

(2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.

(3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.

(4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. **Program Monitoring and Data Reporting:** The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

(1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see http://trainethelp.usaid.gov/), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see http://trainethelp.usaid.gov/) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).

(2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see http://trainethelp.usaid.gov/), to report and manage Participant Training data.

c. **Health and Accident Insurance:**

(1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer's Representative.

(2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.

(3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. **Immigration Requirements:**

(1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).

(2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. **Language Proficiency:** The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. **Pre-departure Orientation:** The recipient must conduct pre-departure orientation for U.S-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods (see http://pdf.usaid.gov/pdf_docs/PNADT444.pdf).

g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer

any known violations by Exchange Visitors of visa or other immigration requirements or conditions.

h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.

i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."

j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA5. VOLUNTARY POPULATION PLANNING ACTIVITIES – SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)

APPLICABLITY: *This provision is applicable to all awards involving any aspect of voluntary population planning activities.*

a. Voluntary Participation and Family Planning Methods:

(1) The recipient agrees to take any steps necessary to ensure that funds made available under this award will not be used to coerce any individual to practice methods of family planning inconsistent with such individual's moral, philosophical, or religious beliefs. Further, the recipient agrees to conduct its activities in a manner which safeguards the rights, health, and welfare of all individuals who take part in the program.

(2) Activities which provide family planning services or information to individuals, financed in whole or in part under this agreement, must provide a broad range of family planning methods and services available in the country in which the activity is conducted or must provide information to such individuals regarding where such methods and services may be obtained.

b. Requirements for Voluntary Family Planning Projects

(1) A family planning project must comply with the requirements of this paragraph.

(2) A project is a discrete activity through which a governmental, nongovernmental, or public international organization provides family planning services to people and for which funds obligated under this award, or goods or services financed with such funds, are provided under this award, except funds solely for the participation of personnel in short-term, widely attended training conferences or programs.

(3) Service providers and referral agents in the project must not implement or be subject to quotas or other numerical targets of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning. Quantitative estimates or indicators of the number of births, acceptors, and acceptors of a particular method that are used for the purpose of budgeting, planning, or reporting with respect to the project are not quotas or targets under this paragraph, unless service providers or referral agents in the project are required to achieve the estimates or indicators.

(4) The project must not include the payment of incentives, bribes, gratuities or financial rewards to (i) any individual in exchange for becoming a family planning acceptor or (ii) any personnel performing functions under the project for achieving a numerical quota or target of total number of births, number of family planning acceptors, or acceptors of a particular method of contraception. This restriction applies to salaries or payments paid or made to personnel performing functions under the project if the amount of the salary or payment increases or decreases based on a predetermined number of births, number of family planning acceptors, or number of acceptors of a particular method of contraception that the personnel affect or achieve.

(5) A person must not be denied any right or benefit, including the right of access to participate in any program of general welfare or health care, based on the person's decision not to accept family planning services offered by the project.

(6) The project must provide family planning acceptors comprehensible information about the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method. This requirement may be satisfied by providing information in accordance with the medical practices and standards and health conditions in the country where the project is conducted through counseling, brochures, posters, or package inserts.

(7) The project must ensure that experimental contraceptive drugs and devices and medical procedures are provided only in the context of a scientific study in which participants are advised of potential risks and benefits.

(8) With respect to projects for which USAID provides, or finances the contribution of, contraceptive commodities or technical services and for which there is no subaward or contract under this award, the organization implementing a project

for which such assistance is provided must agree that the project will comply with the requirements of this paragraph while using such commodities or receiving such services.

(9)

i) The recipient must notify USAID when it learns about an alleged violation in a project of the requirements of subparagraphs (3), (4), (5), or (7) of this paragraph.

ii) The recipient must investigate and take appropriate corrective action, if necessary, when it learns about an alleged violation in a project of subparagraph (6) of this paragraph and must notify USAID about violations in a project affecting a number of people over a period of time that indicate there is a systemic problem in the project.

iii) The recipient must provide USAID such additional information about violations as USAID may request.

c. Additional Requirements for Voluntary Sterilization Programs

(1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

(2) The recipient must ensure that any surgical sterilization procedures supported, in whole or in part, by funds from this award are performed only after the individual has voluntarily appeared at the treatment facility and has given informed consent to the sterilization procedure. Informed consent means the voluntary, knowing assent from the individual after being advised of the surgical procedures to be followed, the attendant discomforts and risks, the benefits to be expected, the availability of alternative methods of family planning, the purpose of the operation and its irreversibility, and the option to withdraw consent any time prior to the operation. An individual's consent is considered voluntary if it is based upon the exercise of free choice and is not obtained by any special inducement or any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation.

(3) Further, the recipient must document the patient's informed consent by (i) a written consent document in a language the patient understands and speaks, which explains the basic elements of informed consent, as set out above, and which is signed by the individual and by the attending physician or by the authorized assistant of the attending physician; or, (ii) when a patient is unable to read adequately a written certification by the attending physician or by the authorized assistant of the attending physician that the basic elements of informed consent above were orally presented to the patient, and that the patient thereafter

consented to the performance of the operation, the receipt of this oral explanation must be acknowledged by the patient's mark on the certification and by the signature or mark of a witness who speaks the same language as the patient.

(4) The recipient must retain copies of informed consent forms and certification documents for each voluntary sterilization procedure for a period of three years after performance of the sterilization procedure.

d. Prohibition on Abortion-Related Activities:

(1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and, (v) lobbying for or against abortion. The term "motivate," as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

(2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent, or consequences of abortions is not precluded.

e. The recipient must insert this provision in all subsequent subagreements, including subawards and contracts, involving family planning or population activities that will be supported, in whole or in part, from funds under this award.

[END OF PROVISION]

RAA6. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

APPLICABILITY: *This provision is applicable when human subjects are involved in research financed by the award.*

a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported

by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.

b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103. Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed "at least equivalent" to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA7. CARE OF LABORATORY ANIMALS (MARCH 2004)

APPLICABILITY: *This provision is applicable when laboratory animals are involved in research performed in the U.S. and financed by the award.*

a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.

b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.

c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animals Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA8. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (NOVEMBER 1985)

APPLICABILITY: *This provision is applicable to property titled in the name of the cooperating country or such public or private agency as the cooperating country government may designate.*

a. Except as modified by the schedule of this grant, title to all equipment, materials and supplies, the cost of which is reimbursable to the recipient by USAID or by the cooperating country, must at all times be in the name of the cooperating country or such public or private agency as the cooperating country may designate, unless title to specified types or classes of equipment is reserved to USAID under provisions set forth in the schedule of this award. All such property must be under the custody and control of recipient until the owner of title directs otherwise or completion of work under this award or its termination, at which time custody and control must be turned over to the owner of title or disposed of in accordance with its instructions. All performance guarantees and warranties obtained from suppliers must be taken in the name of the title owner.

b. The recipient must maintain and administer in accordance with sound business practice a program for the maintenance, repair, protection, and preservation of Government property so as to assure its full availability and usefulness for the performance of this grant. The recipient must take all reasonable steps to comply with all appropriate directions or instructions which the Agreement Officer may prescribe as reasonably necessary for the protection of the Government property.

c. The recipient must prepare and establish a program, to be approved by the appropriate USAID Mission, for the receipt, use, maintenance, protection, custody and care of equipment, materials and supplies for which it has custodial responsibility, including the establishment of reasonable controls to enforce such program. The recipient must be guided by the following requirements:

(1) Property Control: The property control system must include but not be limited to the following:

(i) Identification of each item of cooperating country property acquired or furnished under the award by a serially controlled identification number and by description of item. Each item must be clearly marked "Property of (insert name of cooperating country)."

(ii) The price of each item of property acquired or furnished under this award.

(iii) The location of each item of property acquired or furnished under this award.

(iv) A record of any usable components which are permanently removed from items of cooperating country property as a result of modification or otherwise.

(v) A record of disposition of each item acquired or furnished under the award.

(vi) Date of order and receipt of any item acquired or furnished under the award.

(vii) The official property control records must be kept in such condition that at any stage of completion of the work under this award, the status of property acquired or furnished under this award may be readily ascertained. A report of current status of all items of property acquired or furnished under the award must be submitted yearly concurrently with the annual report.

(2) Maintenance Program: The recipient's maintenance program must be consistent with sound business practice, the terms of the award, and provide for:

(i) Disclosure of need for and the performance of preventive maintenance,

(ii) Disclosure and reporting of need for capital type rehabilitation, and

(iii) Recording of work accomplished under the program:

(A) Preventive maintenance - Preventive maintenance is

maintenance generally performed on a regularly scheduled basis to prevent the occurrence of defects and to detect and correct minor defects before they result in serious consequences.

(B) Records of maintenance - The recipient's maintenance program must provide for records sufficient to disclose the maintenance actions performed and deficiencies discovered as a result of inspections.

(C) A report of status of maintenance of cooperating country property must be submitted annually concurrently with the annual report.

d. Risk of Loss:

(1) The recipient is not liable for any loss of or damage to the cooperating country property, or for expenses incidental to such loss or damage except that the recipient is responsible for any such loss or damage (including expenses incidental thereto):

(i) Which results from willful misconduct or lack of good faith on the part of any of the recipient's directors or officers, or on the part of any of its managers, superintendents, or other equivalent representatives, who have supervision or direction of all or substantially all of the recipient's business, or all or substantially all of the recipient's operation at any one plant, laboratory, or separate location in which this award is being performed;

(ii) Which results from a failure on the part of the recipient, due to the willful misconduct or lack of good faith on the part of any of its directors, officers, or other representatives mentioned in (i) above:

(A) To maintain and administer, in accordance with sound business practice, the program for maintenance, repair, protection, and preservation of cooperating country property as required by (i) above; or

(B) To take all reasonable steps to comply with any appropriate written directions of the Agreement Officer under b. above;

(iii) For which the recipient is otherwise responsible under the express terms designated in the schedule of this award;

(iv) Which results from a risk expressly required to be insured under some other provision of this award, but only to the extent of the insurance so required to be procured and maintained, or to the extent of insurance actually procured and maintained, whichever is greater; or

(v) Which results from a risk which is in fact covered by insurance or for which the grantee is otherwise reimbursed, but only to the extent of such insurance or reimbursement;

(vi) Provided, that, if more than one of the above exceptions is applicable in any case, the recipient's liability under any one exception is not limited by any other exception.

(2) The recipient must not be reimbursed for, and must not include as an item of overhead, the cost of insurance, or any provision for a reserve, covering the risk of loss of or damage to the cooperating country property, except to the extent that USAID may have required the recipient to carry such insurance under any other provision of this award.

(3) Upon the happening of loss or destruction of or damage to the cooperating country property, the recipient must notify the Agreement Officer thereof, must take all reasonable steps to protect the cooperating country property from further damage, separate the damaged and undamaged cooperating country property, put all the cooperating country property in the best possible order, and furnish to the Agreement Officer a statement of:

(i) The lost, destroyed, or damaged cooperating country property;

(ii) The time and origin of the loss, destruction, or damage;

(iii) All known interests in commingled property of which the cooperating country property is a part; and

(iv) The insurance, if any, covering any part of or interest in such commingled property.

(4) The recipient must make repairs and renovations of the damaged cooperating country property or take such other action as the Agreement Officer directs.

(5) In the event the recipient is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the cooperating country property, it must use the proceeds to repair, renovate or replace the cooperating country property involved, or must credit such proceeds against the cost of the work covered by the award, or must otherwise reimburse USAID, as directed by the Agreement Officer. The recipient must do nothing to prejudice USAID's right to recover against third parties for any such loss, destruction, or damage, and upon the request of the Agreement Officer, must, at the Government's expense, furnish to USAID all reasonable assistance and cooperation (including assistance in the prosecution of suits and the execution of instruments or assignments in favor of the Government) in obtaining recovery.

e. Access: USAID, and any persons designated by it, must at all reasonable times have access to the premises wherein any cooperating country property is located, for the purpose of inspecting the cooperating country property.

f. Final Accounting and Disposition of Cooperating Country Property: Within 90 days after completion of this award, or at such other date as may be fixed by the Agreement Officer, the recipient must submit to the Agreement Officer an inventory schedule covering all items of equipment, materials and supplies under the recipient's custody, title to which is in the cooperating country or public or private agency designated by the cooperating country, which have not been consumed in the performance of this award. The recipient must also indicate what disposition has been made of such property.

g. Communications: All communications issued pursuant to this provision must be in writing.

[END OF PROVISION]

RAA9. COST SHARING (MATCHING) (FEBRUARY 2012)

APPLICABILITY: *This provision, along with 22 CFR 226, is applicable when the recipient has agreed or is required to cost share or provide a matching share.*

a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.

b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA10. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

APPLICABILITY: *This provision is applicable where performance of the award will take place in "Covered" Countries, as described in ADS 206 (see 206.5.3).*

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

b.

(1) For any loan over $1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.

(2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.

c.

(1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

(2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

"The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140."

[END OF PROVISION]

RAA11. INVESTMENT PROMOTION (NOVEMBER 2003)

APPLICABILITY: *The following clause is required for grants and cooperative agreements when the program includes gray-area activities or investment-related activities where specific activities are not identified at the time of obligation but could be for investment-related activities, as described in ADS 225 (see 225.3.1.8).*

a. Except as specifically set forth in this award or otherwise authorized by USAID in writing, no funds or other support provided hereunder may be used for any activity that involves investment promotion in a foreign country.

b. In the event the recipient is requested or wishes to provide assistance in the above area or requires clarification from USAID as to whether the activity would be consistent with the

limitation set forth above, the recipient must notify the Agreement Officer and provide a detailed description of the proposed activity. The recipient must not proceed with the activity until advised by USAID that it may do so.

c. The recipient must ensure that its employees and subrecipients and contractors providing investment promotion services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all contracts and other subagreements entered into hereunder.

[END OF PROVISION]

RAA12. REPORTING HOST GOVERNMENT TAXES (JUNE 2012)

***APPLICABILITY**: This provision is applicable to all USAID agreements that obligate or subobligate FY 2003 or later funds except for agreements funded with Operating Expense, Pub. L. 480 funds, or trust funds, or agreements where there will be no commodity transactions in a foreign country over the amount of $500. Please insert address and point of contact at the Embassy, Mission, or CFO/CMP as appropriate under section (b) of this provision.*

a. By April 16 of each year, the recipient must submit a report containing:

(1) Contractor/recipient name.

(2) Contact name with phone, fax and e-mail.

(3) Agreement number(s).

(4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of $500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.

(5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).

(6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.

(7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.

b. Submit the reports to: [insert address and point of contact at the Embassy, Mission, or CFO/CMP as appropriate, may include an optional "with a copy to"].

c. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes are allowable in accordance with the Standard Provision, "Allowable Costs," and must be reported as required in this provision.

d. The recipient must include this reporting requirement in all applicable subagreements, including subawards and contracts.

[END OF PROVISION]

RAA13. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

***APPLICABILITY**: Include this provision in agreements funded from the following accounts:*

- *Development Assistance, including assistance for sub-Saharan Africa,*
- *Global Health Programs, and*
- *Micro and Small Enterprise Development Program Account.*

Further information found in the Mandatory Reference for ADS 303, "Guidance on Funding Foreign Government Delegations to International Conferences," (http://inside.usaid.gov/ADS/300/350maa.pdf).

a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.

b. Definitions:

(1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.

(2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.

(3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA14. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)

***APPLICABILITY**: This provision must be included in any award anticipated to use FY04-FY13 funds available for HIV/AIDS activities.*

An organization, including a faith-based organization, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care—

(a) Shall not be required, as a condition of receiving such assistance—

(1) To endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(2) To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and

(b) Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described in paragraph (a) above.

[END OF PROVISION]

RAA15. CONDOMS (JUNE 2005)

***APPLICABILITY:** This provision must be included in any agreement financing HIV/AIDS activities.*

Information provided about the use of condoms as part of projects or activities that are funded under this agreement must be medically accurate and must include the public health benefits and failure rates of such use and must be consistent with USAID's fact sheet entitled, "USAID: HIV/STI Prevention and Condoms." This fact sheet may be accessed at: transition.usaid.gov/our_work/global_health/aids/TechAreas/prevention/condomfactsheet.html

[END OF PROVISION]

RAA16. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING (APRIL 2010)

APPLICABILITY: *This provision must be included in any agreement financing HIV/AIDS activities. For awards to Alliance for Open Society International (AOSI), Pathfinder, or a member of the Global Health Council (GHC) or InterAction (with the exception of DKT International, Inc.), the Agreement Officer must include the following footnote at the end of paragraph (b)(1):*

> *"Any enforcement of this clause is subject to Alliance for Open Society International v. USAID, 05 Civ. 8209 (S.D.N.Y., orders filed on June 29, 2006 and August 8, 2008) (orders granting preliminary injunction) for the term of the Orders."*
>
> *The lists of members of GHC and InterAction can be found at: http:/transition.usaid.gov/business/business_opportunities/cib/pdf/GlobalHealthMemberlist.pdf.*

a. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

b.

(1) Except as provided in (b)(2) and (b)(3), by accepting this award or any subaward, a non-governmental organization or public international organization awardee/subawardee agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children.

(2) The following organizations are exempt from (b)(1): the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.

(3) Contractors and subcontractors are exempt from (b)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

(4) Notwithstanding section (b)(3), not exempt from (b)(1) are recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS

programs under this assistance award, any subaward, or procurement contract or subcontract by:

(i) Providing supplies or services directly to the final populations receiving such supplies or services in host countries;

(ii) Providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or

(iii) Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

c. The following definitions apply for purposes of this provision:

"Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

"Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.

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

d. The recipient shall insert this provision, which is a standard provision, in all subawards, procurement contracts or subcontracts.

e. This provision includes express terms and conditions of the award and any violation of it shall be grounds for unilateral termination of the award by USAID prior to the end of its term.

[END OF PROVISION]

RAA17. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

APPLICABILITY: *This provision must be included in Request for Applications (RFAs), and in awards.*

a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies,

activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities. The full text of the policy paper can be found at the following Web site:
pdf.usaid.gov/pdf_docs/PDABQ631.pdf

b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA18. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)

APPLICABILITY: *This provision must be included in solicitations (e.g., Requests for Applications (RFAs) or Annual Program Statements), and in awards involving construction.*

a. One of the objectives of the USAID Disability Policy is to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations, and other donors in fostering a climate of nondiscrimination against people with disabilities. As part of this policy USAID has established standards for any new or renovation construction project funded by USAID to allow access by people with disabilities (PWDs). The full text of the policy paper can be found at the following Web site: pdf.usaid.gov/pdf_docs/PDABQ631.pdf.

b. USAID requires the recipient to comply with standards of accessibility for people with disabilities in all structures, buildings or facilities resulting from new or renovation construction or alterations of an existing structure.

c. The recipient will comply with the host country or regional standards for accessibility in construction when such standards result in at least substantially equivalent accessibility and usability as the standard provided in the Americans with Disabilities Act (ADA) of 1990 and the Architectural Barriers Act (ABA) Accessibility Guidelines of July 2004. Where there are no host country or regional standards for universal access or where the host country or regional standards fail to meet the ADA/ABA threshold, the standard prescribed in the ADA and the ABA will be used.

d. New Construction. All new construction will comply with the above standards for accessibility.

e. Alterations. Changes to an existing structure that affect, the usability of the structure will comply with the above standards for accessibility unless the recipient obtains the Agreement Officer's advance approval that compliance is technically infeasible or constitutes an undue burden or both. Compliance is technically infeasible where structural conditions would require removing or altering a load-bearing member that is an essential part of the structural frame or because other existing physical or site constraints prohibit modification or addition of elements, spaces, or features that are in full and strict compliance with the minimum requirements of the standard. Compliance is an undue burden where it entails either a significant difficulty or expense or both.

f. Exceptions. The following construction related activities are excepted from the requirements of paragraphs a. through d. above:

(1) Normal maintenance, reroofing, painting or wall papering, or changes to mechanical or electrical systems are not alterations and the above standards do not apply unless they affect the accessibility of the building or facility; and

(2) Emergency construction (which may entail the provision of plastic sheeting or tents, minor repair and upgrading of existing structures, rebuilding of part of existing structures, or provision of temporary structures) intended to be temporary in nature. A portion of emergency construction assistance may be provided to people with disabilities as part of the process of identifying disaster- and crisis-affected people as "most vulnerable."

[END OF PROVISION]

RAA19. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)

Applicability: *This provision must be included in any grant or cooperative agreement that*

(1) uses funds made available to carry out the Trafficking Victims Protection Act of 2000, Division A of P.L. 106-386; and

(2) covers a program that targets victims of severe forms of trafficking in persons (as defined below) and provides services to individuals while they are still engaged in activities that resulted from such victims being trafficked.

"Severe forms of trafficking in persons" means

(1) sex trafficking in which a commercial sex act is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age; or

(2) the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.

By accepting this award, the recipient hereby states that it does not promote, support, or advocate the legalization or practice of prostitution. This statement may be true by virtue of the organization's lack of any policy regarding the issue.

[END OF PROVISION]

RAA20. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)

APPLICABILITY: *This provision must be included in any award that uses funds made available to carry out the Trafficking Victims Protection Act of 2000, Division A of P.L. 106-386, for a program that targets victims of severe forms of trafficking in persons. "Severe forms of trafficking in persons" means*

(1) sex trafficking in which a commercial sex act is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age; or

(2) the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.

The recipient must not provide funds made available to carry out this award to any organization that has not stated in either a grant application, a grant agreement, or both, that it does not promote, support, or advocate the legalization or practice of prostitution. Such a statement is not required, however, if the sub-recipient organization provides services to individuals solely after they are no longer engaged in activities that resulted from such victims being trafficked. If required, the sub-recipient organization's statement may be true by virtue of the organization's lack of any policy regarding the issue.

[END OF PROVISION]

RAA21. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)

APPLICABILITY: *This provision must be included in any award that uses funds made available specifically under the Trafficking Victims Protection Act of 2000, Division A of P.L. 106-386.*

None of the funds made available under this award may be used to promote, support, or advocate the legalization or practice of prostitution. However, this prohibition does not preclude assistance designed to ameliorate the suffering of, or health risks to, victims while they are being

trafficked or after they are out of the situation that resulted in such victims being trafficked. The recipient must insert this provision in all subagreements under this award.

[END OF PROVISION]

RAA22. CENTRAL CONTRACTOR REGISTRATION AND UNIVERSAL IDENTIFIER (OCTOBER 2010)

APPLICABILITY: *This provision is required in accordance with 2 CFR 25, Award Term for Central Contractor Registration and Universal Identifier. Agreement Officers (AOs) must include this provision in all assistance solicitations and all awards, unless the AO exempts an organization from compliance with the provision under one of the following exceptions, from paragraph d. below:*

Exceptions. The requirements of this provision to obtain a Data Universal Numbering System (DUNS) number and maintain a current registration in the Central Contractor Registration (CCR) do not apply, at the prime award or subaward level, to.

(1) Awards to individuals

(2) Awards less than $25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)

(3) Awards where the AO determines, in writing, that these requirements would cause personal safety concerns.

a. Requirement for Central Contractor Registration (CCR). Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the CCR until you submit the final financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another award term.

b. Requirement for Data Universal Numbering System (DUNS) numbers. If you are authorized to make subawards under this award, you:

(1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you unless the entity has provided its DUNS number to you.

(2) May not make a subaward to an entity unless the entity has provided its DUNS number to you.

c. Definitions. For purposes of this award term:

(1) Central Contractor Registration (CCR) means the Federal repository into which

an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR Internet site (currently at www.ccr.gov).

(2) Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866-705-5711) or the Internet (currently at fedgov.dnb.com/webform).

(3) Entity, as it is used in this award term, means all of the following, as defined at 2 CFR 25, subpart C:

(i) A governmental organization, which is a State, local government, or Indian tribe;

(ii) A foreign public entity;

(iii) A domestic or foreign nonprofit organization;

(iv) A domestic or foreign for-profit organization; and

(v) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

(4) Subaward:

(i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

(ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. --.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

(iii) A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

(5) Subrecipient means an entity that:

(i) Receives a subaward from you under this award; and

(ii) Is accountable to you for the use of the Federal funds provided by the subaward.

ADDENDUM (JUNE 2012):

a. Exceptions. The requirements of this provision to obtain a Data Universal Numbering System (DUNS) number and maintain a current registration in the Central Contractor Registration (CCR) do not apply, at the prime award or subaward level, to:

(1) Awards to individuals

(2) Awards less than $25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)

(3) Awards where the Agreement Officer determines, in writing, that these requirements would cause personal safety concerns.

b. This provision does not need to be included in subawards.

[END OF PROVISION]

RAA23. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (OCTOBER 2010)

APPLICABILITY: *This provision is required in accordance with 2 CFR 170, Award Term for Reporting Subawards and Executive Compensation. AOs must include this provision in all assistance solicitations and all awards expected to exceed $25,000, unless an exemption applies under paragraph d. of the provision or the exemptions listed below in this applicability statement. If the AO determines that an exemption applies, the AO must provide guidance to the recipient on reporting with generic information.*

Exemptions.

(1) The requirements to report under this provision do not apply to:

(i) Awards to individuals

(ii) Awards less than $25,000

(2) When the AO determines, in writing, that these requirements would cause personal safety concerns, reporting under this provision can be accomplished using generic information.

a. Reporting of first-tier subawards.

(1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that obligates $25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the

American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

(2) Where and when to report.

(i) You must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.

(ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

(i) The total Federal funding authorized to date under this award is $25,000 or more;

(ii) In the preceding fiscal year, you received—

(A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)

(2) Where and when to report. You must report executive total compensation

described in paragraph b.(1) of this award term:

(i) As part of your registration profile at www.bpn.gov/ccr.

(ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

(1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if–

(i) In the subrecipient's preceding fiscal year, the subrecipient received—

(A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

(ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)

(2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:

(i) To the recipient.

(ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under $300,000, you are exempt from the requirements to report:

(1) Subawards, and

(2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

(1) Entity means all of the following, as defined in 2 CFR 25:

(i) A governmental organization, which is a State, local government, or Indian tribe;

(ii) A foreign public entity;

(iii) A domestic or foreign nonprofit organization;

(iv) A domestic or foreign for-profit organization; and

(v) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

(2) Executive means officers, managing partners, or any other employees in management positions.

(3) Subaward:

(i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

(ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. __.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non- Profit Organizations").

(iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

(4) Subrecipient means an entity that:

(i) Receives a subaward from you (the recipient) under this award; and

(ii) Is accountable to you for the use of the Federal funds provided by the subaward.

(5) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

(i) Salary and bonus.

(ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

(iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

(iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

(v) Above-market earnings on deferred compensation which is not tax-qualified.

(vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds $10,000.

[END OF PROVISION]

RAA.24 PATENT REPORTING PROCEDURES (JULY 2012)

APPLICABILITY: *This provision is applicable whenever the agreement finances research activities, or patentable processes or practices.)*

PATENT REPORTING PROCEDURES (JULY 2012)

As incorporated by 22 CFR 226.36 and the standard provision "APPLICABILITY OF 22 CFR PART 226," the clause at 37 CFR 401.14 ("Patent Rights (Small Business Firms and Nonprofit

Organizations)") is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (http://www.iedison.gov) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer's Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

[END OF REQUIRED AS APPLICABLE PROVISIONS]

ATTACHMENT E – INITIAL ENVIRONMENTAL EXAMINATION

SUMMARY OF PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)
For
Achieving Universal Diagnosis and Appropriate Case Management for Malaria

PROGRAM/ACTIVITY DATA

IEE Number:	**GH-12-020**
Program/Project Number:	RFA-OAA-12-000014.
Country:	**Global**
Functional Objective:	**Investing in People**
Program Area:	**Health**
Program Elements:	**Malaria (primary), Tuberculosis, Neglected Tropical Diseases, HIV/AIDS**
Funding Period:	**2012-2017**
Life of Activity Funding:	**Five (5) years**

Life of PIEE: Five years from date of signing or at the time of any change/amendment to the Program.

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

PIEE Prepared by: GH/HIDN/ID

Current date: March 27, 2012

ENVIRONMENTAL ACTION RECOMMENDED

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

SUMMARY OF FINDINGS

The purpose of this Programmatic Initial Environmental Examination (PIEE) is to review the overall activities and the potential environmental impact that will be undertaken by the soon to be awarded Achieving Universal Diagnosis and Appropriate Case Management of Malaria program (henceforth called the program).

The purpose of this project is to provide technical and implementation support to the President's Malaria Initiative (PMI) focus and non-focus countries that need assistance scaling up diagnostic

testing and case management of malaria and other infectious diseases, such as tuberculosis (TB) and neglected tropical diseases (NTDs). The project will specifically:

1) Strengthen laboratory capacity to diagnose malaria and other priority infectious diseases;
2) Scale-up diagnostic testing for malaria in facilities without laboratories and at the community level; and
3) Strengthen the clinical case management of malaria.

The Program Programmatic Initial Environmental Examination (PIEE) evaluates the potential impacts of the Program activities and has determined that a **Negative Determination with Conditions** is appropriate for the actions described in the document. Other actions not described in the paper will require supplemental environmental analysis. For subsequent sub-awards, a supplemental IEE (SIEE) will be required. SIEEs will be executed for sub-awards to ensure and document country specific compliance with agreed environmental mitigation.

THRESHOLD ENVIRONMENTAL DETERMINATIONS

The overall environmental determination for the Achieving Universal Diagnosis and Appropriate Case Management of Malaria program is a **Negative Determination, with conditions**.

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

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

SUMMARY OF MONITORING AND REPORTING MEASURES

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

2. **AOR Responsibilities:** The AOR and/or on-site manager or their representative of the Program/Project will undertake field visits, as possible, and consultations with implementing partners to jointly assess the environmental impacts of ongoing activities, and associated mitigation and monitoring conditions

a. The AOR, in consultation with the mission activity managers and implementing partners, Mission Environmental Officers (MEO), Regional Environmental Officers (REO), and/or Bureau Environmental Officers as appropriate, will actively monitor and evaluate whether environmental consequences unforeseen under activities covered by this PIEE arise during implementation, and modify or end activities as appropriate. If additional activities are added at the primary award level that are not described in this document, an amended PIEE must be prepared.

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

4. **Environmental Mitigation and Monitoring Plans**: It is expected that subsequent funds will either be core or field support funds awarded at the bi-lateral or the core level. For each major core and country activity under this program, an Environmental Mitigation and Monitoring Plan (EMMP) will be completed by the implementing partner and submitted to the AOR, the Global Health Bureau Environmental Officer (BEO), and the Mission Environmental Officer or the Regional Environmental Officer for their review.
   a. The EMMP must be completed prior to the start of activities during the annual workplanning process,
   b. Implementing partners will provide an Environmental Mitigation and Monitoring Plan (EMMP) that covers core and country specific activities.
   c. This EMMP will be a detailed implementation plan for the conditions prescribed in this document.
   d. The EMMP will be submitted to the GH BEO prior to the commencement of activities that trigger mitigation measures. The GH BEO will have 10 days to provide comments on the EMMP. After 10 days, the EMMP will be considered final and approved. The mitigation measures and monitoring criteria found in the EMMP should be incorporated into pertinent Performance Monitoring Plans and Annual Work plans.
   e. The implementing partners' Project Work Plan will identify those activities outlined in this PIEE that have potential impacts to the environment and discuss plans for environmental management, mitigation approaches, and monitoring measures. Implementing partners will be required to include Environmental Compliance Monitoring in their project work plan and monitoring and evaluation plan
   f. An evaluation of the implementation of the EMMP must be part of the mid, and end of project evaluations, if conducted.
   g. Operating Units will ensure that implementing partners have sufficient capacity to complete to implement mitigation and monitoring measures
   h. The EMMP must be stored in project files

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

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

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

APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED:

Recommended By: _____ 4/16/12
Elizabeth Fox, Office Director,
GH/HIDN Date

Recommended By: _____ 4/13/12
Sonali Korde, AOR, GH/HIDN/ID
Date

Concurrence: _____ 4/17/12
Teresa Bernhard Date
Global Health Bureau Environmental Officer

Approved: X
Disapproved: _____

Filename: **\\Ausnapnaswash01\gh.pub\PMI_II\IMaD\RFA_2012\~Slaria_Diagnosis_Case Management PIEE.doc**

PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)

ACHIEVING UNIVERSAL DIAGNOSIS AND APPROPRIATE CASE MANAGEMENT OF MALARIA PROGRAM

TABLE OF CONTENTS

ACRONYM LIST

AO	Agreement Officer
AOR	Agreement Officer's Representative
BEO	Bureau Environmental Officer
CO	Contracting Officer
EMMR	Environmental Mitigation and Monitoring Report
FAR	Federal Acquisition Regulation
FY	Fiscal Year
GH	Bureau for Global Health
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
IMaD	Improving Malaria Diagnostics
LOE	Level of Effort
M&E	Monitoring and Evaluation
MEO	Mission Environmental Officer
MNCH	Maternal, Newborn, and Child Health
MOH	Ministry of Health
NGO	Non governmental Organization
NTDs	Neglected Tropical Diseases
OP	Operating Plan
OAA	Office of Acquisition and Assistance
PIEE	Programmatic Initial Environmental Examination
PMI	President's Malaria Initiative
PR	Program Results
PRH	Population, Reproductive Health
RDT	Rapid Diagnostic Test
REO	Regional Environmental Officer
RFA	Request for Application
SIEE	Supplemental Initial Environmental Examination
TB	Tuberculosis
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE) ACHIEVING UNIVERSAL DIAGNOSIS AND APPROPRIATE CASE MANAGEMENT OF MALARIA PROGRAM

PROGRAM/ACTIVITY DATA

IEE Number	**GH-12-020**
Program/Project Number:	RFA-OAA-12-000014.
Country:	**Global**
Functional Objective:	**Investing in People**
Program Area:	**Health**
Program Elements:	**Malaria (primary), TB, NTDs, HIV/AIDS**
Funding Period:	**2012-2017**
Life of Activity Funding:	**Five (5) years**

SECTION 1: Background and Activity/Program Description

Purpose and Scope of PIEE

The purpose of this document is to review the overall activities undertaken by the Achieving Universal Diagnosis and Appropriate Case Management for Malaria program and provide threshold determinations of environmental impact and conditions for mitigation.

Section 1 of this document covers the categories of activities undertaken by the program; Section 2 is background information on the geographical coverage; Section 3 provides an evaluation of the potential environmental impacts of the Program activities; Section 4 provides the threshold environmental determination for the Program activities; and Section 5 describes mitigation measures required for implementation.

Overview of the Achieving Universal Diagnosis and Appropriate Case Management for Malaria Project

Background

The purpose of this project is to provide technical and implementation support to the President's Malaria Initiative (PMI) focus and non-focus countries that need assistance scaling up diagnostic testing and case management of malaria and other infectious diseases, such as tuberculosis (TB) and neglected tropical diseases (NTDs). The project will specifically:

1) Strengthen laboratory capacity to diagnose malaria and other priority infectious diseases;
2) Scale-up diagnostic testing for malaria in facilities without laboratories and at the community level; and
3) Strengthen the clinical case management of malaria.

Illustrative project activities include the following:

1) Undertake baseline laboratory assessments in countries to determine malaria diagnostic capacity
2) Train health workers in malaria diagnostic methods and clinical methods for fever diagnosis
3) Support Ministries of Health and local health authorities to conduct on-site training and supervision visits of health workers
4) Develop and streamline national malaria diagnostics guidelines, training curriculum, malaria diagnostic job aids, and standard operating procedures
5) Technical assistance to establish National Archives of Malaria Slides for training, competency assessment, and quality assurance of malaria microscopy
6) Provide integrated laboratory strengthening support for other priority infectious diseases

SECTION 2: Country and Environmental Information

Locations Affected and Local Environmental Regulations

Activities under the Achieving Universal Diagnosis and Appropriate Case Management for Malaria Project may take place in any of the USAID Mission countries or in countries covered by USAID Regional Missions. Environmental procedures are detailed in national policies. Applicable country and environmental information will be detailed for each country activity in the Supplemental Initial Environmental Examination that is required before implementation of activities.

Location conditions

The majority of the activities will be in the form of technical assistance that may take place at both rural, peri urban and urban levels. All activities will take place in existing structures and no structures will be built to accommodate activities under this project.

SECTION 3: Evaluation of Project/Program Issues

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

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

1) Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, rapid diagnostic tests (RDTs), microscopes, laboratory supplies and reagents.

2) Actions that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency obstetric care techniques, administration of injectables, HIV or TB testing, disease diagnosis and treatment, etc).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section Table 3a:
Activities Potential Negative Environmental Impacts

Investing in People: Health Program Areas	**Procurement, Storage, Management and Disposal of Public Health Commodities**	**Direct or Indirect generation, and need for disposal of hazardous and highly hazardous medical waste (as defined in Section 3 of this IEE)**
Program Name and activity	Such as: Laboratory reagents and supplies Antibiotics Vaccines Other pharmaceuticals RDTs HIV test kits ARVs TB drugs NTD drugs Antimalarial drugs Packing materials for products	Generation of sharps Generation of hazardous and highly hazardous medical waste, including blood. Generation of sputum and other waste

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

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

	See EGSSAA Chapter 8, "Healthcare Waste: Generation, Handling, Treatment and Disposal" (http://www.encapafrica.org/EGSSAA/Word_English/medwaste.doc) for additional condtitions on proper handling and disposal of medical waste. Other important references to consult are "WHO's Safe Management of Wastes from Healthcare Activities" http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/

SECTION 4: Recommended Determinations and Conditions for Implementation

4a. Determination

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

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

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

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

1. Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies and reagents.
2. Training professional and paraprofessional health care workers in methods that result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency obstetric care techniques, administration of injectables, HIV or TB testing, malaria diagnosis, etc)

Table 4a: Determinations for Activities Executed Under This Program

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

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

Monitoring Conditions

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

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

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

4. **Environmental Mitigation and Monitoring Plans**: It is expected that subsequent funds will either be core or field support funds awarded at the bi-lateral or the core level. For each major core and country activity under this program, an Environmental Mitigation and Monitoring Plan (EMMP) will be completed by the implementing partner and submitted to the AOR, the Global Health Bureau Environmental Officer (BEO), and the Mission Environmental Officer or the Regional Environmental Officer for their review.
    a. The EMMP must be completed prior to the start of activities during the annual workplanning process,
    b. Implementing partners will provide an Environmental Mitigation and Monitoring Plan (EMMP) that covers core and country specific activities.
    c. This EMMP will be a detailed implementation plan for the conditions prescribed in this document.
    d. The EMMP will be submitted to the GH BEO prior to the commencement of activities that trigger mitigation measures. The GH BEO will have 10 days to provide comments on the EMMP. After 10 days, the EMMP will be considered final and approved. The mitigation measures and monitoring criteria found in the EMMP should be incorporated into pertinent Performance Monitoring Plans and Annual Work plans.
    e. The implementing partners' Project Work Plan will identify those activities outlined in this PIEE that have potential impacts to the environment and discuss plans for environmental management, mitigation approaches, and monitoring measures. Implementing partners will be required to include Environmental Compliance Monitoring in their project work plan and monitoring and evaluation plan
    f. An evaluation of the implementation of the EMMP must be part of the mid, and end of project evaluations, if conducted.
    g. Operating Units will ensure that implementing partners have sufficient capacity to complete to implement mitigation and monitoring measures
    h. The EMMP must be stored in project files

5. **Environmental Mitigation And Monitoring Report**: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.
    a. The environmental mitigation and monitoring report will be submitted to the AOR each year with the annual report.
    b. The EMMR will record the environmental mitigation and monitoring measures outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.

c. Based on the process outlined in the Project Work Plan, the implementing partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.
d. The EMMR must be stored in project files

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

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

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

The EMMP must be completed by each organization carrying out activities under the Program/Project prior to the implementation of activities. At the end of the year (November 1) the partner will create a report called an Environmental Mitigation and Monitoring Report. It will include the organization's EMMP and any resulting activities taken as a result of the mitigation and monitoring measures. An Environmental Verification Form (EVF) should have been used for sub projects/awards and will be submitted to the local MEO and GH BEO for review and approval. The EMMR, and the EMMP reporting form are quite similar in that the EMMR includes all aspects of the EMMP plus the annual reporting requirements. The prime Achieving Universal Diagnosis and Appropriate Case Management of Malaria Project implementing partners are responsible for ensuring that the EMMPs are reviewed and approved by the C/AORs and the Mission Environmental Officer (MEO) and submitted to the GH BEO.

1. The Environmental Mitigation and Monitoring Plan,
2. The Environmental Mitigation and Monitoring Report

The Environmental Mitigation and Monitoring Plan (EMMP)
Implementing partners will use the EMMP to describe the specific actions they will undertake under each category of activity when the IEE conditions reveal potential environmental threats as outlined in Section 3 of this PIEE. In these cases, mitigation will be

undertaken as described in the conditions described in the PIEE. The Mitigation Plan also identifies the person responsible for monitoring compliance with mitigation and the indicator, method and frequency of monitoring.

The Environmental Mitigation and Monitoring Report (EMMR)
This form reports on the results of applying the mitigation measures described in the Mitigation Plan and identifies outstanding issues with respect to required conditions. In some cases, digital photos will be the best way to document mitigation and should be included in the report.

The Achieving Universal Diagnosis and Appropriate Case Management of Malaria Project
Environmental Mitigation and Monitoring Plan Template

Category of Activity from Section 4 of PIEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 3 of the P IEE)	Description of Mitigation Measures for these activities as required in Section 5 of PIEE	Who is responsible for monitoring	Monitoring Indicator	Frequency of Monitoring	Budget
Describe activity	Describe impacts	Describe specific mitigation and monitoring measures to be implemented to avoid, offset or mitigate the potential impacts	Describe the person (by title) who is responsible for ensuring the implementation of the mitigation measure	Determine how the success or failure of the mitigation measure will be monitored.	Document how often the measure will be monitored	Indicate the amount of funding to be used for this mitigation measure.
EXAMPLE: Education, technical assistance, training for those activities that do not directly or indirectly generate hazardous medical waste, etc.	No environmental impacts anticipated as a result of these activities.	Education, technical assistance and training activities that inherently affect the environment include discussion of prevention and mitigation of potential negative environmental effects.	A/COR	Discussion of environmental impact included in education, technical assistance, training and other materials	Annual	

Environmental Mitigation and Monitoring Report (EMMR)

List each Mitigation Measure from column 3 in the EMMP Mitigation Plan	Status of Mitigation Measures	List any outstanding issues relating to required conditions	Remarks

Certification for EMMP

I certify the completeness and the accuracy of the mitigation and monitoring plan described above for which I am responsible and its compliance with the PIEE:

_____ _____

Signature Date

_____

Print Name

_____

Organization

_____

BELOW THIS LINE FOR USAID USE ONLY

Agreement / Contracting Officer's Representative: _____ Date: _____

Mission Environmental Officer: _____ Date: _____

Bureau Environmental Officer: _____ Date: _____

Regional Environmental Advisor: (if appropriate) _____ Date: _____

Note: if clearance is denied, comments must be provided to applicant

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.: o use the oldest batch first; o 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? o Warm season in warm climates within **24 hrs** o In the cool season in warm climates within **48 hrs** o In the warm season in temperate climates within **48 hrs**				

16. *Treatment mechanisms for hazardous and highly hazardous waste.* (The most important function of treatment is disinfection). • Are wastes being burned in the open air, in a drum or brick incinerator, or a single-chamber incinerator? • If not are they being buried safely (in a pit with an impermeable plastic or clay lining)? • Is the final disposal site (usually a pit) surrounded by fencing or other materials and in view of the facility to prevent accidental injury or scavenging of syringes and other medical supplies?				
17. If the waste is transported off-site, are precautions taken to ensure that it is transported and disposed of safely?				

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

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

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

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

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