REQUEST FOR PROPOSALS

Protocol development and implementation for a randomized controlled trial to evaluate the immune response from two standard purified protein derivative tuberculin solutions to detect latent tuberculosis infection.

RFP Release Date:	October 26, 2021
Questions Due Date:	November 01, 2021. Submission of questions or requests for clarification must be submitted in writing via email to ProcurementVietnam@fhi360.org by 5:00 pm Hanoi. Please note that questions and answers to questions will be shared with all applicants, through an annex to the original post on the NGO Resource Center website. The full questions and answers will be released to all applicants three days following the question due date. Please do not contact any FHI 360 employees regarding this RFP. Contacting individual employees may be cause for disqualification. No Telephone Inquiries Will Be Answered.
Proposal Due Date:	November 08, 2021, 5:00pm Hanoi. Complete proposals must be submitted via email to ProcurementVietnam@fhi360.org no later than 5:00 pm Hanoi.
Anticipated Contract Start Date:	November, 2021

Issued by FHI 360/ Vietnam

The contents of this Request for Proposals are the responsibility of FHI 360 and do not necessarily reflect the views of USAID or the United States Government.

OVERVIEW

Family Health International (FHI 360) office in Vietnam requires the services of a clinical research organization (CRO) to support operations and data-collection for a randomized controlled trial to evaluate the immune response from two standard purified protein derivate tuberculin solutions to detect latent tuberculosis infection in Vietnam. The assessment is funded by USAID under the cooperative agreement #72044020CA00002 "Support to End Tuberculosis Project".

BACKGROUND

The primary aim of this study is to compare the intradermal immune reaction to two purified protein derivative (PPD) tuberculin solutions, which are used to detect latent tuberculosis (TB) infection. This method, called "tuberculin skin testing", has been the standard method for over forty years to detect exposure to TB. This randomized controlled trial will compare a PPD tuberculin solution that is approved by the United States Food and Drug Administration, Aplisol, with the current PPD tuberculin solution that is utilized in Vietnam, Bulbio. A secondary objective of this study will be to compare the intradermal immune reaction from Aplisol and Bulbio PPD tuberculins to an in vitro immune response, which will be elicited on whole blood using a commercial immunoglobulin release assay (IGRA), QuantiFERON-TB-Plus. IGRAs are also a standard method of detecting latent TB infection, which is newer than tuberculin skin testing and also more expensive.

The study will enroll approximately 800 participants in two provinces of Vietnam. Participants will be recruited from community campaigns for TB "case finding"; most campaign participants are household contacts of pulmonary TB patients or other groups that are high risk for TB, including smokers, diabetics, elderly, or those with underlying lung disease. Following study data collection training, trained clinic providers will recruit potential participants and obtain written informed consent prior to enrollment from eligible participants. Data will be collected on paper forms and then electronically entered and uploaded to a secure database. Participants will have the study procedures performed on the day of enrollment, and they will return 48 to 72 hours after the study procedures to have the final results interpreted.

SCOPE OF WORK

Under the leadership of the Vietnam National Tuberculosis Program/National Lung Hospital and with assistance from FHI 360, the CRO will facilitate all study operations and data collection over a total period of approximately 12 months, from inception to implementation to data cleaning and initial analysis. The NTP and FHI 360 will lead scientific investigation with approval of all protocols and study instruments, facilitation of study site inclusion and overall data quality assurance. FHI 360 will facilitate institutional review board approvals in the US, conduct analysis on a de-identified database, and draft the final report. The CRO or NTP will complete other study reporting and NTP will lead results approval and dissemination.

The CRO will be responsible for the following:

1. **Protocol development and approval:** The CRO will assist on protocol development, including research and ethics approval at the Vietnam National Lung Hospital and Ministry of Health
2. **Shipping, importation, customs approval:** The CRO will support the NTP to obtain approval from the Drug Administration of Vietnam for importation and customs approval/clearance.
3. **Study launch and enrollment**: Enrollment will likely comprise approximately 1-2 months at the most, depending upon the number of districts to meet the required sample size. The CRO will be responsible for training and monitoring the sites throughout enrollment.
    a. Conduct training of site-staff and study staff in-line with the study protocol: In each health facility included in the study, there will be at least one designated medical professional

currently on facility staff who will recruit, enroll, and collect and enter data from participants. This designated provider(s) will be trained in human subject research ethics, informed consent, data collection using the study tools, and critical values for urgent clinical attention. Staff will be trained by the CRO, which will include practical components to ensure competency conducting data collection. The CRO is responsible for oversight and for delivering targeted refresher trainings as may be required throughout the period of implementation.

b. Ensure oversight and monitoring of study enrollments: The CRO will monitor the quality of data in the entered forms, the number of enrolled participants required for the study and ensure that all participants have an accompanying written informed consent form appropriately filed.

4. **Data collection and monitoring**: The CRO will be responsible for ensuring that all operations and data collection activities are conducted with strict adherence to the study protocol and ethical approvals. The NTP and FHI 360 will provide the contracted CRO with the approved study protocol and all study instruments upon award such as eligibility checklists, etc.

   a. Set up a secure database for data storage: The CRO will be responsible for electronic storage of study data and will provide final datasets to the NTP and FHI 360 for analysis. The data entry and management platform will be developed by the CRO and pre-tested and periodically monitored by FHI 360 staff. The database will contain field entry limits and automated skip patterns to minimize data entry errors, further limited by cross-comparison with the paper record for query. The CRO will work with the NTP and FHI 360 as necessary to clarify or conduct checks on data during analysis. The CRO will establish safety monitoring standards within their manual of operations, in collaboration and by direction of the NTP that comply with Good Clinical Practice (GCP) standards.

   b. Conduct data entry; data cleaning; and data quality assurance: The CRO will monitor the quality of data in all forms and questionnaires, including review of forms for adherence to skip patterns, correct completion of all fields (particularly lab results), and Study ID. On-site monitoring will occur on an as-needed basis and include review of consent forms to verify all have been signed and are being stored securely and separately from the log-book and data collection instruments. The monitor will conduct re-training based on data quality issues detected at monitoring and/or assess enrollment against facility records. Paper-based instruments will be collected at least monthly in strict adherence with security protocols.

   c. Data analysis: The CRO will be responsible for data cleaning and finalization of the raw dataset. FHI 360 will be responsible for finalization of the analytical dataset and for the analyses.

All tasks must be proposed and conducted within the anticipated study time frame:

November-December 2021: protocol development and finalization
December 2021-January 2022: ethics and scientific approval in the United States and in Vietnam
February 2022 – April 2022: importation and customs approval
April – May 2022: shipping of purified protein derivative tuberculin (Aplisol and Bulbio) solutions
June 2022: Site training
July – August 2022: Study implementation and enrollment
September-October 2022: data cleaning and initial analysis

SUBMISSION REQUIREMENTS

FHI 360 is requesting interested firms to provide the following:

1. **Technical Approach**: Not to exceed a **five-page narrative** explaining the applicant's approach for implementing the activity, including proposed implementation plan and projected timeframe. The technical approach should include:
    - An overview of the proposed training methodology and plan for effective site monitoring to ensure effective training and effective and compliant enrollment of study participants.
    - A description of the data collection and quality control process to be instituted, including risk mitigation.
    - A description of the secure server and procedures for data entry, user permissions and data extraction.
    - A deliverables table that summarizes the anticipated deliverables, based on the tasks described above, and due date for submission to FHI 360.

2. **Corporate Capabilities and Past Experience Statement**: Not to exceed **two-page narrative** detailing the organization's capabilities to perform the scope of work indicating past experience overseeing studies in Vietnam, delivering training and managing secure data collection and delivery. As an annex, details of two organizational references from previous funders/investors, clients, or partners including contact information (names, company or organization, phone number and email) must be provided.

3. **Staffing/Personnel Statement:** This section must include a statement demonstrating the proposed personnel's relevant skills, qualifications and past experience to successfully complete this assignment, not to exceed **two pages**. As an annex the applicant should include:
    - CVs of the proposed personnel who will conduct the work may be include (maximum 2 pages per CV)
    - A biodata form (Attachment B) for each proposed personnel who will conduct the work

4. **Cost Proposal**: The cost proposal will be based on the tasks indicated above, the deliverables proposed in the Technical Approach and the illustrative calendar. The budget must be presented in the format included as Attachment A and must contain detailed line item costs, a budget narrative, and any supporting documentation that clearly show how the budgeted amounts were calculated. The applicant must include the total fee per deliverable proposed in the Technical Approach.

    When preparing the budget and the budget narrative, the applicant must follow these instructions:
    - Budgets must be accompanied by a brief narrative explanation and justification for each line item. The budget narrative must include data to support actual costs and/or methodologies to support cost estimates. The budget narrative should be presented in such a way as to be easily referenced from the budget and should provide sufficient information so that FHI 360 may review a proposed budget for reasonableness. All projected costs must be in accordance with the organization's standard practices and policies.
    - Budgets must be sufficiently detailed to demonstrate reasonableness and completeness. Offerors including budget information determined to be unreasonable, incomplete, unnecessary for the completion of the proposed project, or based on a methodology that is not adequately supported may be deemed unacceptable.
    - Budgets must be submitted in VND.
    - If the budget includes an indirect rate, offerors must attach a Negotiated Indirect Rate Cost Agreement (NICRA), or an independent auditor-certified indirect rate based upon the last 3 years of audited financial statements. If the offeror does not have a copy of this to support the indirect rate proposed, they must break out the costs and charge the costs as fixed amounts and must be shown as separate line items in the budget and charge the costs as direct expenses shown via line

items in the budget. If the costs are charged as fixed amounts, in the budget narrative please explain the methodology and calculation behind the estimated fixed amounts.

5. **Other Attachments**
    1. Registration certificate for the organization in Vietnam

Responses to this RFP should be submitted by email to ProcurementVietnam@fhi360.org no later than 5:00 pm, November 08, 2021, Hanoi time. with subject line "RFP Aplisol Study Implementation." Any proposals received after this date and time may not be accepted and shall be considered non-responsive. FHI 360 will acknowledge receipt of the quotation by return email within 24 hours.

Any questions or requests for clarification can be submitted in writing to the same email address above by **November 01, 2021 at 5:00 P.M. Hanoi.** No telephone inquiries will be answered.

ELIGIBLE APPLICANTS

This competition is open to any non-governmental, non-profit entity or private sector (for-profit) entity that meets the criteria set forth in this RFP. To be minimally eligible for funding, offerors must comply with the following conditions:

- Organizations must be legally registered or otherwise authorized to conduct business in Vietnam

CRITERIA FOR EVALUATION

The criteria presented below have been tailored to the requirements of this RFP. A total of 100 points are possible for the complete proposal. The relative importance of each criterion is indicated by approximate weight by points.

Evaluation Criteria	Points
Technical Approach • Understanding of the subject matter and requirements for conducting a rigorous study in a healthcare setting. • Comprehensiveness of proposed approach and technical soundness of methodology and reasoning why the methodology was chosen. • Implementation plan and proposed timeline are realistic and include all proposed elements of the activity.	35 points
Corporate Capabilities and Past Experience • Experience and capacity of the organization(s) in managing studies and data collection and adequacy of resources.	30 points
Staffing/Personnel • Proposed staff person(s) who will be responsible for implementation have the relevant skills and past experience to successfully complete the assignment. • The proposed management structure is reasonable and sufficient to implement this work.	15 points
Budget • Proposed budget is reasonable and all costs included are allocable to this activity and allowable under USAID rules and regulations.	20 points
TOTAL	**100 points**

CONTRACTING MECHANISM

A firm fixed-price subcontract may be awarded in VND to the responsive vendor whose proposal will be evaluated I accordance with the evaluation criteria. The anticipated ceiling for the award is US$ 100,000.

TERMS and CONDITIONS

1. FHI 360 may cancel an RFP and/or not make awards.
2. FHI 360 may reject any or all of the responses to its RFP.
3. Issuance of an RFP does not constitute award commitment by FHI 360.
4. FHI 360 reserves the right to disqualify any application based on offeror failure to follow RFP instructions.
5. FHI 360 will not reimburse applicants for the cost of preparing and submitting an application to an RFP.
6. FHI 360 reserves the right to issue an award on the basis of an initial evaluation of offers without further discussion.
7. FHI 360 may award grants for only part of the activities listed in an RFP.
8. FHI 360 reserves the right to check an applicant's donor references.
9. FHI 360 also reserves the right to reject any or all applications received without explanation.
10. FHI 360 has the right to issue amendments to the RFP at any time.

Request for Proposals Firm Guarantee:

All information submitted in connection with this RFP will be valid for **thirty (30) days** from the RFP due date. This includes, but is not limited to, cost, pricing, terms and conditions, service levels, and all other information. If your firm is awarded the contract, all information in the RFP and negotiation process is contractually binding.

Offer Verification:

FHI 360 may contact offerors to confirm validity of the offer, contact person, address, and bid amount.

False Statements in Offer:

Offerors must provide full, accurate, and complete information as required by this solicitation and its attachments.

(End of RFP)