Issue Date: **October 26, 2023**
Deadline for Question/Clarifications: November 6, 2023; 1:00PM, Washington, DC Time
Closing Date: **December 8, 2023**
Closing Time: **1:00PM, Washington, DC Time**

Subject: Notice of Funding Opportunity (NOFO) Number: **7200AA24RFA00001**

Project Title: **Ending Neglected Diseases through Operational Research (ENDOR)**

Catalog of Federal Domestic Assistance (CFDA) Number: 98.001

Ladies/Gentlemen:

The United States Agency for International Development (USAID) is seeking applications for a Cooperative Agreement from qualified entities to implement the Ending Neglected Diseases through Operational Research (ENDOR) project. Eligibility for this award is not restricted. USAID welcomes applications from both US and non-US organizations.

USAID intends to make an award to the applicant(s) who best meet the objectives of this funding opportunity based on the merit review criteria described in this notice of funding opportunity (NOFO) subject to a risk assessment. Eligible parties interested in submitting an application are encouraged to read this NOFO thoroughly to understand the type of project sought, application submission requirements, and selection process.

To be eligible for award, the applicant must provide all information as required in this NOFO and meet eligibility standards in Section C of this NOFO. This funding opportunity is posted on www.grants.gov and may be amended. It is the responsibility of the applicant to regularly check the website to ensure they have the latest information pertaining to this notice of funding opportunity and to ensure that the NOFO has been received from the internet in its entirety. USAID bears no responsibility for data errors resulting from transmission or conversion process. If you have difficulty registering on www.grants.gov or accessing the NOFO, please contact the Grants.gov Helpdesk at 1-800-518-4726 or via email at support@grants.gov for technical assistance.

USAID may not award to an applicant unless the applicant has complied with all applicable unique entity identifier and System for Award Management (SAM) requirements detailed in Section D.6.g. The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin registration early in the process.

Please send any questions to the point(s) of contact identified in Section G. The deadline for questions is shown above. Responses to questions received prior to the deadline will be furnished to all potential applicants through an amendment to this notice posted to www.grants.gov.

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

Thank you for your interest in USAID projects.

Sincerely,

Anna Nelson

Anna Nelson
Agreement Officer

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SECTION A: PROJECT DESCRIPTION

This funding opportunity is authorized under the Foreign Assistance Act (FAA) of 1961, as amended. The resulting award will be subject to 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and USAID's supplement, 2 CFR 700, as well as the additional requirements found in Section F.

1. Overall USAID NTD Program Summary:

USAID supports disease-endemic countries to control and/or eliminate Neglected Tropical Diseases (NTDs) with proven, cost-effective public health interventions to treat and measure treatment impact against 7 NTDs: lymphatic filariasis (LF), blinding trachoma (TRA), onchocerciasis (OV), schistosomiasis (SCH), plus three intestinal worms, collectively known as soil-transmitted helminths (STH).

USAID's current flagship implementation projects include Act to End NTDs | West (Act | West) and Act to End NTDs | East (Act | East). These consortia of partners implement the objectives of USAID's NTD Program and include the following: the Act | West Project led by FHI 360, with Helen Keller International, Health Development International, Deloitte, World Vision, and American Leprosy Mission; and the Act | East Project led by RTI International, with The Carter Center, Light for the World, Save the Children, and WI-HER. These two flagship consortia are centrally funded and managed, and support national NTD programs in Benin, Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Ghana, Guinea, Haiti, Indonesia, Laos, Mali, Niger, The Philippines, Senegal, Sierra Leone, Tanzania, Togo, Uganda, and Vietnam. USAID also has been supporting the implementation of OV elimination in the Americas for many years. The current award, "Achieve Onchocerciasis Elimination in the Americas (Achieve OEA)" is run by The Carter Center. Additionally, USAID funds the World Health Organization's (WHO) HQ staff and WHO Global NTD Programme initiatives, as well as Regional WHO Offices and Special Programs in AFRO, SEARO, WPRO, and PAHO regions. USAID's NTD Program also has a key, strategic investment in the Promoting the Quality of Medicines Plus (PQM+) project led by the U.S. Pharmacopeia. USAID also maintains a strong relationship with, and provides interagency funding to, the U.S. Centers for Disease Control and Prevention's Division of Parasitic Diseases and Malaria to expand the breadth and reach of global subject matter expertise, diagnostic development and evaluation, surveillance platform evaluation, and other areas mentioned later in this project description.

NTDs cause significant morbidity and mortality worldwide. More than 1.7 billion people, one-seventh of the world's population, suffer from one or more NTDs. Often the source of deep stigma, NTDs cause disability, severe disfigurement, and blindness. These diseases affect the world's most vulnerable populations with devastating, often lifelong disabilities that contribute to

ensnaring individuals, families, and even entire communities in poverty. The USAID NTD Program continues to build on the successes that have been achieved through previous USAID investments to expand national, integrated NTD programs, and will continue to support countries. In doing so, USAID supports countries to effectively access and leverage the drug donations needed to eliminate NTDs, or control those that cannot be eliminated, with current implementation and surveillance strategies. Further, USAID aims to strengthen health systems for longer term integration and provision of NTD services after elimination/control targets have been achieved. Much success in reaching WHO validation, or verification of elimination, has been achieved for multiple NTDs through all of these investments. A critical component, however, that underpins the success of multi-disease elimination/control projects as they encounter barriers to these goals, is the implementation of operational research (OR) to advance novel intervention strategies to accelerate progress, remove barriers to implementing existing strategies, and fine-tune monitoring and evaluation to ensure the public health impact of overwhelmingly successful mass drug administration (MDA).

Since the 2012 London Declaration on NTDs, the Bill & Melinda Gates Foundation (BMGF) has been a key partner in the global OR agenda for NTDs. Since 2014, USAID and BMGF have co-sponsored the Coalition for Operational Research on NTDs (COR-NTD) through a Global Development Alliance agreement, leveraging donor resources and increasing the impact of the research. Under ENDOR, USAID envisions an informal consultative stakeholders group (CSG), organized and led by the ENDOR recipient organization(s), comprised of USAID, the U.S. interagency, contributing donors such as BMGF, country-led researchers, national NTD programs, WHO, and others. The CSG will monitor the evolving OR needs of national NTD programs and the gaps in the WHO 2030 NTD Roadmap, to identify ways in which available support is non-duplicative, complimentary, and most effectively channeled to inform OR research projects under ENDOR. BMGF anticipates supporting the coalition organizations awarded under ENDOR as a principal co-investor.

A previous USAID investment with the Drugs for Neglected Diseases initiative (DNDi), to develop and evaluate macrofilaricide drugs against the adult worms of LF and OV, concluded in 2019. The goal of this investment was to position two to four macrofilaricide drug candidates in field clinical trials (Phase 2 and/or 3), prioritizing areas that are co-endemic for loiasis, to accelerate elimination by providing alternative drug regimens safe to administer in loa co-endemic areas, and/or to reduce the number of MDA rounds required to reach elimination for LF and OV. Two such drug candidates were identified and trial evidence supported their advancement through the clinical development pipeline. Phase 3 studies are ongoing in endemic areas of central and western Africa. Further to this investment with DNDi, a Filarial Clinical Research Platform was established to ensure necessary linkages between national NTD programs, clinical trialists, epidemiological modelers, quality infrastructure, and regulatory needs to support ongoing clinical trial capacity for any candidates - which would allow for interventions to be

more rapidly and effectively evaluated in endemic settings and eventually registered for use. Further macrofilaricide development and clinical trial evaluation will NOT be part of the ENDOR program.

Activities supported under ENDOR may be worldwide, though the current USAID implementation country program focus referenced above will serve as key countries where ENDOR should collaborate to remove barriers to elimination/control goals. At the same time, providing research findings to the global evidence base for wider meta-analyses, and translation for global project impact, will be central to the project goals of ENDOR and are further elaborated in the Monitoring, Evaluation, and Learning (MEL) Plan.

2. Problem Statement:

National NTD programs, and the NGOs that support them, frequently encounter challenges and barriers in program implementation, monitoring and evaluation, and management of morbidity due to NTDs; and these problems prevent them from achieving their control and elimination goals. With 2030 elimination/control deadlines nearing, it is clear that a "business as usual" approach is not adequate to meet USAID's program objectives. With expanding resources to support program implementation, there is a greater need to draw on the research community to ensure that these resources are focused appropriately to meet program challenges. A global OR portfolio is needed to improve existing disease mapping, develop monitoring and evaluation strategies, evaluate and introduce improved diagnostics, inform best practices and policy change through OR studies, provide capacity building initiatives for local scientists and program staff, and employ innovative solutions to improve and sustain NTD health services for affected populations.

3. ENDOR Goals and Objectives:

Under this five-year cooperative agreement, USAID intends to transfer federal Global Health (GH) assistance funds by awarding one cooperative agreement to an organization or to a consortium of organizations. WHO's 2030 NTD Roadmap Gap Assessment, and recent WHO NTD Global Partners Meeting, highlight several gaps in disease-specific strategies for mapping, monitoring and evaluation, availability of accurate and field-friendly diagnostics, and sustainable public health and surveillance systems, to name some. Within USAID's existing flagship implementation projects, Act | East led by RTI and Act | West led by FHI360, endemic countries and implementing partners frequently encounter these highlighted challenges in implementation. Increasingly, there are challenges in approaching post-elimination strategies, such as country-specific periodic surveillance and provision of NTD services after elimination/control has been reached (thereafter community-wide drug treatments have ended).

Given the breadth of the gaps and barriers, the rapid progress of endemic countries in implementing and achieving their programmatic objectives, as well as continually evolving WHO policy and guidance, the recipient(s) is expected to research activities that will need to be designed and implemented and with a high degree of flexibility that results in a near real-time ability to centralize, analyze, and disseminate research findings and lessons learned across the USAID research portfolio. Where needed, ENDOR may be leading the synthesis and dissemination of OR findings to relevant WHO technical working groups or advisory groups, such as the WHO Diagnostic Technical Advisory Group for NTDs and NTD diseases-specific working groups.

By focusing on efficiency and effectiveness, ENDOR will support national governments, local research institutions, and local NGOs by addressing the following high level Focus Areas:

1. Fostering and convening a network of local and international research investigators, including young and mid-career researchers, and identifying and prioritizing NTD OR needs in a more diverse and equitable manner;

2. Defining and undertaking relevant coordinated research initiatives as prioritized by USAID and USAID NTD Program implementing partners to target the gaps and barriers highlighted by the WHO 2030 NTD Roadmap and the NTD community;

3. Improving the timeliness and quality of OR initiatives through issuance of subaward agreements under ENDOR directly to local and endemic country institutions in response to persistent and new challenges, and translating these into programmatic solutions to solve endemic country issues; and

4. Working collaboratively with the NTD donor community to ensure that support for research is equitable and appropriate to meet project needs.

More specifically, the project will provide technical assistance and OR subject matter expertise that may include, but not be limited to, the following key Program Areas of USAID's NTD program:

1. Convening-power and global technical leadership on a wide array of NTD elimination and control implementation and end-game challenges;
2. Informing the evidence-base for improving global disease-specific monitoring and evaluation strategies and sustainable surveillance approaches;
3. Advancing improvements for diagnostics through consensus-based prioritization, performance evaluation, and accelerated regulatory processes with a wide array of multilateral, institutional, donor, and research partners;

4. Strengthening the capacity of early and mid-career NTD researchers to conceive, design, implement, and manage OR projects in their home countries, leveraging the expertise of local research institutions, NGOs, and national NTD programs;
5. Evaluating and proposing strategies to mitigate operational and social barriers to NTD service provision; and
6. Evaluating and technical assistance provision for evidence-based clinical competencies for NTD services of affected populations and pursuing linkages to strategic integration within the national health system.

To prioritize and operationalize an OR agenda for USAID's funding, ENDOR will issue subawards, primarily through fixed amount awards (FAAs), to local NGOs, research institutions, government entities and parastatals. Through COR-NTD, This operational model has proven to encourage local ownership and increase capacity building as organizations and government entities are directly involved in the management and design of FAAs to ensure that research provides locally-driven solutions. A key objective of the project will be to strengthen host country programs' technical and operational capacities to conceive, design, implement, and report on OR findings that address challenges in their endemic communities, and inform the global evidence base and best practices.

Part of the rationale for the OR network is to increase the likelihood that such research translations will occur through improved communication linkages among researchers, policy makers, program implementers, donors, and endemic communities. A key aspect of this should reflect an understanding of the opportunities for regionally based technical and strategic convenings for such opportunities and models or strategies for decentralization of reporting research findings in a more equitable and inclusive manner to promote capacity building.

Engagement of endemic-country programs, NGOs, key donors, and WHO from the beginning stages of developing the OR agenda is also critical to the eventual success and sustainability of the work supported by ENDOR. Continuing to strengthen such contributions and linkages that exist in the NTD community will be a key aspect under ENDOR. An informal CSG (organized and led by the ENDOR recipient organization(s)—with representatives from USAID, the U.S. interagency, other donors such as BMGF, country-led researchers, national NTD programs, WHO, and others)—will monitor the evolving OR needs of national NTD programs and the gaps in the WHO 2030 NTD Roadmap, to identify ways in which available support is non-duplicative, complimentary, and most effectively channeled to inform OR research projects under ENDOR.

ENDOR will leverage the recipient's deep technical, programmatic experience and institutional capacity to carry out the Goals and Objectives of ENDOR such as research oversight, technical assistance, and coordination with OR expertise on NTDs and with extensive experience working with multi-country teams to develop and operationalize complex research projects to translate

research findings into practice. USAID anticipates that ENDOR will issue a significant amount of subawards in order to implement and achieve the Goals and Objectives. Much of this work shall focus on sub-Saharan Africa, but ENDOR will be global in scope and shall provide both research opportunities and benefits for all national programs currently targeting preventive chemotherapy NTDs (PC-NTDs); however, possible expansion into other diseases may be at the discretion and future guidance of USAID.

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SECTION B: FEDERAL AWARD INFORMATION

1. Estimate of Funds Available and Number of Awards Contemplated

USAID intends to award one (1) Cooperative Agreement pursuant to this notice of funding opportunity. Subject to funding availability and at the discretion of the Agency, USAID intends to provide up to $45M in total USAID funding over a five (5) year period. This Activity will be incrementally funded over the life of the Activity. Actual funding amounts are subject to availability of appropriated funds.

2. Start Date and Period of Performance for Federal Awards

The anticipated period of performance is five (5) years. The estimated start date will be March 1, 2024.

3. Substantial Involvement

USAID's substantial involvement during the implementation of this Agreement will be limited to the elements listed below:

a. Approval of the Recipient(s)'s Implementation Plans:

Implementation plans include, but are not limited to: annual workplans, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, knowledge management plans, event planning/management, international meeting preparation, and research studies/protocols.

USAID requires the approval of implementation plans annually to ensure alignment with stated goals, milestones, and outputs. The implementation plan communicates how and when the Recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the Recipient(s) and the AOR team. The AOR will ensure that the implementation plan fits within the scope, terms, and conditions of the agreement.

b. Collaborative Involvement in the Selection of Partners under ENDOR and Country Selection:

USAID requires the approval of selection of partners and sub-recipients under ENDOR to ensure alignment with the stated objectives of a given research project or initiative. This

may involve site visits by USAID to assess the organizational competencies or risks under the agreement.

c. Collaborative Involvement in the Substantive Direction/Re-direction of Interrelationships with Other Projects or Initiatives:

USAID requires the involvement in any substantive direction/re-direction of projects, in whole or in part, to complement or supplement that of other activities in the global OR community to ensure proper donor alignment of investments, custodianship of financial resources, and to ensure maximal impact of data for translation into program practices under ENDOR's goals and objectives.

d. Collaborative Involvement in Monitoring Progress Toward Achievement of the Objectives and Expected Achievements during the Course of the Agreement:

USAID requires the involvement of joint monitoring visits to research institutions or country sites, as well as quarterly (at minimum) progress meetings with the prime partner of ENDOR, as well as other sub-recipients as needed.

e. Approval of Specified Key Personnel:

Designation of Key Personnel positions, approval of Key Personnel, and any changes for the positions listed below:

- Project Director
- Deputy Project Director for Research Operations

All individuals proposed as Key Personnel must meet the criteria described below. The Recipient must submit, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the project. No replacement shall be made by the Recipient without concurrence of the AOR and the written consent of the AO.

f. Concurrence on the Substantive Provisions of Subawards:

AO prior approval is required for the subaward, transfer, or contracting out of any work under an award, except those approved in the award. The term 'subawards' includes sub-agreements, FAAs, and contracts under assistance. Some of the subaward approval responsibilities may be delegated to the AOR as specified in the Agreement Officer's Representative's (AOR) Designation Letter.

4. Authorized Geographic Code

The geographic code for the procurement of commodities and services under this project is 935 (any area or country, except for "prohibited sources").

5. Nature of the Relationship between USAID and the Recipient

The principal purpose of the relationship with the Recipient(s) and under the subject project is to transfer funds to accomplish a public purpose of support or stimulation of the ENDOR activity, which is authorized by Federal statute. The successful Recipient(s) will be responsible for ensuring the achievement of project objectives and the efficient and effective administration of the award through the application of sound management practices. The Recipient(s) will assume responsibility for administering Federal funds in a manner consistent with underlying agreements, project objectives, and the terms and conditions of the Federal award.

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SECTION C: ELIGIBILITY INFORMATION

1. Eligible Applicants

Eligibility for this NOFO is not restricted. U.S. and non-US organizations may participate under this NOFO. USAID welcomes applications from organizations which have not previously received financial assistance from USAID.

Faith-based organizations are eligible to apply for federal financial assistance on the same basis as any other organization and are subject to the protections and requirements of Federal law.

U.S. federal government agencies and entities are not eligible for this award.

2. Cost Sharing or Matching

USAID has determined that no cost share or matching will be required under this award.

3. Other

An applicant may submit only one (1) application per organization; no individual investigator/ project director applications will be accepted.

RISK ASSESSMENT

In order for an award to be made, the USAID Agreement Officer must evaluate the risks posed by applicants as outlined in 2 CFR 200.205 and ADS 303.3.9. This means that the applicant must possess, or must have the ability to obtain, the necessary management and technical competence to conduct the proposed project, and must agree to practice mutually agreed-upon methods of accountability for funds and other assets provided or funded by USAID.

In evaluating the risks posed by applicants, the Federal Awarding Agency uses a risk-based approach and may consider:

1. Financial stability;
2. Quality of management systems and ability to meet the management standards prescribed in this part;
3. History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

4. Reports and findings from audits performed under Subpart F—Audit Requirements of this part or the reports and findings of any other available audits;
5. The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities; and
6. That applicant is otherwise qualified to receive an award under applicable laws and regulations (e.g., Nondiscrimination, Lobbying, Debarment/Suspension, Terrorist Financing, etc.).

In the absence of a positive risk assessment, an award can ordinarily not be made. Awards to potential new partners may be significantly delayed if USAID must undertake necessary preaward reviews of these organizations to make an adequate risk assessment. These organizations should take this into account and plan their implementation dates and activities accordingly.

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SECTION D: APPLICATION AND SUBMISSION INFORMATION

1. Agency Point of Contact

For submission of Question and Applications: endor@usaid.gov

2. Questions and Answers

Questions regarding this NOFO should be submitted to endor@usaid.gov no later than the date and time indicated on the cover letter, as amended. Any information given to a prospective applicant concerning this NOFO will be furnished promptly to all other prospective applicants as an amendment to this NOFO, if that information is necessary in submitting applications or if the lack of it would be prejudicial to any other prospective applicant.

3. General Content and Form of Application

Preparation of Applications:
USAID is interested in receiving applications with models and partnerships that would result in optimal flexibility and country-centered approaches. Each applicant must furnish the information required by this NOFO. Applications must be submitted in two separate parts: the Technical Application and the Business (Cost) Application. This subsection addresses general content requirements applying to the full application. Please see subsections 5 and 6, below, for information on the content specific to the Technical and Business (Cost) applications. The Technical application must address technical aspects only, while the Business (Cost) Application must present the costs and address risk and other related issues.

Both the Technical and Business (Cost) Applications must include a cover page containing the following information:

- Name of the organization(s) submitting the application;
- Identification and signature of the primary contact person (by name, title, organization, mailing address, telephone number and email address) and the identification of the alternate contact person (by name, title, organization, mailing address, telephone number and email address);
- Project name;
- Notice of Funding Opportunity number;
- Name of any proposed sub-recipients or partnerships (identify if any of the organizations are local organizations, per USAID's definition of 'local entity' under ADS 303; and

- A Unique Entity Identifier (UEI) number shall be included for each organization listed on the cover page.

Any erasures or other changes to the application must be initialed by the person signing the application. Applications signed by an agent on behalf of the applicant must be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

Applicants may choose to submit a cover letter in addition to the cover pages, but it will serve only as a transmittal letter to the AO. The cover letter will not be reviewed as part of the merit review criteria.

Applications must comply with the following:

- USAID will not review any pages in excess of the page limits noted in the subsequent sections. Please ensure that applications comply with the page limitations.
- Written in English.
- Use standard 8 ½" x 11", single sided, single-spaced, 12 point Times New Roman font, 1" margins, left justification and headers and/or footers on each page including consecutive page numbers, date of submission, and applicant's name.
- 10 point font can be used for graphs and charts.
- Applications must be submitted via Microsoft Word or PDF formats with budget submitted in Microsoft Excel.
- The estimated start date identified in Section B of this NOFO must be used in the cost application.
- The technical application must be a searchable and editable Word or PDF format as appropriate.
- The Cost Application must include an Excel spreadsheet with all cells unlocked and no hidden formulas or sheets. A PDF version of the Excel spreadsheet may be submitted in addition to the Excel version at the applicant's discretion, however, the official cost application submission is the unlocked Excel version.

Applicants must review, understand, and comply with all aspects of this NOFO. Failure to do so may be considered as being non-responsive and may be evaluated accordingly. Applicants should retain a copy of the application and all enclosures for their records.

4. Application Submission Procedures

Applications must be submitted by email to endor@usaid.gov. Applications in response to this NOFO must be submitted no later than the closing date and time indicated on this notice, or as

amended. Late applications may not be considered. Applicants must retain proof of timely delivery in the form of a system generated document (i.e. delivery receipt).

Submissions must include the NOFO number and applicant's name in the subject line heading. Technical and cost applications must be kept separate. In addition, for an application sent by multiple emails, the subject line must also indicate whether the email relates to the Technical or Cost application, and the desired sequence of the emails and their attachments if files are large (e.g. "No. 1 of 4", etc.). For example, if your cost application is being sent in two emails, the first email should have a subject line that states: "[NOFO number], [organization name], Cost Application, Part 1 of 2".

USAID's preference is that the Technical Application and the Cost Application each be submitted as consolidated email attachments, e.g. that you consolidate the various parts of a Technical Application into a single document before sending it. If this is not possible, please provide instructions on how to collate the attachments. USAID will not be responsible for errors in compiling electronic applications if no instructions are provided or are unclear.

After submitting an application by email, applicants should immediately check their own email system to confirm that the attachments were indeed 'sent'. If an applicant discovers an error in transmission, please send the material again and note in the subject line of the email that it is a "corrected" submission. Do not send the same email more than once unless there has been a change, and if so, please note that it is a "corrected" email. Applicants should additionally check their spam and other such folders in the event responses may have been received/archived therein.

Applicants are reminded that email is NOT instantaneous, and in some cases delays of several hours occur from transmission to receipt. Therefore, applicants are requested to send the application in sufficient time ahead of the deadline. For this NOFO, the initial point of entry to the government infrastructure is the USAID mail server.

There may be a problem with the receipt of *.zip files due to anti-virus software. Therefore, applicants are discouraged from sending files in *.zip format as USAID cannot guarantee their acceptance by the internet server. File size must not exceed the 25 MB limit per e-mail. Please contact the agreement specialist through endor@usaid.gov for any guidance.

5. Technical Application Format

The technical application should be specific, complete, results-oriented, and presented concisely. The application must demonstrate the applicant's capabilities and expertise with respect to achieving the goals of this project as outlined in the Project Description for ENDOR. The

application should take into account the focus areas of the project and merit review criteria found in this NOFO.

The Technical Application must not exceed 35 pages, excluding the cover page, table of contents, executive summary page and annexes. Only information specifically requested to be included as an annex will be considered during review for technical merit. Unless otherwise indicated, a page in the Technical Application that contains a table, chart, graph, etc. will be counted as a page within the page limitation. Information that exceeds page limitations will not be furnished to the Selection Committee.

a) **Cover Page** (See Section D.3 above for requirements)

b) **Table of Contents**
Include major sections and page numbering to easily cross-reference and identify merit review criteria.

c) **Executive Summary (One page)**
The Executive Summary must provide a high-level overview of key elements of the Technical Application in line with the Project Description.

d) **Technical and Programmatic Approach (no more than 30 pages).**
Any references cited shall be included in the technical application, as Annex 1.

1) **Project Background and Context**
   a) Describe the current state of NTD OR, including knowledge gaps and opportunities that are related to ENDOR, including an overview of OR needs and priorities for accelerating the elimination of LF, TRA, OV; and the extent to which they demonstrate much the same for sustainable control strategies for SCH and STH.

   b) Describe the global NTD OR landscape and its link to achieving USAID's goals for elimination/control under the flagship Act | East and Act | West projects, as well as the WHO 2030 NTD Roadmap priorities.

   c) Describe institutional capabilities for applying technical skills, experience, and knowledge to collaboratively guide the expansion of a research evidence base and translate that into NTD program improvements and policy change, in partnership and with guidance from, USAID, WHO, and other relevant partners.

2) **Technical and Project Strategy and Methodology**
    a) Provide strategies for evidence-based, feasible, and effective approaches to OR that address the Focus Areas through a research translation and sustainability lens.

    b) Provide evidence of capabilities of the prime partner and any relevant subpartners in utilizing partnerships, complimentary investments, and strategies to engage other OR stakeholders, including endemic-country national programs, local research institutions, NGOs, the U.S. interagency, BMGF, and other key stakeholders.

3) **Project Outputs, Monitoring, Evaluation and Learning**
    a) Propose a brief, illustrative MEL Plan with demonstrated ability for yielding outputs and outcomes, and explain how those translate to impact which can be monitored and reported. Please submit up to ten (10) pages under Annex 2 (this is not included in the 30-page limit referenced above).

    b) Propose a "collaboration, learning, and adaptation" feedback loop to translate research findings into improved public health practice.

4) **Approach to Localization Aspects**
    a) Propose a model for mentorship, capacity building, a decentralized research award structure, an implementation and management structure with local organizations; as well as means to disseminate findings through more regional opportunities.

5) **Understanding of Gender, Diversity, Equity & Inclusion (GDEI)**
    a) Demonstrate a fundamental understanding of GDEI concepts, as they pertain to the expansion of local and regional award opportunities for underrepresented groups and countries, to achieve USAID's goals.

    b) Describe how GDEI will be thoughtfully incorporated into the technical approaches, methodologies, data analyses, and access to populations that could benefit from OR translation.

e) Management Structure (not including the organizational chart, no more than 2 pages)

Applications should describe a functional management plan for the proposed project, including:

a) A concise description of the roles for each consortium partner or sub-recipient and their associated technical capacities and how these capacities can be used under ENDOR.

b) An illustrative subaward management structure with proposed lines of authority among the prime, other consortium partners, and sub-recipients; as well as the division of roles/responsibilities between these partners and other technical or resource organizations. (Provided as Annex 6, below).

c) A management approach for convening, prioritizing, renewing processes, and award management systems to address urgent and emerging OR needs for accelerating progress.

d) A clear approach to partnership coordination; technical, financial, and administrative management and oversight; and design, development, and implementation of OR activities mentioned in the Technical Approach.

e) Applicants must include an organizational chart to illustrate the proposed management structure (please see Annex 5 for more information).

f) Staffing Plan (not including the staffing matrix and CVs; no more than 3 pages)

Applicants should provide a staffing matrix that identifies Key Personnel (see below) and non-Key Personnel, including the level of effort (LOE), area of expertise, organizational/institutional affiliation, and geographic region(s) of focus for each position (please see Annex 5 for more information). Applicants should also provide a narrative describing how the proposed combination of Key Personnel and other long- and short-term staff will demonstrate efficient use of resources, and collectively possess the technical and management expertise required to achieve the goals in the Technical Approach.

Key Personnel:

Key Personnel are those individuals whose performance is critical to the success of ENDOR. The applicant must designate two (2) Key Personnel, one for each of the positions listed below:

- Project Director
- Deputy Project Director for Research Operations

Applicants may propose additional Key Personnel by stating the proposed positions, the roles and responsibilities, and the minimum required qualifications. Applicants must also provide a CV and letter of commitment, as required for all Key Personnel. For each of the proposed Key Personnel positions, applicants must describe, at a minimum, the rationale for proposing the individual and explain how the Key Personnel complement each other's

skills and qualifications in a manner that will result in a strong, balanced, and high-quality team.

The applicant must submit the following documents for each Key Personnel candidate:

- Current CV (please see Annex 3 for more information, maximum three pages for each individual) including:
    - all professional work experience with start and end dates (month and year); and
    - the names of three (3) professional references, who are not employed by the prime applicant or any of the proposed consortium partners, with contact information (email and phone number).

- Signed statement of commitment (please see Annex 3 for more information), confirming immediate availability, from each Key Personnel candidate (maximum 1 page for each individual).

Key Personnel Qualifications:

Project Director: the applicant must designate a Project Director who will serve as the main point of contact for ENDOR, provide overall technical strategy and direction for all project activities and staff, be responsible for global and institutional technical leadership, and ensure administrative, fiscal, and regulatory oversight of the project. The role will serve as the principal institutional liaison to USAID, and as needed, with USAID's implementing partners, other donors, and WHO. At least 50% LOE is required for the Project Director position.

The proposed Project Director must have:

- Master's degree or higher in a relevant field;
- At least ten (10) years of demonstrated leadership in research and development (R&D), technical expertise in infectious diseases and global health, and management of the overall alignment, strategy, and execution across all partners and sub-partners to ensure the satisfaction of programmatic objectives;
- Minimum of five (5) years of demonstrated leadership and senior managerial experience overseeing a team (or teams) of cross-cutting expertise in support staff and/or consultants; and
- Fluency in English oral and written communication.

Deputy Project Director for Research Operations: the applicant must designate a Deputy Project Director for Research Operations who will serve as the secondary point of contact for ENDOR, providing back-up support to the Project Director as well as project-wide

technical, operational, and administrative oversight. At least 50% LOE is recommended for the Deputy Project Director for Research Operations.

The proposed Deputy Project Director for Research Operations must have:

- Master's degree or higher in a relevant field;
- At least seven (7) years of demonstrated technical experience in multiple cross-cutting areas, such as NTD elimination/control strategies and implementation, research project management, randomized controlled trials and epidemiological studies, regulatory compliance, performance evaluation of diagnostics and surveillance approaches, social science, and data analytics;
- Minimum of three (3) years of demonstrated leadership and managerial experience overseeing a team (or teams) of support staff and/or consultants;
- Minimum of three (3) years of providing technical and programmatic expertise on NTD OR needs and endemic country operations and challenges to key stakeholders; and
- Fluency in English oral and written communication.

g) Annexes

The annexes **do <u>not</u> count as part of the Technical Application page limit.** The following annexes are required:

a) Annex 1 - *References* for relevant work cited.

b) Annex 2 - *Illustrative MEL Plan* (no more than five pages)

c) Annex 3 - *CVs for all Key Personnel* (no more than three pages each) with signed letters of commitment for all Key Personnel (no more than one page each). Both signed and electronic signatures are acceptable.

d) Annex 4 - *Sub-recipient Letters of Intent* specifying respective roles and stating commitment to participate (no more than one page per organization).

e) Annex 5 - Proposed *Staffing Matrix and Organizational Chart* including staff skills by technical area, institutional affiliation, and geographic location (no more than two pages).

f) Annex 6 - *Illustrative subaward management structure* including proposed lines of authority among the prime, other consortium partners, and potential sub-recipients as an organogram; as well an associated narrative of these roles/responsibilities between the partners and other technical or resource organizations.

6. Cost Application Format

The Business (Cost) Application must be submitted separately from the Technical Application. While no page limit exists for the cost application, applicants are encouraged to be as concise as possible while still providing the necessary details. The business (cost) application must illustrate the entire period of performance using the budget format shown in the SF-424A.

Prior to award, applicants may be required to submit additional documentation deemed necessary for the AO to assess the applicant's risk in accordance with 2 CFR 200.206. Applicants should not submit any additional information not required with their initial application.

The Cost Application must contain the following sections (which are further elaborated below this listing with the letters for each requirement):

a) Cover Page (See Section D.3 above for requirements)

b) SF 424 Form(s)

The applicant must sign and submit the cost application using the SF-424 series. Standard Forms can be accessed electronically at https://www.grants.gov/web/grants/forms/sf-424-family.html. Standard Forms can be accessed electronically at www.grants.gov or using the following links:

Instructions for SF-424	https://www.grants.gov/web/grants/forms/sf-424-family.html
Application for Federal Assistance (SF-424)	https://www.grants.gov/web/grants/forms/sf-424-family.html
Instructions for SF-424A	https://www.grants.gov/web/grants/forms/sf-424-family.html
Budget Information (SF-424A)	https://www.grants.gov/web/grants/forms/sf-424-family.html
Instructions for SF-424B	https://www.grants.gov/web/grants/forms/sf-424-family.html
Assurances (SF-424B)	https://www.grants.gov/web/grants/forms/sf-424-family.html

Failure to accurately complete these forms could result in the rejection of the application.

c) Required Certifications and Assurances

The applicant must complete the following documents and submit a signed copy with their application:

(1) "Certifications, Assurances, Representations, and Other Statements of the Recipient" ADS 303mav document found at https://www.usaid.gov/ads/policy/300/303mav
(2) Assurances for Non-Construction Programs (SF-424B)
(3) Certificate of Compliance: Please submit a copy of your Certificate of Compliance if your organization's systems have been certified by USAID/Washington's Office of Acquisition and Assistance (M/OAA).

d) Budget and Budget Narrative

The Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by project year, including itemization of the federal and non-federal amounts. Files must not contain any hidden or otherwise inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make an award, and may result in a rejection of the cost application. The Budget Narrative must be submitted in Word or as a PDF, and must contain sufficient detail to allow USAID to understand the proposed costs. The applicant must ensure that budgeted costs address any additional requirements identified in Section F, such as Branding and Marking. The Budget Narrative must be thorough, including sources for costs, to support USAID's determination that the proposed costs are fair and reasonable.

The Budget file must include the following worksheets or tabs and contents, at a minimum:

- Summary Budget, inclusive of all project costs (federal and non-federal), broken down by major budget category and by year for activities implemented by the applicant and any potential sub-applicants for the entire period of the project. See below for Summary Budget Template
- Detailed Budget, including a breakdown by year, sufficient to allow the Agency to determine that the costs represent a realistic and efficient use of funding to implement the applicant's project and are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.
- Detailed Budgets for each sub-recipient, for all federal funding and cost share, broken down by budget category and year, for the entire implementation period of the project.

A sample summary budget is shown below:

Cost Element	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Salaries and Wages						
Fringe Benefits						
Travel						
Equipment						
Supplies						
Subawards						
Other Direct Costs						
Total Direct Costs						
Total Indirect Costs						
Total						

The Detailed Budget must contain the following budget categories and information, at a minimum:

1) Salaries and Allowances – Must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services. The applicant's budget must include position title, salary rate, LOE, and salary escalation factors for each position. Allowances, when proposed, must be broken down by specific type and by position. Applicants must explain all assumptions in the Budget Narrative. The Budget Narrative must demonstrate that the proposed compensation is reasonable for the services rendered and consistent with what is paid for similar work in other activities of the applicant. Applicants must provide their established written policies on personnel compensation. If the applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and support market research.

2) Fringe Benefits – (if applicable) If the applicant has a fringe benefit rate approved by an agency of the U.S. Government, the applicant must use such rate and provide evidence of its approval. If an applicant does not have a fringe benefit rate approved, the applicant must propose a rate and explain how the applicant determined the rate. In this case, the Budget Narrative must include a detailed breakdown of all items of fringe benefits (e.g.,

superannuation, gratuity, etc.) and the costs of each, expressed in U.S. dollars and as a percentage of salaries.

3) Travel and Transportation – Provide details to explain the purpose of the trips, the number of trips, the origin and destination, the number of individuals traveling, and the duration of the trips. Per Diem and associated travel costs must be based on the applicant's normal travel policies. When appropriate please provide supporting documentation as an attachment, such as company travel policy, and explain assumptions in the Budget Narrative.

4) Procurement or Rental of Goods (Equipment & Supplies), Services, and Real Property – Must include information on estimated types of equipment, models, supplies and the cost per unit and quantity. The Budget Narrative must include the purpose of the equipment and supplies and the basis for the estimates. The Budget Narrative must support the necessity of any rental costs and reasonableness in light of such factors as: rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased.

5) Subawards – Specify the budget for the portion of the project to be passed through to any potential subrecipients, in the form of: sub-assistance agreement, sub-contractor, or fixed-amount awards. See 2 CFR 200 for assistance in determining whether the sub-tier entity is a subrecipient or contractor.

   For any named subrecipient to be approved at time of award, a detailed subaward budget shall be provided. The named subrecipient budgets must align with the same requirements as the applicant's budget, including those related to fringe and indirect costs. Detailed subaward budgets are not required for unnamed subrecipients, who may be approved after award.

   USAID anticipates that approximately 50% of ENDOR funding will be issued to subrecipients annually. Please specify the subaward budget accordingly.

6) Other Direct Costs – This may include other costs not elsewhere specified, such as report preparation costs, passports and visas fees, medical exams and inoculations, as well as any other miscellaneous costs which directly benefit the project proposed by the applicant. The applicant should indicate the subject, venue and duration of any proposed conferences and seminars, and their relationship to the objectives of the project, along with estimates of costs. Otherwise, the narrative should be minimal.

7) Indirect Costs – Applicants must indicate whether they are proposing indirect costs or will charge all costs directly. In order to better understand indirect costs please see Subpart E of 2 CFR 200. The application must identify which approach they are requesting and provide the

applicable supporting information. Below are the most commonly used Indirect Cost Rate methods:

Method 1 - Direct Charge Only
Eligibility: Any applicant
Initial Application Requirements: See above on direct costs

Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)
Eligibility: Any applicant with a NICRA issued by a USG Agency must use that NICRA.

Initial Application Requirements: If the applicant has a current NICRA, submit your approved NICRA and the associated disclosed practices. If your NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Additionally, at the Agency's discretion, a provisional rate may be set forth in the award subject to audit and finalization. See USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance.

Method 3 - De minimis rate of 10% of modified total direct costs (MTDC)
Eligibility: Any applicant that does not have a current NICRA.

Initial Application Requirements: Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate an indirect rate, which the non-Federal entity may apply to do at any time. The applicant must describe which cost elements it charges indirectly vs. directly. See 2 CFR 200 for further information.

Method 4 - Indirect Costs Charged As A Fixed Amount
Eligibility: Non U.S. non-profit organizations without a NICRA may request, but approval is at the discretion of the AO.

Initial Application Requirements: Provide the proposed fixed amount and a worksheet that includes the following:

- Total costs incurred by the organization for the previous fiscal year and estimates for the current year;
- Indirect costs (common costs that benefit the day-to-day operations of the organization, including categories such as salaries and expenses of executive officers, personnel administration, and accounting, or that benefit and are identifiable to more than one project or activity, such as depreciation, rental costs, operations and maintenance of

facilities, and telephone expenses) for the previous fiscal year and estimates for the current year; and
- Proposed method for prorating the indirect costs equitably and consistently across all projects and activities of using a base that measures the benefits of that particular cost to each project or activity to which the cost applies.

If the applicant does not have an approved NICRA and does not elect to utilize the 10% de minimis rate, the AO will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review. USAID is under no obligation to approve the applicant's requested method.

e) Prior Approvals in accordance with 2 CFR 200.407

Inclusion of an item of cost in the detailed application budget does not satisfy any requirements for prior approval by the Agency. If the applicant would like the award to reflect approval of any cost elements for which prior written approval is specifically required for allowability, the applicant must specify and justify that cost. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

f) Approval of Subawards

The applicant must submit information for all subawards that it wishes to have approved at the time of award. For each proposed subaward the applicant must provide the following:
- Name of organization
- Unique Entity Identifier (UEI)
- Confirmation that the subrecipient does not appear on the Treasury Department's Office of Foreign Assets Control (OFAC) list
- Confirmation that the subrecipient does not have active exclusions in the System for Award Management (SAM)
- Confirmation that the subrecipient is not listed in the United Nations Security designation list
- Confirmation that the subrecipient is not suspended or debarred
- Confirmation that the applicant has completed a risk assessment of the subrecipient, in accordance with 2 CFR 200.332(b)
- Any negative findings as a result of the risk assessment and the applicant's plan for mitigation

g) UEI and SAM Registration

Applicants must obtain a Unique Entity Identifier (UEI) and register in the System for Award Management (SAM) (https://sam.gov/) in order to be eligible to receive federal assistance, such as grants and cooperative agreements. Unless an exemption applies (see ADS 303maz), applicants

must be registered in SAM prior to submitting an application for award for USAID's consideration. Recipients must maintain an active SAM registration while they have an active award. Each applicant (unless the applicant is an individual or entity that is exempted from UEI/SAM requirements under 2 CFR 25.110) is required to:

1. Provide a valid UEI for the applicant and all proposed sub-recipients;
2. Be registered in SAM before submitting its application. Please note: UEI numbers may take a few weeks to be granted; and
3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award, application, or plan under consideration by a Federal awarding agency.

Applicants are encouraged to begin the process early. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant.

Applicants can find additional resources for registering in SAM, including a Quick Start Guide and a video, on https://sam.gov/.

h) History of Performance

The applicant must provide information regarding its recent history of performance for all its cost-reimbursement contracts, grants, or cooperative agreements involving similar or related projects, not to exceed three (3) years, as follows:

• Name of the Awarding Organization;
• Award Number;
• Activity Title;
• A brief description of the activity;
• Period of Performance;
• Award Amount;
• Reports and findings from any audits performed in the last three (3) years; and
• Name of at least two (2) updated professional contacts who most directly observed the work at the organization for which the service was performed with complete current contact information, including telephone number and e-mail address for each proposed individual.

If the applicant encountered problems on any of the referenced Awards, it may provide a short explanation and the corrective action taken. The applicant should not provide general information on its performance. USAID reserves the right to obtain relevant information concerning an applicant's history of performance from any sources and may consider such information in its

review of the applicant's risk. The Agency may request additional information and conduct a pre-award survey if it determines that it is necessary to inform the risk assessment.

i) Branding Strategy & Marking Plan

The apparently successful applicant will be asked to provide a Branding Strategy and Marking Plan to be evaluated and approved by the AO and incorporated into any resulting award.

Branding Strategy – Assistance (June 2012)

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

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

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

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

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

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

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

(i) USAID requires the applicant to use the "USAID Identity," comprised of the USAID logo and brandmark, with the tagline "from the American people" as found on the USAID Web site at http://www.usaid.gov/branding, unless Section VI of the RFA or APS states that the USAID Administrator has approved the use of an additional or substitute logo, seal, or tagline.

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

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

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

(v) USAID prefers to fund projects that do not have a separate logo or identity that competes with the USAID Identity. If there is a plan to develop a separate logo to consistently identify this project, the applicant must attach a copy of the proposed logos. Section VI of the RFA or APS will state if an Administrator approved the use of an additional or substitute logo, seal, or tagline.

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

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

(i) Describe the main project message.

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

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

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

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

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

(i) The AO will review the Branding Strategy to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

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

j) Funding Restrictions

Profit is not allowable for recipients or subrecipients under this award. See 2 CFR 200.331 for assistance in determining whether a sub-tier entity is a subrecipient or contractor.

Construction and renovation will not be authorized under this award. Specifically, USAID will not allow the reimbursements or renovations of pre-award or post-award costs under this award without the explicit written approval of the AO in advance.

All commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in Section B.4 of this NOFO and must meet the source and nationality requirements set forth in 22 CFR 228. Procurement of certain Restricted Commodities may be granted at the discretion of the AO or their designee in writing, in accordance with ADS 312.

k) Conflict of Interest Pre-Award Term

CONFLICT OF INTEREST PRE-AWARD TERM (August 2018)

a. Personal Conflict of Interest

1. An actual or appearance of a conflict of interest exists when an applicant organization or an employee of the organization has a relationship with an Agency official involved in the competitive award decision-making process that could affect that Agency official's impartiality. The term "conflict of interest" includes situations in which financial or other personal considerations may compromise, or have the appearance of compromising, the obligations and duties of a USAID employee or recipient employee.

2. The applicant must provide conflict of interest disclosures when it submits an SF-424. Should the applicant discover a previously undisclosed conflict of interest after submitting the application, the applicant must disclose the conflict of interest to the AO no later than ten (10) calendar days following discovery.

b. Organizational Conflict of Interest

The applicant must notify USAID of any actual or potential conflict of interest that they are aware of that may provide the applicant with an unfair competitive advantage in competing for this financial assistance award. Examples of an unfair competitive advantage include but are not limited to situations in which an applicant or the applicant's employee gained access to non-public information regarding a federal assistance funding opportunity, or an applicant or applicant's employee was substantially involved in the preparation of a federal assistance funding opportunity. USAID will promptly take appropriate action upon receiving any such notification from the applicant.

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SECTION E: APPLICATION REVIEW INFORMATION

1. Criteria

The merit review criteria prescribed here are tailored to the requirements of this particular NOFO. Applicants should note that these criteria serve to: (a) identify the significant matters which the applicants should address in their applications, and (b) set the standard against which all applications will be evaluated.

Technical and other factors will be evaluated relative to each other, as described here and prescribed by the Technical Application Format. The Technical Application will be scored by a Merit Review Committee (MER) using the criteria described in this section.

2. Review and Selection Process

a) Merit Review

USAID will conduct a merit review of all applications received that comply with the instructions in this NOFO. Applications will be reviewed and evaluated in accordance with the following criteria shown **in descending order of importance.**

Criterion 1: Technical and Programmatic Approach

The extent to which the application demonstrates a clear understanding of and ability to achieve the objectives of the ENDOR award, to include illustrative indicators of success and a description of how it intends to monitor the program.

Criterion 2: Management Plan, including Staffing

The extent to which the organizational and management plan will enable the project to accomplish the objectives of the ENDOR award effectively and efficiently, including a proposed subaward management system to address the urgent and emerging OR needs for accelerating progress.

Criterion 3: Gender, Diversity, Equity, and Inclusion

The extent to which the application demonstrates that gender, diversity, equity and inclusion (GDEI) will be intrinsic in the technical approaches, methodologies, data analyses and access to populations that could benefit from OR translation.

Other Considerations:

In addition to the merit criteria listed above, applicants may be evaluated for history of performance. Using information provided in Annex 3, USAID may contact the PPI references in order to conduct additional analysis to determine the following criteria:

1. The Applicant and major consortium partners and/or sub-recipients have demonstrated successful experience implementing activities that are similar in matter, size, scope and complexity to this proposed activity.

2. The Applicant and major consortium partners and/or sub-recipients have demonstrated institutional capacity to effectively coordinate and collaborate with a diverse set of organizations working in the same technical areas including, but not limited to other USG agencies, NGOs and PVOs, international organizations, donors and foundations, host governments, and private sector.

3. The Applicant and major consortium partners and/or sub-recipients have demonstrated successful experience working with/through local or regional operational platforms to include embedding of staff in developing country institutions.

4. The Applicant and major consortium partners and/or sub-recipients have demonstrated a solid business management track record to include successful experience in managing subcontracts and subawards with partner organizations in developing countries.

b) Business Review

The Agency will evaluate the cost application of the applicant(s) under consideration for an award as a result of the merit criteria review to determine whether the costs are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.

The Agency will also consider (1) the extent of the applicant's understanding of the financial aspects of the project and the applicant's ability to perform the activities within the amount requested; (2) whether the applicant's plans will achieve the project objectives with reasonable

economy and efficiency; and (3) whether any special conditions relating to costs should be included in the award.

The Business Review will be considered less important than Merit Review but may be considered as part of the overall evaluation.

The AO will perform a risk assessment (2 CFR 200.206). The AO may determine that a pre-award survey is required to inform the risk assessment in determining whether the prospective recipient has the necessary organizational, experience, accounting and operational controls, financial resources, and technical skills – or ability to obtain them – in order to achieve the objectives of the project and comply with the terms and conditions of the award. Depending on the result of the risk assessment, the AO will decide to execute the award, not execute the award, or award with "specific conditions" (2 CFR 200.208).

{END OF SECTION E}

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SECTION F: FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

Award of the agreement contemplated by this NOFO cannot be made until funds have been appropriated, allocated and committed through internal USAID procedures. While USAID anticipates that these procedures will be successfully completed, potential applicants are hereby notified of these requirements and conditions for the award.

2. Administrative & National Policy Requirements

The resulting award from this NOFO will be administered in accordance with the following policies and regulations.

For US organizations: ADS 303, 2 CFR 700, 2 CFR 200, and Standard Provisions for U.S. Non-governmental organizations.

For Non US organizations: ADS 303, Standard Provisions for Non-U.S. Non-governmental Organizations.

See Annex 1, for a list of the Standard Provisions that will be applicable to any awards resulting from this NOFO.

3. Reporting Requirements

Financial Reporting:
To monitor the financial health of this award in an ongoing manner, the recipient must submit accrual costs and pipelines analyses to the AOR by email on a quarterly basis. Further instruction from USAID will be formally communicated to the recipient after award.

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the AO and AOR. These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit the original and two copies of all final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

Project Reporting:
The Recipient(s) will submit the following documents to the AOR electronically within the time period determined in collaboration with the AOR. Guidelines will be provided by the AOR post-award. Reports will be timed and formatted so that they can provide USAID with useful information required for their reporting requirements.

First Year Work Plan and Budget:
The draft First Year Workplan must be submitted by the Recipient within 30 calendar days of the award. The First Year Workplan will not necessarily be for a full year or may be for more than a full year, depending on the start date of the agreement; this will be defined at the time of award.

Annual Workplan and Budget:
Starting with the second year of the award, and for each subsequent year of performance thereafter based on the fiscal year, the Recipient(s) must submit an Annual Workplan and Budget to USAID. The Annual Workplans must be submitted to the AOR for approval, and the submission deadlines for the Annual Workplan and Budget will be communicated by USAID to the Recipient(s).

Gender, Diversity, Equity and Inclusion Strategy:
The Recipient(s) will be asked to conduct a GDEI analysis, after the signing of the Agreement. This analysis will inform a subsequent GDEI Strategy, which will be developed in collaboration with USAID, and finalized within six months of signing the Agreement. The GDEI Strategy will inform the project's technical approach as it is related to GDEI throughout the life of the project and should be reflected as relevant in Annual Workplans, reporting, and activity MEL plan indicators.

Monitoring, Evaluation, and Learning (MEL) Plan:
After the award of ENDOR, the Illustrative Activity MEL Plan will be developed into the overall project MEL Plan for the entire period of performance, in concert with USAID, and must be finalized within 90 calendar days of the award.

Data Management Plan (DMP):
A Data Management Plan (DMP) is a document that describes how the Recipient will manage data during the project. The DMP will facilitate the Recipient and AOR in identifying data deliverables, consider the full data collection process, data management and storage, protection, long-term preservation, and sharing and publication of data, and a plan for curation after the project ends. The DMP should also ensure adequate resources and time to perform all described data management activities. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated annually.

Closeout Plan:
No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for AO's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the AO.

Final Report:
Within 90 calendar days after the completion date of the Cooperative Agreement, the Recipient(s) must submit a Final Report which includes an executive summary of the Recipient(s)'s accomplishments in achieving results, targets not achieved, lessons learned, challenges and conclusions about areas in need of future assistance; an overall description of the Recipient(s)'s activities and attainment of results and sub-results by region, as appropriate, during the life of the Cooperative Agreement; an assessment of the progress made toward accomplishing the life of project (LOP) results and expected results and sub-results, and overall project impact; analysis of the significance of these activities; important findings and recommendations; a fiscal report that describes use of funds expended under this award and overall project cost-effectiveness; and a list of all academic manuscripts developed, accepted and under review and published, and all conference abstracts submitted and accepted. The Recipient(s) shall submit, with the Final Report, a list of all the studies conducted during the LOP and a compilation of all the publications/materials produced. The format of the report will be determined in collaboration with the AOR. The Recipient(s) will submit the Final Report to the AOR. One additional copy will be provided in electronic format to the Development Experience Clearinghouse (DEC). Submission instructions can be found at: http://dec.usaid.gov.

Progress Monitoring Reports:
The Recipient(s) will submit an updated report on progress toward agreed performance indicators every six months after award in the form of a semi-annual report (SAR). The SAR requirements and indicators should be based on the MEL Plan to be finalized by USAID in collaboration with the recipient.

Each report should include information on activities completed during the preceding period of performance in all supported countries, including those centrally at headquarters. Each report may also include the following (this list will be finalized with the USAID management team after signing of the agreement):

- Progress on standard, agreed upon indicators by project or initiative. This would include a description of tangible results and explanation of quantifiable outputs, if appropriate and applicable;
- Significant project successes, blogs, press release videos, and photographs (if requested).

Photographs should comply with guidance provided in the USAID Graphic Standards Manual and should list information on each photo's subject and location;

- A list of all academic manuscripts developed, accepted and under review and published, and all conference abstracts submitted and accepted. The manuscripts and abstracts (e.g., PDF of the published article, image of the file of accepted posters, etc.) should be submitted along with the report;
- A GDEI section reporting related activities and achievement;
- A human subjects protection section reporting related activities and any issues encountered; and
- Planned activities for the next performance period;

Further, notification must be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives and timeliness of the award. These notifications must include a statement of the action taken or contemplated and any assistance needed to resolve the situation to the AOR.

A brief Final Technical Report at the conclusion of each project or initiative under ENDOR should be submitted to the AOR within 30 days of completion. USAID recognizes this may be prior to overall results publication in peer-reviewed journals and/or at scientific conferences, and will be managed under confidentiality agreements when relevant.

Ad Hoc Reports:

The Recipient(s) may be requested to submit ad hoc reports on the status of its activities as requested by USAID. This is anticipated to include updates, presentations, reports, and publications. Examples of such ad hoc reports include, but are not limited to, content for Congressionally-mandated reports: 1) Overall GH Research Report; 2) GH Innovations and Research Development, GH Applied Research Report, GH Research Products Report, and others which may be communicated from the AOR at the direction of the Agency and Congressional mandates. Other data calls and taskers will be communicated by the AOR to the recipients as directed by the Agency's needs during the period of award.

4. Environmental Compliance

As required by the 22 CFR 216, an Initial Environmental Examination (IEE) was completed by the USAID/GH/NTD Office to ensure that proposed interventions adhere to U.S. and host countries' environmental requirements, and that appropriate environmental safeguards are adopted to prevent negative environmental consequences of USAID investment. The environmental determination for the ENDOR IEE was a "negative determination," given the activities proposed under this NOFO will not have a significant effect on the environment.

The partner's environmental compliance obligations under these regulations and procedures are

specified in the attached IEE. **Applicants should reflect illustrative costs for environmental compliance implementation and monitoring in their cost applications.**

Please note the project scope written in the IEE should not influence the Applicant's proposal as these may be outdated. The applicant should only consider the Project Description as laid out in Section A of this NOFO.

An annual screening must be conducted to determine whether activities under ENDOR contained in the categorical exclusion justification remain within the Activity's scope. Changes to the Activity require an environmental review and possible amendment of the negative determination to reflect the new activities. Per ADS 204, the IEE will need to be amended and environmental determination reviewed if there is any new information or changes in interventions that might require revision of the determination.

{END OF SECTION F}

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SECTION G: FEDERAL AWARDING AGENCY CONTACT(S)

1. NOFO Points of Contact

For submission of all Questions and Applications: endor@usaid.gov. It is prohibited to reach out to the USAID NTD Division staff during the NOFO period.

2. Acquisition and Assistance Ombudsman

The A&A Ombudsman helps ensure equitable treatment of all parties who participate in USAID's acquisition and assistance (A&A) process. The A&A Ombudsman serves as a resource for all organizations who are doing or wish to do business with USAID. Please visit this page for additional information: https://www.usaid.gov/work-usaid/acquisition-assistance-ombudsman

The A&A Ombudsman may be contacted via: Ombudsman@usaid.gov

{END OF SECTION G}

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SECTION H: OTHER INFORMATION

USAID reserves the right to fund any or none of the applications submitted. The AO is the only individual who may legally commit the Government to the expenditure of public funds. Any award and subsequent incremental funding will be subject to the availability of funds and continued relevance to Agency programming.

Applications with Proprietary Data

Applicants who include data that they do not want disclosed to the public for any purpose or used by the U.S. Government except for evaluation purpose, should mark the cover page with the following:

> "This application includes data that must not be disclosed, duplicated or used – in whole or in part – for any purpose other than to evaluate this application. If, however, an award is made as a result of – or in connection with – the submission of this data, the U.S. Government will have the right to duplicate, use, or disclose the data to the extent provided in the resulting award. This restriction does not limit the U.S. Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets {insert sheet numbers}."

Additionally, the applicant must mark each sheet of data it wishes to restrict with the following:

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

List of Annexes:

Annex 1: Standard Provisions
Annex 2: List of Acronyms
Annex 3: Past Performance Information
Annex 4: Initial Environmental Examination

{END OF SECTION H}

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SECTION I: NOFO ANNEXES

ANNEX 1 - STANDARD PROVISIONS

(Note: the full text of these provisions may be found at: https://www.usaid.gov/ads/policy/300/303maa, https://www.usaid.gov/ads/policy/300/303mab, and https://www.usaid.gov/ads/policy/300/303mat). The actual Standard Provisions included in the award will be dependent on the organization that is selected (or the type of award, in the case of a FAA). The award will include the latest Mandatory Provisions for either U.S. or non-U.S. Nongovernmental organizations, as appropriate**.** The award will also contain the following "required as applicable" Standard Provisions:

Please note that the resulting award will include all standard provisions (both mandatory and required as applicable) in full text.

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
TBD		RAA1. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (NOVEMBER 2020)
		RAA2. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (NOVEMBER 2020)
		RAA3. NEGOTIATED INDIRECT COST RATE - PROVISIONAL (For-Profit) (DECEMBER 2022)
		RAA4. INDIRECT COSTS – DE MINIMIS RATE (NOVEMBER 2020)
		RAA5. RESERVED
	X	RAA6. VOLUNTARY POPULATION PLANNING ACTIVITIES – SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
X		RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)
X		RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

X		RAA9. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (DECEMBER 2022)
	X	RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)
X		RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)
	X	RAA12. INVESTMENT PROMOTION (DECEMBER 2022)
X		RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2022)
X		RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)
	X	RAA15. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
	X	RAA16. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
	X	RAA17. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING (ASSISTANCE) (SEPTEMBER 2014)
		RAA18. RESERVED
	X	RAA19. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)
	X	RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
	X	RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
	X	RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
X		RAA23. UNIVERSAL IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT (DECEMBER 2022)
X		RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (DECEMBER 2022)
X		RAA25. PATENT REPORTING PROCEDURES (DECEMBER 2022)

	X	RAA26. ACCESS TO USAID FACILITIES AND USAID'S INFORMATION SYSTEMS (AUGUST 2013)
X		RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2022)
		RAA28. RESERVED
		RAA29. RESERVED
X		RAA30. PROGRAM INCOME (AUGUST 2020)
X		RAA31. NEVER CONTRACT WITH THE ENEMY (NOVEMBER 2020)

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR NON-U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
TBD		RAA1. ADVANCE PAYMENT AND REFUNDS (NOVEMBER 2020)
		RAA2. REIMBURSEMENT PAYMENT AND REFUNDS (DECEMBER 2014)
TBD		RAA3. INDIRECT COSTS – NEGOTIATED INDIRECT COST RATE AGREEMENT (NICRA) (NOVEMBER 2020)
		RAA4. INDIRECT COSTS – CHARGED AS A FIXED AMOUNT (NONPROFIT) (JUNE 2012)
		RAA5. INDIRECT COSTS – DE MINIMIS RATE (NOVEMBER 2020)
X		RAA6. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (SAM) (DECEMBER 2022)
X		RAA7. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (DECEMBER 2022)
X		RAA8. SUBAWARDS (DECEMBER 2014)
X		RAA9. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)
X		RAA10. OCEAN SHIPMENT OF GOODS (JUNE 2012)
X		RAA11. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2022)
X		RAA12. PATENT RIGHTS (DECEMBER 2022)
		RAA13. RESERVED
	X	RAA14. INVESTMENT PROMOTION (DECEMBER 2022)
	X	RAA 15. COST SHARE (JUNE 2012)
X		RAA16. PROGRAM INCOME (AUGUST 2020)
X		RAA17. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

	X	RAA18. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)
X		RAA19. PROTECTION OF HUMAN RESEARCH SUBJECTS (JUNE 2012)
	X	RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
	X	RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
	X	RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
	X	RAA23. VOLUNTARY POPULATION PLANNING ACTIVITIES – SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
	X	RAA24. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
	X	RAA25. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
	X	RAA26. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING(ASSISTANCE) (SEPTEMBER 2014)
	X	RAA27. LIMITATION ON SUBAWARDS TO NON-LOCAL ENTITIES (JULY 2014)
X		RAA28. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2022)
		RAA29. RESERVED
		RAA30. RESERVED
X		RAA31. NEVER CONTRACT WITH THE ENEMY (NOVEMBER 2020)

ANNEX 2 - ABBREVIATIONS AND ACRONYMS

A&A	Acquisition and Assistance
ADS	Automated Directives System
AFRO	WHO Africa Regional Office
AO	Agreement Officer
AOR	Agreement Officer's Representative
APS	Annual Program Statement
BMGF	Bill & Melinda Gates Foundation
CFR	Code of Federal Regulations
COR-NTD	Coalition for Operational Research on Neglected Tropical Diseases
CSG	Consultative Stakeholders Group
DEC	Development Experience Clearinghouse
DEI	Diversity, Equity and Inclusion
DMP	Data Management Plan
DNDi	Drugs for Neglected Diseases initiative
ENDOR	Ending Neglected Diseases through Operational Research
EOI	Expression of Interest
FAA	Foreign Assistance Act
FM	Financial Management Office
GDEI	Gender, Diversity, Equity and Inclusion
GH	Global Health
IEE	Initial Environmental Examination
LF	Lymphatic Filariasis
LOE	Level of Effort
LOP	Life of Project
MDA	Mass Drug Administration
MRC	Merit Review Committee
MEL	Monitoring, Evaluation and Learning
MTDC	Modified Total Direct Costs
NGOs	Non-Governmental Organizations
NOFO	Notice of Funding Opportunity
NGO	Non-Governmental Organization
NICRA	Negotiated Indirect Cost Rate Agreement
OAA	Office of Acquisition and Assistance
OFAC	Treasury Department's Office of Foreign Assets Control
OV	Onchocerciasis
OR	Operational Research
PAHO	Pan American Health Organization
PC-NTDs	Preventive Chemotherapy NTDs

PPI	Past Performance Information
PQM+	Promoting Quality Medicines +
R&D	Research & Development
RFA	Request for Application
SAM	System for Award Management
SCH	Schistosomiasis
SEARO	WHO South-East Asia Regional Office
SF-425	Federal Financial Form
STH	Soil-Transmitted Helminths
ToC	Theory of Change
TRA	Trachoma
USAID	United States Agency for International Development
UEI	Unique Entity Identifier
USG	United States Government
WHO	World Health Organization
WPRO	WHO Western Pacific Regional Office

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ANNEX 3 - PAST PERFORMANCE INFORMATION

Past Performance Information (PPI)
(TO BE COMPLETED BY THE APPLICANT)

1.	**Award Number:**
2.	**Contractor/Recipient (Name and Address):**
3.	**Type of Award: _____ _____**
4.	**Complexity of Work: Difficult _____Routine _____**
5.	**Description, location, and relevancy of work:**
6.	**Dollar Value: _____** **Status: Active _____Completed _____**
7.	**Date of Award: _____** **Award Completion Date (including extensions): _____**
8.	**Type and Extent of Subawards:**
9.	**Name, Address, Telephone Number, and E-mail Address of the Awarding Contracting/Agreement Officer and/or the Contracting/Agreement Officer 's Representative (and other references as applicable):**

ANNEX 4: INITIAL ENVIRONMENTAL EXAMINATION

INITIAL ENVIRONMENTAL EXAMINATION

PROJECT/ACTIVITY DATA

Project/Activity Name:	Ending Neglected Diseases through Operational Research (ENDOR)
Geographic Location(s) (Country/Region)**:**	Global
Amendment (Yes/No), if Yes indicate # (1, 2...):	N/A
Implementation Start/End Date (FY or M/D/Y)**:**	January 2024 - January 2029
If Amended, specify New End Date:	
Solicitation/Contract/Award Number(s):	TBD
Implementing Partner(s):	TBD
Bureau Tracking ID:	GH-23-10949
Tracking ID of Related RCE/IEE (if any)**:**	
Tracking ID of Other, Related Analyses:	

ORGANIZATIONAL/ADMINISTRATIVE DATA

Implementing Operating Unit(s): (e.g. Mission or Bureau or Office)	GH/ID
Other Affected Operating Unit(s):	
Lead BEO Bureau:	Global Health
Funding Account(s) (if available)**:**	
Original Funding Amount:	$35-45 million
If Amended, specify funding amount:	
If Amended, specify new funding total:	
Prepared by:	Shailee Patel
Date Prepared:	4/20/2023

ENVIRONMENTAL COMPLIANCE REVIEW DATA

Analysis Type:	X Environmental Examination	☐Deferral
Environmental Determination(s):	X Categorical Exclusion(s) X Negative ☐Positive ☐Deferred (per 22 CFR 216.3(a)(7)(iv)	
IEE Expiration Date (if applicable)**:**	January 2029. Projects and activities that commence within this initial time frame may proceed for the duration of the proposed activities.	
Additional Analyses/Reporting Required:	EMMP, IWMP, Annual EMMR	
Climate Risks Identified (#):	Low 1 Moderate 5 High	
Climate Risks Addressed (#):	Low 1 Moderate 5 High	

THRESHOLD DETERMINATION AND SUMMARY OF FINDINGS

PROJECT/ACTIVITY SUMMARY

The objective of the Enhancing Neglected Tropical Diseases (NTD) Diagnostics and Operational Research (ENDOR) Activity is to support disease endemic-countries and the global NTD community to define and address operational research (OR) gaps and unmet needs hindering progress to reaching NTD control and elimination targets. This activity is expected to be awarded in January 2024 with a period of performance of five years.

ENVIRONMENTAL DETERMINATIONS

Upon approval of this document, the determinations become affirmed, per Agency regulations (22 CFR 216).

TABLE 1: **ENVIRONMENTAL DETERMINATIONS**

Projects/Activities	**Categorical Exclusion Citation (if applicable)**	**Negative Determination**	**Positive Determination** [1]	**Deferral** [2]
Activity 1: NTD Technical Assistance (TA), Capacity Building, and Training programs				
Sub-activity 1.1: Conduct technical assistance, training, and capacity-building activities	X Categorical Exclusion, per 22 CFR 216.2(c)(2)(i). Education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.)	☐	☐	☐
Sub-activity 1.2: Provide funding for researchers and institutions A	X Categorical Exclusion, per 22 CFR 216.2(c)(2)(vii). Institution building grants to research and educational institutions in the United States such as those provided for under section 122(d) and title XII of chapter 2 of part I of the FAA (22 USCA	☐	☐	☐

[1] Positive Determinations require preparation of a Scoping Statement and Environmental Assessment.
[2] GH does not grant deferrals during the IEE process.

Projects/Activities	Categorical Exclusion Citation (if applicable)	Negative Determination	Positive Determination [1]	Deferral [2]
	2151 p. (b) 2220a. (1979))			
	☐	X	☐	☐
Activity 2: Research and Development (Field and Laboratory Diagnostic Testing)				
Sub-activity 2.1: Conduct field testing commodities and diagnostics	☐	X	☐	☐
Sub-activity 2.2: Conduct diagnostics laboratory testing to detect the presence of NTD	☐	X	☐	☐
Activity 3: Healthcare Commodities Inventory Management, Sourcing, Procurement, Storage, Distribution, Quality Control Management, Treatment and/or Disposal				
Sub-activity 3.1: Quantification and/or forecasting of health commodities and inventory management	☐	X	☐	☐
Sub-Activity 3.2: Procurement of health commodities		X	☐	☐
Sub-Activity 3.3: Operation and maintenance of storage facilities containing public health commodities	☐	X	☐	☐
Sub-Activity 3.4: Distribution and/or transportation of public health commodities	☐	X	☐	☐
Sub-Activity 3.5: Collection, transport, treatment, and/or disposal of healthcare commodities and expired or hazardous products	☐	X	☐	☐

CLIMATE RISK MANAGEMENT

USAID's NTD Division completed the Climate Risk Management Screening by consulting with technical backstops in the division and conducting a literature review of the effects of climate change on infectious diseases with a focus on neglected tropical diseases. Additionally, the Division completed the Climate Assessment tool on climatelinks.org. This assessment and other resources helped to identify specific climate risks and opportunities to address them. Please refer to Annex for further CRM.

BEO SPECIFIED CONDITIONS OF APPROVAL

N/A

IMPLEMENTATION

In accordance with 22 CFR 216 and Agency policy, the conditions and requirements of this document become mandatory upon approval. This includes the relevant limitations, conditions and requirements in this document as stated in Sections 3, 4, and 5 of the IEE and any BEO Specified Conditions of Approval.

This IEE is valid through January 2029. Projects and activities covered under this IEE may proceed for their entire proposed duration provided the project or activities commence within the five-year validity period and the activities remain in the scope of this IEE.

This IEE may be subject to re-evaluation or modification to determine if the activities undertaken may remain within the scope of the approved IEE. If no change in the scope of significant environmental issues are identified during the initial 5-year validity period, this IEE may be extended without the need for a supplemental environmental analysis.

Missions, Bureaus, and Independent Offices that buy-into a GH mechanism covered under this IEE may use this for compliance with 22 CFR 216; however, each Mission, Bureau, or Independent Office must follow their own procedures as required.

USAID APPROVAL OF INITIAL ENVIRONMENTAL EXAMINATION

PROJECT/ACTIVITY NAME: Ending Neglected Tropical Diseases through Operational Research (ENDOR) Activity

Bureau Tracking ID: _____GH-23-10949_____

Approval:	Paul Mahanna, Office Director, Office of Infectious Disease [*required*]	Date
Clearance:	Joseph Shott, AOR, GH/ID/NTD [*required*]	Date
Clearance:	Dennis Durbin, Climate Integration Lead and Environmental Officer [*required*]	Date

DISTRIBUTION:

- Project Files
- Environmental Compliance Database (environmentalcompliancesupport@usaid.gov)
- Bureau for Global Health (ghcompliancesupport@usaid.gov)

INITIAL ENVIRONMENTAL EXAMINATION

Contents

1.0 PROJECT/ACTIVITY DESCRIPTION

1.1 PURPOSE OF THE IEE

The purpose of this document, in accordance with Title 22, Code of Federal Regulations, Part 216 (22 CFR 216), is to provide a preliminary review of the reasonably foreseeable effects on the environment of the USAID intervention described herein and recommend determinations and, as appropriate, conditions, for these activities. Upon approval, these determinations become affirmed, and specified conditions become mandatory obligations of implementation. This IEE also documents the results of the Climate Risk Management process in accordance with USAID policy (specifically, ADS 201mal).

This IEE is a critical element of USAID's mandatory environmental review and compliance process meant to achieve environmentally sound design and implementation. Potential environmental impacts should be addressed through formal environmental mitigation and monitoring plans (EMMPs) and/or Environmental Assessments (EAs), if needed.

1.2 PROJECT/ACTIVITY OVERVIEW

The purpose of the Enhancing Neglected Tropical Diseases (NTD) Diagnostics and Operational Research (ENDOR) Activity is to improve the evidence base for action to control and/or eliminate targeted NTDs. The Activity will address global operational research needs by defining and researching important questions hindering successful implementation of NTD programs and progress towards the World Health Organization's 2030 control and elimination goals. ENDOR will aim to strengthen linkages among partners by engaging researchers, country level program staff, implementing partners and the donor community. This activity is expected to be awarded in January 2024 with a period of performance of five years.

1.3 PROJECT/ACTIVITY DESCRIPTION

USAID's Neglected Tropical Diseases (NTD) program targets seven of the most prevalent NTDs: lymphatic filariasis (LF), schistosomiasis (SCH), onchocerciasis, trachoma, and three soil-transmitted helminthiases (STH). Since its launch in 2006, USAID's NTD program has focused on supporting efforts to introduce and scale up the delivery of preventive drug treatments which are aimed at controlling, and in some cases eliminating, these diseases. This approach, known as Mass Drug Administration (MDA), is safe, effective, cost efficient, and endorsed by the World Health Organization (WHO). Because of USAID's focus on this strategy, many USAID-supported countries have achieved control and elimination targets and additional countries are on track to reach these benchmarks within the next five years.

Despite great progress, current diagnostic, therapeutic tools, and program strategies for many NTDs are not sufficient. As countries approach disease elimination targets, programmatic challenges often emerge. The ENDOR Activity will support operational research to address these emerging challenges, specifically to guide programmatic decision making, to inform and standardize the documentation process needed to verify elimination of diseases, and to set guidelines for post-intervention surveillance to ensure diseases are not re-introduced in formally endemic areas.

USAID has three key objectives in designing this Activity:

- Support the development of strategies to overcome obstacles to scale-up, such as difficult populations and ancillary programs to strengthen implementation of Mass Drug Administration (MDA) and accelerate progress.
- Support the development and implementation of tools for determining elimination and control such as sampling strategies for populations, simplified diagnostic tools, and monitoring tools.
- Support activities that will advance program sustainability, such as the research and testing of long-term drug effectiveness and responsible exit strategies.

Given the scope of work, many of the activities that will be supported by ENDOR will involve field work and laboratory work. ENDOR has three activities with potential environmental aspects or impact:

Activity 1: NTD Technical Assistance (TA), Capacity Building, and Training programs: ENDOR will support capacity building activities to strengthen countries' abilities to conduct laboratory tests and generate quality-assured laboratory data, design proposals and manage operational research (OR) grants, and manage and use data for decision making.

- **Sub-activity: 1.1: Conduct technical assistance, training, and capacity-building activities:** ENDOR will support laboratory capacity building with the objectives to develop a network of high-quality labs to support NTD programs and engage lab network partners in the testing and validation of new diagnostic tools. Additionally, ENDOR will provide funding opportunities for local African researchers and institutions to design and manage small-scale NTD research projects. Through this intervention, ENDOR will aim to strengthen the research capacity among African NTD researchers and institutions.
- **Sub-activity: 1.2: Provide funding for researchers and institutions:** ENDOR will provide funding opportunities for local African researchers and institutions to design and manage small-scale NTD research projects. Through this intervention, ENDOR will aim to strengthen the research capacity among African NTD researchers and institutions.

Activity 2: Research and Development (Field and Laboratory Diagnostic Testing): To measure impact and document progress toward disease elimination targets, the ENDOR Activity will support the development, improvement, and implementation of diagnostic tools. After diagnostic tools have passed the initial phases of development, field validation studies are typically conducted to assess quality, evaluate performance, and determine suitability for use in the field. As NTDs generally impact communities in rural and remote regions, it is essential to test new diagnostic tools in the field within resource-limited settings prior to full-scale implementation. In addition to diagnostics, ENDOR will support the development and field testing of surveillance and monitoring and evaluation (M&E) tools to monitor that infection levels are sustained below target thresholds.

- **Sub-activity 2.1: Conduct field testing:** ENDOR will support the procurement, transportation, storage and field evaluation of diagnostics and ancillary supplies to properly perform tests and detect NTDs in endemic communities. Some of the supplies may include consumables, glassware, sharps, filter paper, stains, and related reagents to run point-of care diagnostic evaluations.
- **Sub-activity 2.2: Conduct diagnostic laboratory testing to detect the presence of NTDs:** To perform field tests, samples of bodily fluids may be collected as a comparator to those analyzed in the field setting for comparing the performance in the controlled laboratory environment. The specimens collected are from humans, which may include

blood, stool, or urine. The usual method to collect a blood sample is a finger- or heel-prick. For stool and urine samples, a container with proper labeling is given to an individual to provide the sample. Only small quantities of bodily fluids are necessary to perform these tests. ENDOR implementing partners will pay close attention to the proper handling and storage of all samples as any tampering could impact the quality of results.

Activity 3: Healthcare Commodities Inventory Management, Sourcing, Procurement, Storage, Distribution, Quality Control Management, Treatment and/or Disposal.

- **Sub-activity 3.1: Conduct forecasting and supply planning activity:** Under ENDOR will entail conducting diagnostic and commodities forecasting and supply planning prior to initiation of any research activity.
- **Sub-activity 3.2: Conduct contracting and procurement of commodities:** This activity entails the procurement, transport, and storage of laboratory commodities and diagnostics. ENDOR will procure diagnostic tools and ancillary supplies necessary to perform the tests to detect the presence of NTDs. This process will require shipping and additional transport prior to arriving at the laboratory. The commodities and diagnostics may be stored at the laboratory for a period of time before use.
- **Sub-activity 3.3: Storage of healthcare commodities through a warehouse, at the site, etc:** The commodities and diagnostics required for research may be stored at the laboratory for a period of time before use.
- **Sub-activity 3.4: Distribution of healthcare commodities:** Supplying research with diagnostics and commodities will require shipping and additional transport prior to arriving at the laboratory.
- **Sub-activity 3.5: Collection, transport, treatment, and/or disposal of healthcare commodities or hazardous waste/products:** To detect the presence of NTDs, laboratory analysis on samples of bodily fluids may be performed. Additionally, to conduct these analyses, sometimes hazardous chemicals such as formalin or ethidium bromide may be used. All hazardous chemicals used in the lab are properly stored and disposed of according to national standards and regulations.
- **Sub-activity 3.6: Quality control-management of expired, off-specification, recalled, damaged, or mishandled healthcare commodities:**

TABLE 2: DEFINED OR ILLUSTRATIVE PROJECTS/ACTIVITIES AND SUB-ACTIVITIES

Activity 1: NTD Technical Assistance (TA), Capacity Building, and Training programs:
Sub-activity 1.1: Conduct technical assistance, training, and capacity-building activities
Sub-activity 1.2: Provide funding for researchers and institutions
Activity 2: Research and Development (Field and Laboratory Diagnostic Testing)
Sub-activity 2.1: Conduct field testing commodities and diagnostics
Sub-activity 2.2: Conduct diagnostics laboratory testing to detect the presence of NTD
Activity 3: Healthcare Commodities Inventory Management, Sourcing, Procurement, Storage, Distribution, Quality Control Management, Treatment and/or Disposal
Sub-activity 3.1: Quantification and/or forecasting of health commodities and inventory management
Sub-activity 3.2: Procurement of health commodities
Sub-activity 3.3: Operation and maintenance of storage facilities containing public health commodities
Sub-activity 3.4: Distribution and/or transportation of public health commodities
Sub-activity 3.5: Collection, transport, treatment, and/or disposal of healthcare commodities or hazardous waste

Will this project/activity involve construction[3] as defined by ADS 201 and 303? Yes ☐ No X

2.0 BASELINE ENVIRONMENTAL INFORMATION

2.1 LOCATIONS AFFECTED AND ENVIRONMENTAL CONTEXT (ENVIRONMENT, PHYSICAL, CLIMATE, SOCIAL, THREATENED AND ENDANGERED SPECIES)

The activities supported by this grant are implemented globally but are concentrated mostly in Africa and Asia regions. The supported countries may change depending on the progress of research studies and identified needs for new studies. Future EMMRs from ENDOR will include specific country and research study conditions.

2.2 APPLICABLE AND APPROPRIATE PARTNER COUNTRY AND OTHER INTERNATIONAL STANDARDS (E.G. WHO), ENVIRONMENTAL AND SOCIAL LAWS, POLICIES, AND REGULATIONS

ENDOR implementing partners will work with national, regional, and local counterparts to ensure the activities follow the country's environmental regulations and standards. ENDOR will closely monitor compliance with national laws and WHO guidelines during procurement, distribution, storage, and disposal of public health commodities. Observations will be documented in future EMMRs.

2.3 COUNTRY/MINISTRY/MUNICIPALITY ENVIRONMENTAL CAPACITY ANALYSIS (AS APPROPRIATE)

N/A

[3] **Construction, as defined by ADS 201 and 303,** includes: construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures. In the box below, describe any construction planned for this project/activity. Refer to ADS 201maw for required Construction Risk Management procedures.

3.0 ANALYSIS OF POTENTIAL ENVIRONMENTAL RISK

ACTIVITY 1: NTD TECHNICAL ASSISTANCE (TA), CAPACITY BUILDING, AND TRAINING PROGRAMS

TABLE 3A. POTENTIAL IMPACTS – ACTIVITY 1

Project/Activity	Potential environmental and social impacts
Activity 1: NTD Technical Assistance (TA), Capacity Building, and Training programs	
Sub-activity 1.1: Conduct technical assistance, training, and capacity-building activities	**These activities qualify for Categorical Exclusion, per 22 CFR 216.2(c)(2)(i).** Education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.)
Sub-activity 1.2: Provide funding for researchers and institutions	**These activities qualify for Categorical Exclusion, per 22 CFR 216.2(c)(2)(vii).** Institution building grants to research and educational institutions in the United States such as those provided for under section 122(d) and title XII of chapter 2 of part I of the FAA (22 USCA 2151 p. (b) 2220a. (1979))

ACTIVITY 2: RESEARCH AND DEVELOPMENT (FIELD AND LABORATORY DIAGNOSTIC TESTING)

TABLE 3B. POTENTIAL IMPACTS – ACTIVITY 2

Project/Activity	Potential environmental and social impacts
Project/Activity 2: Research and Development (Field and Laboratory Diagnostic Testing)	
Sub-activity 2.1: Conduct field testing commodities and diagnostics	Mismanagement of laboratory commodities and diagnostics in the field could cause: ● Procurement of an oversupply of diagnostics/lab commodities, creating additional waste ● Health impacts for workers as those handling healthcare waste may be in direct contact with hazardous waste during disposal activities
Sub-activity 2.2:Conduct diagnostics laboratory testing to detect the presence of NTD	Laboratory research may use hazardous and toxic chemicals and result in the generation of various solid and hazardous wastes, including chemical and biological wastes. Air emissions resulting from laboratory operations may generate hazardous air pollutants that can be harmful to human health and the environment. In addition, water used during laboratory research may become contaminated and require control or treatment prior to discharge to avoid contamination of water systems. Additionally, mishandling of bodily fluids could facilitate transmission of diseases as potentially dangerous bacteria and viruses could be present in a sample.

ACTIVITY 3: **HEALTHCARE COMMODITIES INVENTORY MANAGEMENT, SOURCING, PROCUREMENT, STORAGE, DISTRIBUTION, QUALITY CONTROL MANAGEMENT, TREATMENT AND/OR DISPOSAL**

TABLE 3C. POTENTIAL IMPACTS – ACTIVITY 3

Project/Activity	Potential environmental and social impacts

Activity 3: Healthcare Commodities Inventory Management, Sourcing, Procurement, Storage, Distribution, Quality Control Management, Treatment and/or Disposal	
Sub-activity 3.1: Quantification and/or forecasting of health commodities and inventory management	Procuring an oversupply of health commodities increases the probability of products expiring on the shelf and requiring disposal. With higher disposal requirements, damaged and expired pharmaceuticals create a larger waste stream of potentially hazardous waste and associated environmental impacts. Disposing a large amount of pharmaceuticals also creates greater entry points of pharmaceuticals to be diverted from the waste stream into the community for improper and possibly hazardous consumption.
Sub-activity 3.2: Procurement of health commodities	Procurement or acceptance of donated health commodities that are defective, expired, or counterfeit may lead to public health impacts due to the potential of these commodities being unsafe and/or ineffective if used by consumers. Adverse health and environmental impacts may also occur if defective, expired, or counterfeit health commodities are not properly managed and disposed.
Sub-activity 3.3: Operation and maintenance of storage facilities containing public health commodities	Improper storage of public health commodities can result in pharmaceuticals being damaged due to failure to meet storage condition requirements, theft through inadequate security, damage from pests, and hazards such as fire. Environmental and social impacts may result from damaged products getting into the environment or local community due to improper storage. In addition, equipment used to operate the storage facility (e.g., mobile equipment, chillers, HVAC systems, fuel storage tanks) should be properly maintained to prevent accidents or spills from occurring that may lead to health or environmental impacts.
Sub-activity 3.4: Distribution and/or transportation of public health commodities	Improper distribution and/or transportation of public health commodities can result in reduction in PHC quality (e.g., damaged or defective supplies) through inadequate temperature or humidity controls. Environmental impacts may occur from the use of vehicles to distribute supplies (e.g., fuel operation, maintenance) or if an accident or spill occurs during transportation that releases commodities to the environment. Unsecured vehicles can result in theft.
Sub-activity 3.5: Collection, transport, treatment, and/or disposal of healthcare commodities or hazardous waste/products	Improper transportation, treatment and/or disposal of HCW may lead to adverse health and environmental impacts. Workers and others handling HCW may be in direct contact with hazardous waste during treatment and/or disposal activities, which could lead to health impacts. Environmental impacts may occur from the use of vehicles to transport wastes (e.g., fuel operation, maintenance) and/or traffic accidents resulting in spills.

3.1 THREATENED AND ENDANGERED SPECIES

The activities proposed include work in already developed areas, clinical settings, and existing infrastructure. Therefore, the activities are not likely to adversely impact threatened and endangered species, or their critical habitat. Activity level actions that include construction or infrastructure improvements should be assessed for the presence of threatened or endangered species, or their critical habitat. Any activity that may adversely impact threatened or

endangered species or their critical habitat may not proceed without an Environmental Assessment.

4.0 ENVIRONMENTAL DETERMINATIONS

4.1 RECOMMENDED ENVIRONMENTAL DETERMINATIONS

The following table summarizes the recommended determinations based on the environmental analysis conducted. Upon approval, these determinations become affirmed, per 22 CFR 216. Specified conditions, detailed in Section 5, become mandatory obligations of implementation, per ADS 204.

TABLE 4: **ENVIRONMENTAL DETERMINATIONS**

Projects/Activities	Categorical Exclusion Citation (if applicable)	Negative Determination	Positive Determination [4]	Deferral[5]
Activity 1: NTD Technical Assistance (TA), Capacity Building, and Training programs				
Sub-activity 1.1: Conduct technical assistance, training, and capacity-building activities	**Categorical Exclusion, per 22 CFR 216.2(c)(2)(i).** Education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.)	☐	☐	☐
Sub-activity 1.2: Provide funding for researchers and institutions	**Categorical Exclusion, per 22 CFR 216.2(c)(2)(vii).** Institution building grants to research and educational institutions in the United States such as those provided for under section 122(d) and title XII of chapter 2 of part I of the FAA (22 USCA 2151 p. (b) 2220a. (1979))	☐	☐	☐
Activity 2: Research and Development (Field and Laboratory Diagnostic Testing)				
Sub-activity 2.1: Conduct field testing commodities and diagnostics		X	☐	☐
Sub-activity 2.2: Conduct		X	☐	☐

[4] Positive Determinations require preparation of a Scoping Statement and Environmental Assessment.
[5] GH does not grant deferrals during the IEE process.

diagnostics laboratory testing to detect the presence of NTD				
Activity 3: Healthcare Commodities Inventory Management, Sourcing, Procurement, Storage, Distribution, Quality Control Management, Treatment and/or Disposal				
Sub-activity 3.1: Quantification and/or forecasting of health commodities and inventory management		X	☐	☐
Sub-activity 3.2: Procurement of health commodities		X	☐	☐
Sub-activity 3.3: Operation and maintenance of storage facilities containing public health commodities		X	☐	☐
Sub-activity 3.4: Distribution and/or transportation of public health commodities		X	☐	☐
Sub-activity 3.5: Collection, transport, treatment, and/or disposal of healthcare commodities or hazardous waste/products		X	☐	☐

4.2 CLIMATE RISK MANAGEMENT

This section summarizes the methodology used and findings of the CRM Screening, in accordance with ADS 201mal. The project design team, in consultation with the CIL, considered the potential effect of climate risks/stressors on the sustainability of the project (changing precipitation patterns, rising temperature, floods, droughts, fires, landslides, etc.) in addition to the impact of project activities on the climate (increased greenhouse gas emissions, land use changes, etc.). See Annex 1 for the complete CRM table.

The results of the assessment concluded that one activity had low climate risks and five activities had a moderate climate risk. ENDOR will plan to address the risks and leverage opportunities for climate change resilience. Reference Annex 1 for the complete CRM table.

5.0 CONDITIONS AND MITIGATION MEASURES

5.1 CONDITIONS

The environmental determinations in this IEE are contingent upon full implementation of the following general implementation and monitoring requirements, as well as ADS 204 and other relevant requirements.

5.1.1 During Pre-Award:

5.1.1.1 Pre-Award Briefings: As feasible, the design team and/or the cognizant environmental officer(s) (e.g., MEO, REA, BEO) will provide a pre-award briefing for potential offerors on environmental compliance expectations/responsibilities at bidders' conferences.

5.1.1.2 Solicitations: The design team, in coordination with the A/CO, will ensure solicitations include environmental compliance requirements and evaluation criteria. A/CO will ensure technical and cost proposal requirements include approach, staffing, and budget sufficient for complying with the terms of this IEE.

5.1.1.3 Awards: The A/COR, in coordination with the A/CO, will ensure all awards and sub-awards, include environmental compliance requirements.

5.1.1.4 Training: The A/COR and AM(s) assigned to this project are to enroll in and successfully complete the Bureau for Global Health Environmental Management Process Training online course prior to receiving GH BEO clearance on this document.

5.1.2 During Post-Award:

5.1.2.1 Post-Award Briefings: The A/COR and/or the cognizant environmental officer(s) (e.g., MEO, REA, BEO) will provide post-award briefings for the IP on environmental compliance responsibilities.

5.1.2.3 Workplans and Budgeting: The A/COR will ensure the IP integrates environmental compliance requirements in work plans and budgets to comply with requirements, including EMMP implementation and monitoring.

5.1.2.4 Staffing: The A/COR, in coordination with the IP, will ensure all awards have staffing capacity to implement environmental compliance requirements.

5.1.2.5 Records Management: The A/COR will maintain environmental compliance documents in the official project/activity file and upload records to the designated USAID environmental compliance database system.

5.1.2.6 Host Country Environmental Compliance: The A/COR will ensure the IP complies with applicable and appropriate host country environmental requirements unless otherwise directed in writing by USAID. However, in the case of a conflict between the host country and USAID requirements, the more stringent shall govern.

5.1.2.7 Work Plan Review: The A/COR will ensure the IP verifies, at least annually or when activities are added or modified, that activities remain with the scope of the IEE. Activities outside of the scope of the IEE cannot be implemented until the IEE is amended.

5.1.2.8 IEE Amendment: If new activities are introduced or other changes to the scope of this IEE occur, an IEE Amendment will be required.

5.1.2.14 USAID Monitoring Oversight: The A/COR or designee, with the support of the cognizant environmental officer(s) (e.g., MEO, REA, BEO), will ensure monitoring of compliance with established requirements (e.g., by desktop reviews, site visits, etc.).

5.1.2.16 Environmental Compliance Mitigation and Monitoring Plan: The A/COR will ensure the IP develops, obtains approval for, and implements Environmental Mitigation and Monitoring Plans (EMMPs) that are responsive to the stipulated environmental compliance requirements.

5.1.2.17 Environmental Compliance Reporting: The A/COR will ensure the IP includes environmental compliance in regular project/activity reports, using indicators as appropriate; develops and submits the Environmental Mitigation and Monitoring Reports (EMMRs); and completes and submits a Record of Compliance (RoC) describing their implementation of EMMP requirements in conjunction with the final EMMR or at the close of sub activities (as applicable). And where required by Bureaus or Missions, ensure the IP prepares a closeout plan consistent with contract documentation for A/COR review and approval that outlines responsibilities for end-of-project operation, the transition of other operational responsibilities, and final EMMR with lessons learned.

5.1.2.18 Corrective Action: When noncompliance or unforeseen impacts are identified, IPs notify the A/COR, place a hold on activities, take corrective action, and report on the effectiveness of corrective actions. The A/COR initiates the corrective action process and ensures the IP completes and documents their activities. Where required by Bureaus or Missions, ensure Record of Compliance is completed.

5.1.2.19 Threatened and Endangered Species: Activities that may adversely impact the continued existence of threatened or endangered species or their critical habitat are not authorized. Activity level actions that include construction or infrastructure improvements must be assessed for the presence of threatened or endangered species, or their critical habitat. Any activity that may adversely impact threatened or endangered species or their critical habitat may not proceed without an Environmental Assessment.

5.2 AGENCY CONDITIONS

5.2.1 Sub-award Screening: The A/COR will ensure the IP uses an adequate environmental screening tool to screen any sub-award applications and to aid in the development of EMMPs.

5.2.2 Programmatic IEEs (PIEE): PIEEs stipulate requirements for additional environmental examination of new or country specific projects/activities. The A/COR of any project/activity being implemented under a PIEE will ensure appropriate reviews are conducted, typically through a Supplemental IEE, and approved by the cognizant BEO.

5.2.3 Supplemental IEEs (SIEEs): An SIEE will be prepared for any new project/activity being planned which fall under a PIEE. The SIEE will provide more thorough analysis of the planned activities, additional geographic context and baseline conditions as well as specific mitigation and monitoring requirements.

5.2.4 Other Supplemental Analyses: The A/COR will ensure supplemental environmental analyses that are called for in the IEE are completed and documented.

5.2.5 Resolution of Deferrals: If a deferral of the environmental threshold determination was issued, the A/COR will ensure that the appropriate 22CFR216 environmental analysis and documentation is completed and approved by the BEO before the subject activities are implemented.

5.2.6 Positive Determination: If a Positive Determination threshold determination was made, the A/COR will ensure a Scoping Statement, and if required an Environmental Assessment (EA), is completed and approved by the BEO before the subject activities are implemented.

5.2.7 Compliance with human subject research requirements: The AM, A/COR shall assure that the IP and sub-awardees, -grantees, and -contractors demonstrate completion of all

requirements for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this IEE and ensure appropriate records are maintained. All documentation demonstrating completion of required review and approval of human subject trials must be in place prior to initiating any trials and cover the period of performance of the trial as described in the research protocol.

5.3 MITIGATION MEASURES

The mitigation measures presented in this section constitute the minimum required based on available information at the time of this IEE and the environmental analysis in Section 4. These measures shall provide general direction for completing the project/activity Environmental Mitigation and Monitoring Plan (EMMP) and/or the EA and PERSUAP, if required.

ACTIVITY 1: NTD Technical Assistance, Capacity Building, and Training Programs

TABLE 5A. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 1

Project/Activity	Mitigation Measure(s)
Activity 1: NTD Technical Assistance (TA), Capacity Building, and Training programs	
Sub-activity 1.1: Conduct technical assistance, training, and capacity-building activities	**These activities qualify for Categorical Exclusion, per 22 CFR 216.2(c)(2)(i).** Education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.)
Sub-activity 1.2: Provide funding for researchers and institutions	**These activities qualify for Categorical Exclusion, per 22 CFR 216.2(c)(2)(vii).** Institution building grants to research and educational institutions in the United States such as those provided for under section 122(d) and title XII of chapter 2 of part I of the FAA (22 USCA 2151 p. (b) 2220a. (1979))

ACTIVITY 2: Research and Development (Field and LABORATORY Diagnostic Testing)

TABLE 5B. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 2

Project/Activity	Mitigation Measure(s)
Activity 2: Research and Development (Field and Laboratory Diagnostic Testing)	
Sub-activity 2.1: Conduct field testing commodities and diagnostics	• Develop, provide training for, and implement a laboratory environmental, health, and safety (EHS) manual with standard operating procedures (SOPs) that address the management of waste streams associated with site operations. • Field technicians will be required to wear PPE (**only** BSL2) while conducting lab work. There will be routine checks to ensure laboratories have sufficient PPE supplies. • Sharps should be collected and stored in puncture proof, and tamper-proof containers with fitted covers. • Highly infectious waste should be immediately sterilized by autoclaving or high temperature incineration • On-site collection of waste should be handled at frequent intervals to avoid accumulation • In any area that produces hazardous waste, implementing partners will use separate bins

Sub-activity 2.2: Conduct diagnostics laboratory testing to detect the presence of NTD	• Lab personnel will be required to wear PPE while conducting lab work. There will be routine checks to ensure laboratories have sufficient PPE supplies. • Sharps should be collected and stored in puncture proof, and tamper-proof containers with fitted covers. • Highly infectious waste should be immediately sterilized by autoclaving or high temperature incineration • On-site collection of waste should be handled at frequent intervals to avoid accumulation • In any area that produces hazardous waste, implementing partners will use separate bins

ACTIVITY 3: HEALTHCARE COMMODITIES INVENTORY MANAGEMENT, SOURCING, PROCUREMENT, STORAGE, DISTRIBUTION, QUALITY CONTROL MANAGEMENT, TREATMENT AND/OR DISPOSAL

TABLE 5C. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 3

Project/Activity	Mitigation Measure(s)
Activity 3: Healthcare Commodities Inventory Management, Sourcing, Procurement, Storage, Distribution, Quality Control Management, Treatment and/or Disposal	
Sub-activity 3.1: Quantification and/or forecasting of health commodities and inventory managements	• ENDOR will provide oversight on aspects of essential supply chain management, including estimating demand, distribution, and storage issues of time and temperature. • ENDOR partners will conduct quantitative analysis to determine supply needs and perform routine inventory counts to avoid procuring an oversupply or commodity diversion • ENDOR will help identify bottlenecks that could result in the generation of expired/unused drugs at all levels of the distribution chain • ENDOR will develop a supply plan
Sub-activity 3.2: Procurement of health commodities	• Implementing partners will ensure procured public health commodities are stored according to the information provided on the Materials Safety Data will Sheet (MSDS). • Procure health commodities that comply with international and host country regulations and shipping and packaging requirements to ensure that only appropriate products enter the supply system. • Maintain copies of procurement records and copies of quality documents on file. • Develop and implement an inspection and quality assurance process for assessing and monitoring product quality.
Sub-activity 3.3: Operation and maintenance of storage facilities containing public health commodities	• Develop, implement, and train staff on standard operating procedures (SOPs) for the safe and effective storage of PHC to reduce damage or early expiration. • Provide workers with training on SOPs, proper handling, use, and disposal of pharmaceuticals and health commodities • ENDOR will assure facilities have adequate procedures and capacities in place to properly handle, label, treat, store, and transport pharmaceuticals and other wastes • Ensure that the implementing partners have standard operating procedures (SOPs) established for properly transporting, treating, and disposing of healthcare waste offsite in conformance with host country requirements and international best practices. Considerations include but are not limited to waste exportation protocols (if applicable), operational and

	monitoring requirements, and appropriate transport and disposal documents and records. • Packaging and disposal of all public health commodities will be treated using the guidelines provided in the WHO safe management of wastes from health-care activities and/or applicable national government policies whichever is more rigorous
Sub-activity 3.4: Distribution and/or transportation of public health commodities	• Develop, implement, and train staff on standard operating procedures (SOPs) for the safe, bulk distribution and/or transportation of PHCs being transported in motorized vehicles. • Provide workers with training on SOPs, proper handling, use, and disposal of laboratory commodities and diagnostics • Provide workers with adequate PPE and provide trainings on proper PPE attire • The project will assure facilities have adequate procedures and capacities in place to properly handle, label, treat, store transport pharmaceuticals and other wastes • Vehicles storing commodities during transportation and distribution will be locked when unattended • Commodities will be stored properly and in appropriate containers during transportation to mitigate the risk of spillage • ENDOR will develop and implement standard operating procedures (SOPs) for the safe and effective distribution and storage of commodities to reduce damage or early expiration.
Sub-activity 3.5: Collection, transport, treatment, and/or disposal of healthcare commodities or hazardous waste/products	• Provide workers with training on proper handling, use, and disposal of laboratory commodities and medical waste • Packaging and disposal of all public health commodities will be treated using the guidelines provided in the WHO safe management of wastes from health-care activities. • Ensure standard operating procedures are in place for properly transporting and disposing of medical waste and follow country regulations • Ensure standard operations procedures are in plate for properly managing expired and damaged stocks of consumables/products. • Maintain documentation and records of procedures and waste management and contractor licenses, as appropriate. • Sharps should be collected and stored in puncture proof, and tamper-proof containers with fitted covers. • Highly infectious waste should be immediately sterilized by autoclaving or high temperature incineration • On-site collection of waste should be handled at frequent intervals to avoid accumulation • In any area that produces hazardous waste, use separate bins for hazardous waste and general waste

6.0 LIMITATIONS OF THIS INITIAL ENVIRONMENTAL EXAMINATION

The determinations recommended in this document apply only to projects/activities and sub-activities described herein. Other projects/activities that may arise must be documented in either a separate IEE, an IEE amendment if the activities are within the same project/activity, or

other type of environmental compliance document and shall be subject to an environmental analysis within the appropriate documents listed above.

Other than projects/activities determined to have a Positive Threshold Determination, it is confirmed that the projects/activities described herein do not involve actions normally having a significant effect on the environment, including those described in 22 CFR 216.2(d). The activities described herein are not likely to adversely impact threatened or endangered species or their critical habitat. Any activity that is likely to adversely affect threatened or endangered species or their critical habitat will result in a Positive Determination and necessitate production of a Scoping Statement and Environmental Assessment.

In addition, other than projects/activities determined to have a Positive Threshold Determination and/or a pesticide management plan (PERSUAP), it is confirmed that the projects/activities described herein do not involve any actions listed below. Any of the following actions would require additional environmental analyses and environmental determinations:

- Support project preparation, project feasibility studies, or engineering design for activities listed in §216.2(d)(1);
- Affect endangered and threatened species or their critical habitats per §216.5, FAA 118, FAA 119;
- Provide support to extractive industries (e.g. mining and quarrying) per FAA 117;
- Promote timber harvesting per FAA 117 and 118;
- Lead to new construction, reconstruction, rehabilitation, or renovation work per §216.2(b)(1);
- Support agro-processing or industrial enterprises per §216.1(b)(4);
- Provide support for regulatory permitting per §216.1(b)(2);
- Lead to privatization of industrial facilities or infrastructure with heavily polluted property per §216.1(b)(4);
- Research, testing, or use of genetically engineered organisms per §216.1(b)(1), ADS 211
- Assist the procurement (including payment in kind, donations, guarantees of credit) or use (including handling, transport, fuel for transport, storage, mixing, loading, application, clean-up of spray equipment, and disposal) of pesticides or activities involving procurement, transport, use, storage, or disposal of toxic materials. Pesticides cover all insecticides, fungicides, rodenticides, etc. covered under the Federal Insecticide, Fungicide, and Rodenticide Act per §216.2(e) and §216.3(b).

7.0 REVISIONS

Per 22 CFR 216.3(a)(9), when ongoing programs are revised to incorporate a change in scope or nature, a determination will be made as to whether such change may have an environmental impact not previously assessed. If so, this IEE will be amended to cover the changes. Per ADS 204, it is the responsibility of the USAID A/COR to keep the MEO/REA and BEO informed of any new information or changes in the activity that might require revision of this environmental analysis and environmental determination.

ATTACHMENTS:

Annex 1: Climate Risk Management Summary Table for Activity
Annex 1: Activity Green Meeting checklist

ANNEX 1. **ACTIVITY** CLIMATE RISK MANAGEMENT SUMMARY TABLE

Tasks/Defined or Illustrative Interventions	**Climate Risks[6]**	**Risk Rating[7]**	**How Risks are Addressed[8]**	**Opportunities to Strengthen Climate Resilience[9]**
Education, training, capacity building, technical assistance	Disruption or delayed events due to extreme weather events caused by climate change	Low	USAID and implementing partners will monitor the potential for adverse weather and find alternate locations for events when able	None
Procurement, storage, distribution of public health commodities	Disruptions in commodities supply chain due to other infectious disease outbreak or extreme weather/climate event	Moderate	USAID will work with the implementing partner to develop contingency plans for minimizing disruptions of commodity supply chains	USAID will leverage other existing resources such as early warning systems that can detect future extreme weather or climate events that can disrupt supply chains
Conduct field validation and testing of diagnostics and other tools in the field	Delayed/canceled assessments due to infectious disease outbreak or extreme climate change event	Moderate	USAID will work with implementing partners to ensure that delayed or canceled field-testing activities are rescheduled and completed according to WHO guidelines.	USAID will leverage existing early warning systems to adapt the timing of field-testing activities that may be impacted by extreme weather or climate change events. USAID will work across sectors within the Agency to leverage other USAID funded initiatives to continuously foster informed decision making
	Missed populations while conducting field activities due to displacement from infectious disease outbreak or extreme/weather climate events such as droughts	Moderate	USAID will work with implementing partners and beneficiary country officials to monitor climate events or infectious disease outbreaks that may affect or influence population mobility and will develop a contingency plan to ensure that the intended populations are reached.	
	Emergence or re-emergency of diseases	Moderate	USAID will work with implementing partners to support capacity building	

[6] List key risks related to the defined/illustrative interventions identified in the screening and additional assessment.
[7] Low/Moderate/ High
[8] Describe how risks have been addressed in activity design and/or additional steps that will be taken in implementation. If you chose to accept the risk, briefly explain why.
[9] Describe opportunities to achieve multiple development objectives by integrating climate resilience or mitigation measures

Tasks/Defined or Illustrative Interventions	Climate Risks[6]	Risk Rating[7]	How Risks are Addressed[8]	Opportunities to Strengthen Climate Resilience[9]
	through shifting migratory paths and species habits due to a variety of climate changes		to develop and manage robust surveillance systems that are able to detect emergence or re- emergence of NTDs among communities.	and strengthen surveillance systems. USAID's NTD division will leverage other Global Health Bureau offices such as the Emerging Threats Division to stay informed on the latest tools available and information on shifting migratory paths that could affect NTDs.
	Introduction or re-introduction of NTDs due to altered transmission cycles resulting from shifts in the geographic range, seasonal presence, and biting rates of disease vectors due to changes in temperature, precipitation (especially flood/drought cycles) and ecology.	Moderate	USAID will work with implementing partners to support capacity building to develop and manage strong surveillance systems that are able to detect introduction or re-introduction of NTDs	

Annex 1. **Activity Green Meeting checklist**

Environmentally aware meetings and events are those planned in such a way as to eliminate, reduce, or recycle waste. This Checklist is intended to heighten the environmental consciousness of event planners and demonstrate the advantages of conducting environmentally aware events. This Checklist was adopted from the US Environmental Protection Agency recommendation of the Green Meeting Industrial Council (GMIC), http://www.epa.gov/oppt/greenmeetings/pubs/basic.html.

Preventing and Reducing Waste

- □ Focus on reducing waste, given limited in-country recycling facilities.
- □ Use double-sided printing, recycled content -where available- for promotional materials and handouts.
- □ Avoid mass distribution of handouts. Allow attendees to request copies or provide digital copies via CD, thumb drive, or website.
- □ Provide reusable name badges.
- □ Purchase large volume plastic bottles of water to dispense into glasses at each table, instead of individual sized plastic bottles
- □ Other actions: ____

Recycling and Managing Waste

- □ Where facilities exist, collect paper and recyclable beverage containers in meeting areas.
- □ Collect cardboard and paper in exhibit areas.
- □ Collect cardboard, beverage containers, steel cans, and plastics in food vending areas.
- □ Separate out organic waste for composting, Provide composting guidelines for conference venues.
- □ If reusable containers are not used, encourage use of recyclable containers.
- □ Other actions: ____

Conserving Energy and Reducing Traffic

- □ Seek naturally lighted meeting and exhibit spaces.

- □ Provide shuttle service from hotels to the event site.
- □ Choose meeting sites that have on-site housing.
- □ Other actions: ____

Contracting Food Service and Lodging

- □ Plan food service needs carefully to avoid unnecessary waste.
- □ Consider use of durable food service items instead of disposables.
- □ Donate excess food to charitable organizations, including planning ahead via SOW/contract with the conference venue to ensure this happens.
- □ Work with non-replacement of linens, soaps, etc.
- □ Other actions: ____

Buying Environmentally Aware Products

- □ Use recycled paper for promotional materials and handouts, where available.
- □ Consider selling or providing refillable containers for beverages.
- □ Provide reusable containers for handouts or samples (pocket or file folders, cloth bags).
- □ Where reusable items are not feasible, select products that are made from recovered materials and that also can be recycled.
- □ Other actions: ____

Educating Participants and Exhibitors

- □ Request the use of recycled and recyclable handouts or giveaways.
- □ Request that unused items be collected for use at another event.
- □ Encourage participants to recycle materials at the event.

- Reward participation by communicating environmental savings achieved.

Other actions:

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