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NIH National Institute of Allergy and Infectious Diseases

DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

CRDF Global Request for Proposals (RFP)
INDO-U.S. VACCINE ACTION PROGRAM (VAP) INITIATIVE ON TUBERCULOSIS (TB) RESEARCH: REGIONALPROSPECTIVEOBSERVATIONAL RESEARCH FORTUBERCULOSIS- RePORT INDIA

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I. PROGRAMSNAPSHOT

Eligible Applicant(s)	Investigators from currently active US and Indian RePORT sites, as well as other appropriate Indian/US collaborators.
RFP Opens	Monday, December 10, 2018 (23:59) U.S. Eastern Standard Time (EST)
Submission Deadline	Thursday, February 28th, 2019 (23:59) U.S. Eastern Standard Time (EST)
Eligible Research Scope	To build and enhance biomedical and clinical research capacity in India by establishing long term longitudinal cohorts of TB patients and their contacts (or other high TB risk patients) by supporting participating investigators of the RePORT India consortia and inviting new investigators to evolve a single network.
Project Duration	Up to five (5) years
Award Amounts	One award will be supported through this RFP. This includesUSD1.5 million from NIH through CRDF including administrative function for the lead institution and matching funding support from DBT based on appropriate justification. Overall budget should not exceed 2.25 million annually. Please review Section VII: ALLOWABLE COSTS
Complete RFP& Application Forms	Download RFP and Word version of proposal forms and templates at: crdfglobal.org/funding-opportunities/2019-RePORT India
How to Apply	All proposals must be submitted through the Electronic Proposal Submission (EPS) website: https://eps.crdfglobal.org/2019RePORT-India E-mail attachments and hard copies will not be accepted. For more information and instructions please refer to Section VI A Proposal Submission.
Point of Contact	**Administrative:** Christopher Maxwell, CRDF Global (cmaxwell@crdfglobal.org) Bridget Woolery, CRDF Global (bwoolery@crdfglobal.org) **Technical:** Sudha Srinivasan, (NIH/NIAID) (sudha.srinivasan@nih.gov) Jyoti Logani, (MST/DBT) (Jyoti.logani@nic.in)

II. BACKGROUND

CRDF Global is accepting proposals on behalf of theNational Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health (NIH), and the Government of India's (GOI) Department of Biotechnology, (DBT)to fund a single network of multiple clinical and laboratory research sites addressing an array of TB biomedical and clinical research of importance to India and abroad. The network will be jointly funded by the National Institutes of Health (on the US side)and the Department of Biotechnology Government of India (on the Indian side).

Currently, India accounts for about a quarter of the global TB burden and has the highest burden of both TB and MDR TB of any country. There are an estimated 79,000 multi-drug resistant TB patients among the notified cases of pulmonary TB each year. India is also the country with the second highest number of estimated HIV associated TB cases (https://www.tbfacts.org/). The development of drugs, vaccines and diagnostics for TB is urgently needed to bring the epidemic to an end, and research to achieve these aims is critical. The study of TB patients and their contacts in a longitudinal cohort will increase fundamental understanding of both TB disease and infection and will provide the basis for the development of new tools that can facilitate the rapid end to the TB epidemic, especially in high risk populations such as people living with HIV and those with diabetes mellitus.

Currently RePORT India is a bilateral, multi-organizational collaborative research effort established in 2013 under the Indo-US Vaccine Action Program. The consortium consists of seven clinical research sites in India and five partnering US/(UK) academic partnering institutions. The cohorts have well-characterized TB cases and contacts and systematic bio banking for epidemiology, immunology and biomarker discovery research to address TB in India and beyond. RePORT India was the first consortium to be established as part of the six current global RePORT International network of HIV/ TB consortia.

This announcement invites application(s) from RePORT India and U.S. based investigators to submit collaborative Indian-U.S. research proposals as outlined in this announcement. The aim of this RFP is to create a single network

consisting of multiple clinical and laboratory research sites and a multidisciplinary team of Indian and U.S. investigators that addresses an array of TB research questions of importance to India in the global context.

CRDF Global is an independent nonprofit organization that promotes international scientific and technical collaboration through grants, technical resources, training, and services. Based in Arlington, Virginia with offices in the Eurasia and MENA regions, CRDF Global works with more than 40 countries in the Middle East, North Africa, Eurasia, and Asia. They specialize in bringing isolated scientific communities into the scientific mainstream through a variety of science engagement and capacity-building programs. CRDF Global encourages science cooperation between countries where official relations are strained. For more information visit http://www.crdfglobal.org.

III. SCOPE

This announcement will fund one 5-year application that consists of the following components:

1. A multidisciplinary research team with appropriate leadership structure that will coordinate and oversee the science of the RePORT India Network and administrate the logistic needs of the network and its affiliated clinical research sites.
2. Clinical research sites that will implement a network wide prospective observational cohort(s) based on the framework of the RePORT Common Protocol and associated standards.
3. An array of research studies based on the above cohort(s) and/or clinical data and specimens collected (or previously collected) in the cohort(s).

A competitive application must include all or a subset of the current active RePORT sites. New clinical research sites and/or new investigators may be proposed to extend the geographic or demographic diversity of the current enrolled participants and/or the scientific expertise of the current group of investigators.

If a new clinical research site is proposed, a description of the site should demonstrate an ability to enroll and maintain an observational cohort of participants appropriate to the scientific research described in the proposal.

The number of investigators should correspond to the research described in the application. Furthermore, the essentiality, complementariness and added value of each member of the scientific team *vis a vis* the proposed research should be described.

Research Goals and Objectives

The intent of this initiative is to enhance (research capacity and continue to support building research capacity that combines prospective cohorts and biomedical and clinical research strengths.

For this solicitation, the following research areas are of particular interest and are encouraged:

- Characterization of the immune system in Indian populations with TB disease or *M. tuberculosis* infection
- Novel biomarkers that help identify persons with the highest risk of progression to active TB disease from *M. tuberculosis* infection
- Characterization of the stages of *M. tuberculosis* infection
- Identification of the host (i.e., endocrine system, immune status, etc.) and microbial (i.e., strain type, antigen composition, etc.) factors that determine clinical presentation of TB (pulmonary TB, extra-pulmonary TB)
- Identification of early biomarkers that identify persons who are not completely cured after standard treatment and are at highest risk for recurrence of TB after treatment
- Identification of host and microbial markers that influence and/or predict TB treatment effectiveness (e.g., pharmacogenomics, drug toxicity, drug interaction, dose optimization)
- Determination of the effect of co-infections/co-morbidities specifically HIV and/or diabetes on the development and natural history of TB and individual response to treatment.
- Identification of host and/or microbial markers that indicate the presence of paucibacillary bacterial infection
- Identification of host factors (genetic and other) that correlate with protective immunity
- Identification of environmental, host and microbial factors that determine success of transmission and acquisition of infection
- Identification of host and microbial factors that are responsible for the development of antimicrobial drug resistance
- Pharmacokinetic and pharmaco-dynamic factors in pediatric and adult TB patients on TB and or ARV and or DM treatment with and without complications, co-infections and co-morbidities
- Determine changes in the dynamics of TB transmission and disease over time in well-defined communities

Network Leadership

Network Proposal for a collaborative Research should be submitted by a consortium of Institutes from India. This should be inclusive of a lead Indian Institution & Indian investigators that have adequate service tenure to accommodate key research, coordination and outreach responsibilities

The application must appoint a Lead Indian institution ***which will also serve as Coordinating Center with*** a corresponding Indian Investigator as Project Coordinator and U.S. investigator (PI) to serve as the central contact points for the network, to lead and coordinate activities of the network and represent the network. Only a single networkwill be the recipient of the award and an US investigator can be associated and work with the same. The Coordinating Center in India will also receive additional support for executing the administrative and logistic functions required to manage the consortium and for the coordinating function of the RePORT India consortium such as hosting the Annual RePORT India meeting in conjunction with DBT/NIH; and for support to the coordination hub to organize and provide scientific leadership to the various working groups.

The consortium members must further organize themselves to form a single Leadership Group comprised of collaborating Indian and U.S. investigators. It is anticipated that the lead investigators will draw from among the current RePORT investigators though not mandatory. The establishment of additional scientific and administrative working groups that function under the direction of the Leadership Group is acceptable and encouraged.

Equal numbers of Indian and U.S. investigators in the Leadership Group is not required. However, the number of U.S. investigators should not exceed the number of Indian investigators.

New sites proposed to join the RePORT India consortium should come in partnership with an existing site/team, but in total no more than 2-3 new sites will be supported under this phase of RePORT India.

The application should clearly describe the proposed organizational structure of network, including the leadership group, associated scientific and administrative groups, and clinical research sites.

Support for the US investigators /institutions will be through separate contracts with CRDF, whereas the Indian investigators /Institutions will be supported by DBT.

Clinical Research Sites

The RePORT India Leadership Group will provide oversight for the science of the network, but the administrative leadership of the clinical research site does not require U.S. PI partnership. Partnership between an Indian Investigator and a U.S. investigator for oversight of a clinical research site is optional. Direct funding to the Clinical Research Sites, for implementation of the observational research protocol will be provide. Funding for scientific projects based on the data and/or specimens collected under the observational research protocol will be directed to the Lead Indian Institution unless otherwise requested by the PIs based on the work proposed.

It is expected that the clinical research sites will only implement observational research protocol(s) based on the standards and framework of the RePORT Common Protocol. The clinical research sites must provide, at a minimum, the following:

- **i)** investigators, nurses, site coordinator(s) and other clinical and technical personnel experienced in patient screening, recruitment and retention; adherence to Good Clinical Practices (GCP) and Good Clinical Laboratory Practice (GCLP) and regulations governing the safe and ethical conduct of research involving human subjects; collection and quality control of study data; and maintenance and storage of research records.
- **ii)** Access to a patient pool adequate to ensure the timely screening and enrollment of eligible study participants in accordance with study-specific requirements and within established timelines;
- **iii)** Access to appropriate Institutional Review Boards and or Ethics Committees to oversee and ensure the ethical conduct of the proposed research at the institution.

The implementation of the Common Protocol(s) at the Clinical Research Sites is the responsibility of the Site PI but should be overseen by the leadership of the network.

Research Studies

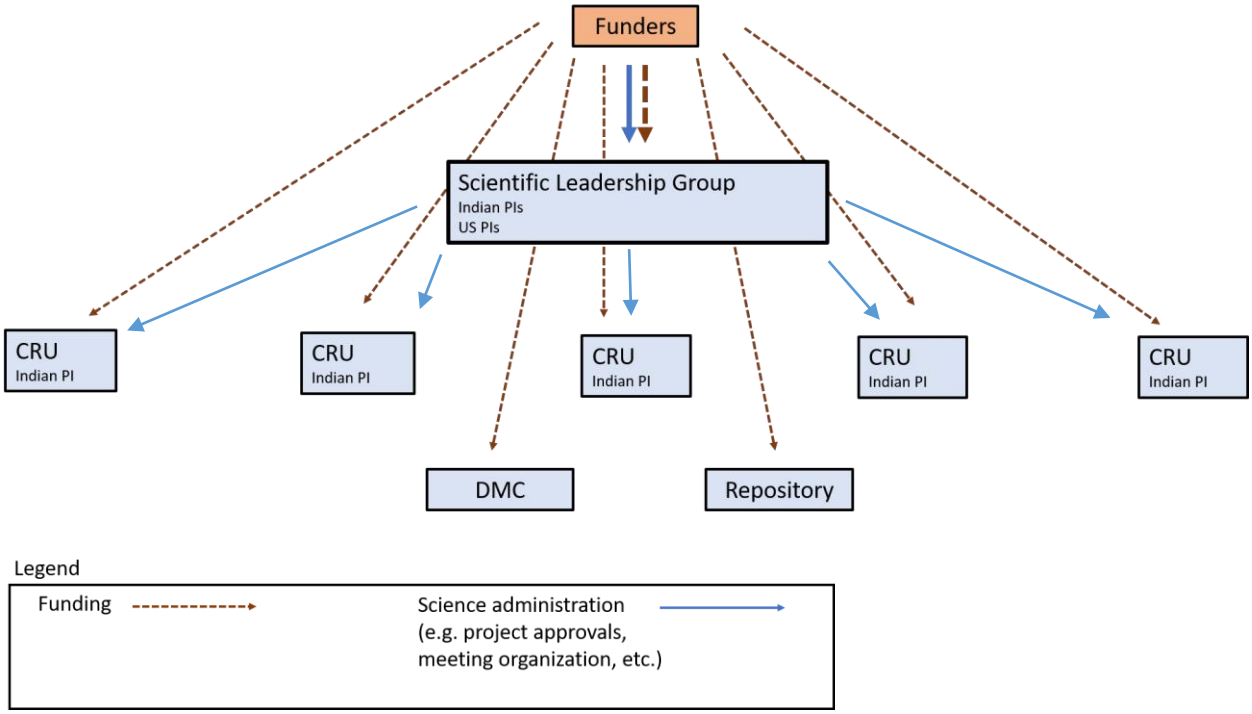
The application should describe an array of research studies that utilize the implemented cohorts and/or data and specimens collected from the clinical research sites (or previously collected under RePORT India CRUs).

The application should include a description of relevant knowledge gaps or obstacles to addressing these gaps and proposed approaches to overcoming these problems and obstacles. The scientific basis for the approaches and methodologies selected to address the scientific questions proposed including a summary of the state of the science in each area should also be included.

i) Study Design: The hypotheses and specific aims should be clearly stated. The study design should specify the type and volume of specimens required, the analyses planned, and protocols which will be used for these analyses.
ii) Statistical Plan: If appropriate, the statistical plan should include sample size calculations and the specific statistical and analytic methods to be used to determine study results.
iii) Impact: A discussion of how the study will advance TB science should be included.

The research should utilize the research capacity existent in India for the processing of samples and analysis of data whenever possible.

New Proposed Structure



Statistical/Data Management and Central Repository

The sponsoring organizations and CRDF Global expect that samples and data generated by this network will be stored in a central repository and data management center to allow analyses and research beyond that proposed in the current application. Samples will be available to the leadership group for joint studies, the CRUs, and outside collaborators to maximize information that can be obtained from this limited resource. Additionally, it is envisioned that the larger TB scientific community, within the rules and processes set up by the leadership group and within the appropriate regulations of India and the United States and the sponsoring organizations will also have access to certain data and samples collected under this program.

The repository management personnel will be available for consultative services for issues relating to collection, transport and storage of clinical samples.

These awards are funded jointly by the Government of India's (GOI) Department of Biotechnology, (DBT) and CRDF Global [utilizing funds provided by the U.S. National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) through separate contracts with each institution as needed].

CRDF Global will address all program-related inquiries, receive/review applications and communicate all results to applicants. CRDF Global will also coordinate the *joint peer* review. A secondary review will be undertaken by the Joint Working Group (JWG) of the Indo-U.S. Vaccine Action Program (VAP). Following these reviews, the most meritorious applications will be awarded for implementation.

IV. ELIGIBILITY

All proposals **must** meet each of the following eligibility criteria:

1. **For ALL Applicants**
   a. The PIs of a cohort research unit (CRU) must possess the skills, knowledge, resources, and professional experience needed to carry out the proposed research and objectives of the initiative.
   b. Renewal applicants/sites must indicate how they will build upon previous efforts
   c. Each PI should be experienced in research collaborations on clinical and/or biomedical studies in TB or HIV/TB.
   d. Each Principal Investigator of the Networks (not necessarily the individual CRU leads) can commit up to 10% effort per year to the project. This 10% effort should also be reflected in the budget proposed in US side only
   e. The participating entities/organizations have to be a legal entity as per Indian law (Indian applicants)
   f. India - Entities eligible to participate:
      - Government of India supported or recognized (Public or Private) academia; research organizations and urban or other local bodies;
      - Government of India recognized not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations, having research as one of the imperative mandates

      ***Note for Indian side**: Academic/Research Partners:*
      Public and/or private universities and research organizations must have a well-established research support system, for basic or applied research; and
      Submission of proof of establishment under Indian statue; recognition documents and registration at Government of India's Public Finance Management System (PFMS) - https://pfms.nic.in shall be obligatory.
      Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research Foundations:
      The Indian private R&D performing institutions and Not-for-profit, NGO(s)/ VO(s)/ Trust(s)/ Research foundations should have experience of at least 3 years in scientific research, teaching, training and extension activities; and
      Proof of registration at 'NGO DARPAN' of NITI Aayog (http://ngodarpan.gov.in/); Certificate of registration under Society Registration Act; certificate of DSIR in-house R&D recognition and registration at Government of India's Public Finance Management System (PFMS) (https://pfms.nic.in) shall be obligatory;

2. **(CRU) Applicants**
   As part of the application for a CRU, the institution/PI and collaborators must document the following capabilities:

   a. Access to and ability to recruit individuals with the following characteristics:
      i. Adults with pulmonary TB (drug susceptible and drug resistant)
      ii. HIV infected and uninfected
      iii. Individuals with recent exposure to active pulmonary TB
      iv. Persons with prevalent co-morbidities that may affect TB or HIV pathogenesis
      v. Healthy individuals who can serve as controls
   b. Access to and ability to enroll the following populations are not required but will be considered advantageous
      i. Individuals with extra pulmonary TB
      ii. Pediatric patients with and without active and/or latent TB including paucibacillary and non-pulmonary cases
      iii. Pregnant women with active TB
   c. Experienced clinical care capabilities with up-to-date training on Good Clinical Practice (GCP), Good Laboratory Practice (GCLP) standards
   d. Expertise in fundamental biomedical research
   e. Expertise in molecular and population epidemiology
   f. Readily available experienced investigators and study staff
   g. Experience in basic data management
   h. Access to a qualified mycobacteriology and clinical laboratory
   i. Ability to collect, catalog and store human specimens and mycobacterial isolates at own unit (independent of repository)
   j. Access to ethical and other medical review boards for review and approval of human research
   k. Experienced financial and administrative management staff
   l. Existing adequate infection control to protect staff and study subjects from TB
   m. Available basic equipment for biomedical and clinical studies
   n. Access to or plans for establishing community engagement activities

3. **New Phase II Applicants**

   Applicants who were previously not part of RePORT India must meet additional criteria outlined below:

   a. The CRU must be located at an institution that is not currently represented in RePORT India. As indicated in the website, the currents sites are mostly in Southern India and the sponsors would like to support institutions in other parts of the country to have geographic (and demographic) representation
   b. The CRU can access certain populations such as pediatric or HIV infected populations which are currently under-represented in RePORT India but which are of critical importance to TB/HV research.

4. **Cost-Share Requirements**
   Awardees with a Negotiated Indirect Cost Rate Agreement (NICRA) from a U.S. federal cognizant agency exceeding 08% (depending on prior agreement), will be required to provide a cost share to cover the difference in cost rate, so that the applied Indirect Cost rate does not exceed 08% of the award's modified total direct costs. Eligible cost shares must be verifiable through appropriate documentation provided by the awardee. See Appendix C for RePORT Program IDC and Cost Share Guidelines.

CRDF Global reserves the right to restrict the participation of any individual or institution in its programs. CRDF Global complies with all U.S. laws and regulations pertaining to export control and the participation of foreign nationals or institutions in its activities. It is the policy of CRDF Global not to conduct any transactions with U.S. restricted entities without appropriate authorization from the U.S. Government.

V. REVIEW OF PROPOSALS

All proposals and information contained therein will remain confidential prior to the award and will be screened for eligibility and completeness upon receipt by CRDF Global. Scientific merit review will take place through a peer-review by subject matter experts identified by CRDF Global. Reviewers will use the evaluation criteria described below to make funding recommendations.

Evaluation Criteria

1. **Scientific Merit:** Considering proposal's adequacy and relevance of scientific background evidence, preliminary results if available, soundness of testable hypothesis, innovative thinking, and demonstration of likely synergy with a collaborative approach.

2. **Research Plan Feasibility:** Considering proposed methodology, resources, personnel and timeline. Please pay attention to described processes or agreements that will facilitate data or laboratory sharing to complete the research. NOTE: It is expected that the infrastructure and resources are already in place to collect specimens and data in compliance with RePORT International standards. Funding from this award cannot be used to establish these necessary standards.

3. **Research Impact:** The probability that the project will result in new concepts, methods, technologies, treatments, services, or preventative interventions that drive the field, or have a positive impact on health of the populations included in RePORT. Indication of a plan to disseminate research findings or describe successful data or specimen sharing.

4. **Personnel Capacity and Budget:** The expertise of the team investigators and other participants, including the strengths and weaknesses of each partner. Budget is reasonable and justifiable to meet project needs.

5. **Benefit to the goals of RePORT India:** Indication that the team investigators are committed to, and engaged in, research that adheres to RePORT India's Common Protocol data and specimen standards. The project's likely contribution to the goal of collaborative research, data and laboratory harmonization, and lessons learned for future collaborative efforts.

CRDF Global will email the lead Indian and US Principal Investigator to inform them of the decision to select their research proposal. All awards are subject to the availability of funding from program sponsors. All decisions by CRDF Global are final.

VI. PROPOSAL PREPARATION AND SUBMISSION

Only proposals received according to the submission instructions and which follow the formatting and include all the required elements listed below will be considered responsive and reviewed.

A. Proposal Submission

All proposals must be submitted electronically through CRDF Global's Electronic Proposal Submission (EPS) website, no later than **Thursday, February28th, 2019 (23:59) U.S. Eastern Standard Time (EST).**

https://eps.crdfglobal.org/2019RePORT-India

Note: Submission through this website **does not** require previous registration.

Once the proposal has been finalized, **the lead Principal Investigator/Coordinator should submit the proposal on behalf of the entire collaborative team through the EPS website**. Proposals should be submitted only once.

After the electronic submission process, the lead Principal Investigator/ coordinator will receive a confirmation message from CRDF Global. Further instructions on electronic proposal submission are available at the above website.

Proposal application materials submitted to CRDF Global must be prepared in English and compiled in the following separate document files for submission to the EPS. Acceptable file formats are MS Word (.doc) or Adobe Acrobat (.pdf).

Required:

1. Completed proposal document (all applicable elements under Section VI.D Proposal Elements)
2. Team co-Investigators and Key Participant bio sketches.

As Applicable:

1. CRDF Global Bioethics form for proposals involving human and/or animal subject research. One Bioethics form per Team Co-Investigator's Primary Institution.

B. CRDF Global Policies and Applicant Resources

Before Writing a Proposal, applicants should review all documents and policies on the CRDF Global Applicant Resources page.

C. Proposal Formatting

- Typed
- Single-spaced
- One-inch margins on ALL sides
- Font size of no less than Arial 10pt (Times New Roman 10pt font is not acceptable) *

**A font size of less than 10 points may be used for mathematical formulas or equations, figure, table or diagram captions and when using a Symbol font to insert Greek letters or special characters. PIs are cautioned, however, that the text must still be readable*.

D. Proposal Elements (required unless otherwise noted)

Applicants are required to follow instructions and use the electronic forms and templates downloadable in a fillable format here: crdfglobal.org/funding-opportunities/2019-RePORT-India

Detailed information for all necessary elements of a proposal is listed below. Appendices may not be included. Any proposal submitted without ALL required information, including signatures and forms, may be disqualified and removed from the competition. Applicants are encouraged to carefully review proposals prior to submission to ensure accuracy and completeness.

The following sections should be compiled into one proposal document.

1. **Project Team Cover Letter and Terms Agreement:** Each project's Investigator(s) must provide a signed statement on institutional letterhead certifying her or his agreement to the collaboration. Use the example Cover Letter in APPENDIX Band include a scanned copy in the proposal document.

2. **Cover Sheet**

- Project title and basic information about the project
- Information about the Project PIs and Institutional Leadership Representatives (individuals who would be responsible for negotiating contractual and financial terms in the event of an award).

This information must also be entered during the electronic proposal submission process.

3. **Project Abstract:** In one concise paragraph, summarize all relevant aspects of the project, with special attention to its goals and objectives, methods, and anticipated results. (No more than 350 words).

4. **Project Narrative:** Thirty (30) pages maximum, including any graphs, diagrams, orphotos. Investigators are cautioned that the Project Narrative must be self-contained, and that URLs providing information related to the proposal should not be used.

   CRDF Global expects strict adherence to the rules of proper scholarship and attribution. The responsibility for proper scholarship and attribution rests with the authors of a proposal; all parts of the proposal should be prepared with equal care for this concern. **All contributing authors, including any Team co-investigators and team participants, should be named and acknowledged at the bottom of the Project Narrative section.**

   The following should be described in the Project Narrative:

   - Overall scope of the proposed research, including scientific hypothesis, study objectives, and specific aims.

   - Detailed methodology including a description of the study design, including the type of study, and whether the Common Protocol associated data and specimen standards are being adhered to for study procedures, inclusion criteria, exclusion criteria, data collection and management, and sample size as well as timeline for the project as described in the Milestone Plan.

   - Specific Roles and responsibilities of Indo-US collaborators as per the objectives and work plan proposed

   - Description of proposed collaboration between CRUs, including the proposed organizational structure of network, the leadership group, associated scientific and administrative groups, and clinical research sites. This should include the division of primary responsibilities.

   - Key personnel: How the competencies of the Team Investigators and team participants will enable the project to be carried out. How the lead institutions will coordinate project implementation and assess progress at regular intervals. Identify any collaborators and provide a brief statement about the nature of the proposed collaboration and how it adds to the research project. (As applicable.)

   - Anticipated results of the project and how they address the evaluation criteria listed in Section V.

   - Facilities, equipment, and other resources available at the participating institution(s) directly applicable to the project. This should address the adequacy of the resources available to perform the effort proposed. The description should be written in narrative form and not include any financial information.

   - If a cost-share is included, how those funds will be used. For in-kind cost-shares, include an explanation of how value is assigned to that contribution.

     Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the proposer, should be included in the proposal only when such information is necessary to convey an understanding of the proposed project. Such information must be clearly marked in the proposal and appropriately labeled as:

     "The following is (proprietary or confidential) information that (name of proposing organization) requests not be released to persons outside of CRDF Global, except for purposes of review and evaluation."

   - **For New CRU applicants:** Description of achievement of the proposed CRU during the past five years. This section should describe the proposed CRU's role as a basic research site and as a clinic site for recruitment and retention of participants and a brief description of the studies undertaken in the past five years, with an emphasis on studies most relevant to the proposed project.

5. **References Cited**: Reference information (for prior research, facts mentioned in the proposal) is required. Each reference must include the names of all authors (in the same sequence in which they appear in the publication),

the article and journal title, book title, volume number, page numbers, and year of publication. If the document is available electronically, the website address should be listed.

6. **Project Milestone Plan**: A milestone plan must be submitted, describing specific milestones to be accomplished by each CRU during project implementation.

   Please note the following when preparing the milestone plan:

   - Milestones are discrete activities that allow the awardee to achieve the overall objectives described in the project narrative. Milestones should reflect realistic accomplishments within the period of performance that can be verified by CRDF Global staff. Examples of such milestones include, but are not limited to: sample collection, sample sharing, data collection, data sharing, data analysis, trainings, or travel for a specific task under the proposed project. **Do not include IRB approval period in your Milestone Plan.**
   - Milestones must be verifiable through submission of documentation or other deliverables (e.g. photos, purchase orders, training materials, reports, or other tangible proof that the activities occurred).
   - Each milestone should be clearly described and include a corresponding deliverable.
   - The amount of funding requested (on a semi-annual basis) should be included in the milestone plan.

7. **Key Participant Data Form**: A Form must be completed for each additional participant on the project, including researchers/engineers, technical/scientific support staff, graduate and undergraduate students, and secondary collaborators.

   - For planned students not yet identified, complete a form as "Planned Student" indicating, at a minimum, the anticipated institution, level of education, and role.
   - Each form should be accompanied by the Biographical Sketch for the team participant. All biographical sketches are to be compiled and submitted in a separate document.

8. **Project Budget.** Complete ONE for each associated Institute inclusive of any Secondary Institutions. The budget should cover the entire award period. PIs should refer to "Allowed Costs" for information listed in the budget.

9. **Budget Narrative Form.** Complete ONE for each associated Institute inclusive of any Secondary Institutions. Should match the associated budget sheets in the Project Budget explaining all included proposal request items.

10. **Statement of Other Support Form:** All Investigators must list current and pending sources of support for all their research projects, **excluding** those that are already included under the "COST-SHARING FROM NON-CRDF SOURCES" section in the Budget. Applicants with grants from U.S. Government sources, such as NIH, should indicate the grant number, duration of the award, and level of effort. If this proposal has also been submitted to another organization, please indicate this information clearly on the form. **Should an investigator have no other sources of support, check the box marked "None" at the top of the form, and include this page with the proposal**.

11. **Institutional Data Form:** Complete ONE for each associated Institute requesting funding.

The following documents should be prepared and uploaded separately from the main proposal file:

1. **Principal Investigators and Key Participant Biosketches in one file(Required)**Applicants must provide copies of all Principal Investigators and key team participants' bio sketches in a file separate from the main proposal file. Biosketches should be prepared using the NIH Biosketch template and instructions available at http://grants.nih.gov/grants/forms/biosketch.htm.

   *Please ensure a Biosketch is included corresponding to each Key Participant Form in the main proposal file.

a) **Human/Animal Subjects Research Documentation (as applicable)**:CRDF Global is committed to ensuring that projects involving human or animal subjects are protected from research risks in conformance with CRDF Global policies. All projects recommended for award that involve human or animal subjects will undergo review by the CRDF Global Bioethics Review Committee (BRC) prior to award request.

   Submit one CRDF Global Bioethics review form per associated Institution for proposals involving human and/or animal subject research. Please refer to instructions for the documentation required at this proposal stage here.

CRDF Global reserves the right to require greater detail if necessary, to proceed with award selection.

VII. ALLOWABLE COSTS

- One award is supported through this RFP. This includes USD 1.5 million from CRDF/NIH and matching funding support from DBT based on appropriate justification, Budget should be commensurate with the workload, objectives of the project and cost of participation. Overall funding should not exceed USD 2.25 million. Administrative function budget for the lead institutionincluded in the above needs to be provided with adequate justification. The budget must meet the following conditions in order to be eligible for review:

  This amount of funds will be allocated as described below:

- Primary US investigators can allocate up to 10% LOE to the CRU budget, but no more than 10%.
- **The Lead institution or coordinating center should budget for less than $150,000 for supporting administrative, coordination and data and laboratory support**. This includes data, laboratory, coordination, and administrative support, as well as coordinating the annual RePORT India Meeting in conjunction with DBT and NIH. The network coordinator center budget should be separated out as its own stand-alone budget, from the lead institution's CRU research activities. The Primary US and Indian PI may only allocate up to 5% LOE towards the administrative function.

Award funds are dispensed on a cost-reimbursable mechanism for actual expenses incurred. Award funds will be dispersed on a **cost-reimbursable basis** upon receipt of invoices and receipts reflecting expenses incurred based on approved budget. Should a grantee require advance funding, significant justification must be submitted to CRDF Global in writing and shall be reviewed by the funder for approval**.** CRDF Global will work with individual award recipients/institutions for any financial resource issues that may arise from the cost-reimbursable policy

No taxes may be included in any budget proposal submitted to CRDF Global and no award will include additional funding to pay taxes.

In the case of an award, a project budget may be subject to revision by CRDF Global Staff based on the justification provided. The following costs are permitted under CRDF Global guidelines for this program:

Indian Site Expenses. The Indian component and its associated budget will be awarded to the Indian PIs by the Department of Biotechnology (DBT) Government of India, based on DBT guidelines and appropriate justification. No Indian taxes may be included in any budget proposal submitted to CRDF Global. All expenses should be based upon Government of India norms.

Eligible costs for funding are: Capital expenditure (equipment's) || Manpower || Consumables || Travel (local and international travel) || Contingency || Overheads || Outsourcing || others. (Academia can factor in additional sub heads (in other category) such as training & awareness; workshops; publications; review meetings, etc. under expenditure based on the requirement of the project).

1. **Non-Recurring Budget to provide** Support for research equipment only, should not be inclusive of computers/ laptops etc.

2. **Recurring Budget for, Manpower, Contingency and Consumables:** Indian team members may request manpower costs associated with work on the project based on the emoluments as per DBT/ ICMR guidelines. Consumables to be inclusive of reagents, and other materials to be used in the research. <u>All requested items must be specifically described and justified in the Budget Narrative (as per DBT format by Indian side).</u>

If the proposal is to include services of professional consultants or service these services must be detailed in the Budget Narrative with a justification as to their necessity for successful execution of the project. Non allowable cost from DBT: i. Civil Construction costs ii. Prosecution/litigation costs iii. Salary of investigators

3. **Travel:** Transportation and per diem support for scientific travel of Indian participants in connection with the project should be requested and described in the Budget Narrative. Travel funds may also be used for domestic travel within the India or for an Indian team member to visit the U.S. Principal Investigator's laboratory/institution (only one visit outside India will be considered for annual support) All travel expenses should be determined according to Government of India guidelines. Expenses for travel associated with the Leadership Group and the Scientific Working Group should NOT be included in the Project Budget.

4. **Indirect Costs (IDCs):** Indian grantees may include in their budgets an allowance for overhead costs. Overhead percentage of total budget costs allowed should follow established Government of India norms.

   Indian participants prepare budget (in Rupees) according to DBT format: Indian participants MUST submit detailed financial plan in Indian Rupees (₹) for entire duration of the project.

U.S. Expenses. Any U.S. component of the proposal will be awarded and administered by CRDF Global. For eligible teams, CRDF Global will distribute funds to the U.S. team on a cost-reimbursable basis. The U.S. portion of the budget <u>should not exceed $150,000 total costs over the 5 years</u> of the award. Allowable expenses include:

1. **Labor Costs** is defined as payments made to individual team participants for work performed on the project

CRDF Global will reimburse participants for labor costs associated with work on the project as permitted by the participants' institutions and based on their current salaries. Labor expenses will be reimbursed for actual hours worked on the project as documented to CRDF Global. Labor rates may include benefits and fringe costs in accordance with employing institute's rates and must be documented in the proposal's budget narrative. Please review the respective institute's salary support policies for external grants.

Student stipends are permissible and may include fringe benefits or tuition remission. For planned students not yet identified, clearly indicate their participation and request for support in the Project Budget and Budget Narrative.

2. **Equipment, Supplies and Services (ESS)**: Includes support for research equipment, including computers and telecommunications devices and/or services, subscriptions to scientific journals, reagents, and other supplies/materials to be used in the research. In general, materials and supplies are defined as tangible personal property, other than equipment, costing less than $1,000 USD, or other lower threshold consistent with the policy established by the proposing institute. Any item of requested equipment valued at more than $1,000 USD must be specifically described and justified in the Budget Narrative.

Budget items should be listed individually – items listed generally as "supplies" or "services" will NOT be accepted. Each line item should be calculated based on actual costs.

3. **Travel**: Transportation and per diem support for travel in connection with the project's research objectives should be requested and described in the Budget Narrative. Travel funds may be used to travel to the collaborating institutions as well as for domestic travel, if applicable. unclear travel expenses on proposals selected to award will undergo remediation that may cause activation delays.

The following cost guidelines should be used in preparing the travel portion of the budget:

a) International Transportation. CRDF Global-supported travelers must purchase the lowest-cost applicable round-trip airfare from their home country. Travelers must comply with the provisions of the Fly America Act. For more information, please refer to the CRDF Global Information for Applicants

b) Travel Allowances. Applicants should refer to the following travel allowance guidelines when preparing their travel budget:

For travel in the U.S., visit: http://www.gsa.gov/portal/content/104877

For non-U.S. travel, refer to https://aoprals.state.gov/content.asp?content_id=184&menu_id=78.

These are the maximum allowances cover lodging, meals, and incidental expenses. Health insurance is mandatory for all travel under CRDF Global awards and should be included in the budget in addition to the travel allowance. Visa fees are allowable expenses and may be included in the budget.

4. **Indirect Costs (IDCs).** Applicants (Primary Institutions and Secondary Institutions) may request indirect costs/overhead expenses on all direct costs except for equipment (over $5,000), capital expenditures, rent, student tuition, participant support costs[1] and Secondary Institution expenses (after the first $25,000). Total direct costs minus these items is considered the modified total direct cost (MTDC) amount for which the IDC rate should be applied. IDCs combined with the total direct costs cannot exceed the funding total allowed to request. Below are helpful calculations:

   - **IDC $** = IDC% x MTDC $
   - **Maximum Total Team budget** = total direct costs $ (including MTDC) + IDCs $

5. **Cost-Share Requirements.** Awardees with a Negotiated Indirect Cost Rate Agreement (NICRA) from a U.S. federal cognizant agency exceeding 08% (depending on prior agreement), will be required to provide a cost share to cover the difference in cost rate, so that the applied Indirect Cost rate does not exceed 08% of the award's modified total direct costs. Eligible cost shares must be verifiable through appropriate documentation provided by the awardee and should be described within the budget narrative. See Appendix C for RePORT Program IDC and Cost Share Guidelines.

[1]ParticipantSupportcostsincludestipendsorsubsistenceallowances, travelallowancesandregistrationfeespaidtooronbehalfofparticipantsortrainees (butnotemployees) inconnectionwithmeetings, conferences, symposiaortrainingprojects, scholarships/fellowships.

VIII. CRDF GLOBAL EXPECTATIONS OF GRANTEES

Awardees from this competition will be expected to:

- Have or provide milestones, objective wise targets and clear plans to publish/present research results in peer-reviewed publications and conference by the end of the award period.
- Submit to CRDF Global invoices for all other project expenses as well as receipts for non-U.S. awardees.
- Submit annual joint progress reports for each year for the entire duration of the award,

IX. ADDITIONAL INFORMATION AND SUPPORT

For further information about this program, please contact the program manager below. **Inquiries by e-mail are strongly encouraged and will result in prompt response**.

Administrative Inquires:
CRDF Global

Christopher Maxwell
1776 Wilson Blvd., Suite 300
Arlington, VA 22209
Phone: 703-526-6752
Email: cmaxwell@crdfglobal.org

Bridget Woolery
1776 Wilson Blvd., Suite 300
Arlington, VA 22209
Phone: 703-526-2327
Email: bwoolery@crdfglobal.org

Technical/Scientific inquires:
Division of AIDS/NIAID/NIH/DHHS

Sudha Srinivasan
5601 Fishers Lane, Rm 9E38
Rockville, MD 20852
Phone: 240-627-3062
Email: sudha.srinivasan@nih.gov

Department of Biotechnology/MST/GOA

Jyoti Malik Logani
Room no-516, 5th Floor
Block-II, CGO Complex, Lodhi Road
New Delhi-110003
Phone: 0091-011-24362329
Email: Jyoti.logani@nic.in

X. CHECKLIST OF ITEMS REQUIRED FOR PROPOSAL SUBMISSION

BEFORE submitting through CRDF Global's Electronic Proposal Submission (EPS) site, please ensure you have the following documents/information prepared as specified and ready to upload from your computer.

A. Proposal Document Checklist

1. Documents/Information combined into a SINGLE PDF, Word, or Rich Text file:

- **General**
  - Proposal topic and project plan are responsive to the RFP
  - Proposed work is appropriate for funding by CRDF Global
  - Team composition matches eligibility requirements
- **Cover Letter and Terms Agreement**
  - One for EACH collaborating investigator and their institution
  - Signed by Investigators and Institute Representatives.
  - On institutional Letterhead
- **CoverSheet**
  - Lead Indian Principal Investigator designated among co-investigators
  - Allfieldsarecompleted
- **ProjectAbstract**
  - Doesnotexceed350 words
- **ProjectNarrative**
  - Allprojectcriteriaare addressed
  - Text is within twenty (20) page limit
  - Formatted properly (typed, single spaced, one-inch margins, page numbers, font no smaller than Arial 10 pt)
  - Authors names are included at end of section
- **ReferencesCited**
- **Project Milestone Plan**
  - Written based on the instructions provided and sample
  - Should include, clear, discrete, verifiable milestones; deliverables must be associated with each milestone
- **Key Participant Information Forms**
  - One for each team participant - all fields completed; does not exceed one (1) page each
- **Proposal Budget**
  - One budget document for each Primary Institution.
  - Follows allowable cost guidelines
  - Cost-shares (if applicable) reported as a monetary value
- **BudgetNarrative Forms**
  - One for EACH Primary Institution
  - All expenses listed in the Budget are described
  - Any equipment valued over $1,000 includes an additional detailed justification
  - For travel expenses, all trips are justified with description of travelers, destination, and duration of travel. Airfare, lodging and per diem costs for each trip are clearly stated and calculated.
- **Statement of Other Support**
  - One form for EACHco-investigator
  - If no other support reported, the form is completed with the co-investigator's name and the "none" box checked at the top of the page

2. Additional Documents to be uploaded to website as SEPARATE files from the main proposal file:

- **Biosketches for all teamparticipants**
  - Uses NIH biosketch format
  - One for eachco-investigator and corresponding Key Participant Form
  - All biosketches compiled into ONE document separate from proposal.

B. Special Documentation Requirements (if applicable)

- ☐ **Proposals involving Human and or Animal Subjects research only**:
  - Bioethics Form submitted for each Primary and Secondary Institutions

C. Submission Requirements

- ☐ **CRDF Global Submission Requirements:** All documents submitted to CRDF Global MUST be entered through the program' specific Electronic Proposal Submission (EPS) website; proposals sent as e-mail attachments will NOT be accepted.

- ☐ The following documents to be uploaded to website as SEPARATE files:
  - Proposal combined into a SINGLE PDF or Word file
  - Biosketchesallteamparticipantscombined into a SINGLE PDF or Word file

APPENDIXA: Application Forms

PROJECTTEAM COVER LETTER AND TERMS AGREEMENT

Please complete using this Template/Sample for each Co-investigator

[INSTITUTE LETTER HEAD]

Re: [Full Proposal Title]

I, [co-Principal Investigator (PI) Name], hereby acknowledge that I have submitted a joint proposal to the **RePORTIndia RFP.**

If awarded, I undertake this research in good faith and will uphold my portion of the collaborative work as proposed in the submission.

I attest that the information contained in this proposal is truthful and that it has been prepared with the full knowledge and consent of [Institutional Leadership Representative Name], leadership representative of [Institution].

I affirm that I have read and understand CRDF Global's policies and standards, including CRDF Global's Plagiarism Policy[2]. I agree to adhere to CRDF Global's Plagiarism Policy, and understand that CRDF Global will not provide funding to an application in which plagiarism exists. If plagiarism is detected, penalties may be imposed up to and including my exclusion from this funding opportunity and barring my participation in future funding opportunities.

_____ _____

Principal Investigator Signature Date

_____ _____

Institutional Leadership Representative Signature[3] Date

COVER SHEET

GENERAL PROJECT INFORMATION	
Project Title (*not to exceed 25 words*)	Title
Amount Requested	Total

[2]Please refer to CRDF Global's Plagiarism and Policy Standards.

[3]Institutional Leadership Representative is an administrative or financial personnel aware of the proposal content prior to submission.

	$Amount.			
Research Categorization[4]	Research Area	Sub-Research Area	Research Focus	
	Research Area	Sub-Research Area	Research Focus	
Research Involves use of Human/Animal subjects		Choose an option...	Length of Project	Months

LEAD INDIAN PRINCIPAL INVESTIGATOR					
INSTITUTION INFORMATION					
Institute Name	Institute Name			Institution Type	Choose a type…
Mailing Address	Building # and Street Name				
	City		Postal Code		Country
PRINCIPAL INVESTIGATOR INFORMATION					
Last Name (Surname)	Last	First Name (Given)	First	Middle (Second/Patronymic)	Middle
Position/Title	Full Title				
PI E-mail	Email 1		Alternative E-mail *(optional)*	Email 2	
Telephone #	Country code + number		Gender	Choose an option…	
INSTITUTION LEADERSHIP REPRESENTATIVE INFORMATION					
Name	Last	First	Middle	Position/Title	Full Title
E-mail	Email		Telephone #	Country code + number	
Total number of sub-team members, including PI, graduate students, secondary collaborators					#

LEAD US PRINCIPAL INVESTIGATOR (IF APPLICABLE)					
INSTITUTION INFORMATION					
Institute Name	Institute Name			Institution Type	Choose a type…
Mailing Address	Building # and Street Name				
	City		Postal Code		Country
PRINCIPAL INVESTIGATOR INFORMATION					

[4]Pleasereferencethe CRDF GlobalResearchAreasdocumentfoundhere: http://www.crdfglobal.org/docs/default-source/cgp-competition-docs/crdf-global-research-areas_jan-2013.pdf?sfvrsn=0

Last Name (Surname)	Last	First Name (Given)	First	Middle (Second/Patronymic)	Middle
Position/Title	Full Title				
PI E-mail	Email 1		Alternative E-mail *(optional)*	Email 2	
Telephone #	Country code + number		Gender	Choose an option…	
INSTITUTION LEADERSHIP REPRESENTATIVE INFORMATION					
Name	Last	First	Middle	Position/Title	Full Title
E-mail	Email		Telephone #	Country code + number	
Total number of sub-team members, including PI, graduate students, secondary collaborators					#

PROJECT INFORMATION FORM

1. Topic *(please select up to three from the following topics)***:**		
☐ Host Immunology	☐ Other Co-morbidities	☐ Active TB Infection
☐ TB Epidemiology	☐ TB and Pregnancy	☐ TB Drug Resistance
☐ TB Treatment	☐ Pediatric TB Infection	☐ TB Social Factors
☐ TB and HIV Co-infection	☐ TB Diagnostics	☐ TB Vaccine
☐ TB and Alcohol	☐ TB Pathogenesis	☐ TB Infection Control
☐ TB and Diabetes	☐ TB Biomarkers	☐ Other (Specify)
☐ TB and Parasitic Co-infection	☐ LTBI	
2. **RePORTIndia sites involved in the proposed study:**		

☐ BJMC	☐ MVDRC	☐ UTHSCT
☐ NIRT	☐ CMC	☐ Rutgers
☐ JIPMER	☐UMASS	☐ JHU
☐ BMMRC	☐ BMC	

3. Proposal includes specimens and/or data from (Mark all that apply):

☐RePORTIndia Common Protocol Cohort A (Active TB cohort)
☐RePORTIndia Common Protocol Cohort B (Latent TB Infection cohort)
☐ Other (specify):

4. **Proposal activities (Mark all that apply):**

☐Request to analyze existing dataset(s)
☐ Request use of current repository specimens for further testing
☐ Request additional new protocol procedures and/or participant visits
☐ Other (specify):

5. Does this project involve additional <u>participant</u> burden?	☐ Yes ☐ No

a. If "Yes" *check all that apply below*

☐ New specimen collection needed
☐ New questionnaire administered
☐ New procedure (e.g., MRI, biopsy)
☐ New or additional consent needed
☐ Additional visit required

b. Detail any anticipated additional RePORT Common Protocol participant burden (in terms of amount of time required, additional visit(s), amount and type of specimens to be collected, etc.) and reimbursement to be provided.

<u>SAMPLE SPECIFICATIONS</u> (*Specimens obtained may not be used for any purpose other than the approved project without prior consultation and permission from the Executive Committee.*)

6. Repository Information:

a. Will this project require the withdrawal of specimens from the RePORT Central Biorepository?

☐ Yes ☐ No If YES, list biorepository site

7. Sample Characteristics: To protect the most valuable and irreplaceable specimens in the RePORTIndia Common Protocol, many consortia have Central Biorepository requests for specimens from certain groups of Common Protocol participants (e.g., Cohort B TB activation cases, Cohort B TB activation cases who enrolls in Cohort A, pediatric active TB cases, TB treatment failure or early relapse, etc.) may trigger additional review by the RePORTInternational Specimen Allocation Committee.

Mark the types of participants whose specimens are targeted by this request as well as the number of

participants in each category.

- ☐ Cohort A general (number of requested participants)
- ☐ Cohort B general (number of requested participants _)
- ☐ Cohort A diabetic (number of requested participants _)
- ☐ Cohort A non-diabetic (number of requested participants)
- ☐ Cohort B diabetic (number of requested participants)
- ☐ Cohort B non-diabetic (number of requested participants)
- ☐ Cohort A TB treatment failure (number of requested participants)
- ☐ Cohort A TB early relapse (number of requested participants)
- ☐ Cohort B TB activation cases (number of requested participants)
- ☐ Cohort B TB activation cases who enroll in Cohort A (number of requested participants)
- ☐ Pediatric Cohort A (active TB) aged 5 years or younger (number of requested participants)
- ☐ Pediatric Cohort A (active TB) aged 6 - 14 years (number of requested participants)
- ☐ Pediatric Cohort B (HHCs) aged 5 years or younger (number of requested participants)
- ☐ Pediatric Cohort B (HHCs) aged 6 - 14 years (number of requested participants)
- ☐ HIV co-infected Cohort A (number of requested participants)
- ☐ HIV co-infected Cohort B (number of requested participants)
- ☐ Other (specify (number of requested participants)

a. Expected number of Person-Visits to be studied:	
b. Expected number of unique participants to be studied	

8. Will this project require serial specimens with explicitly stated comparisons?

☐Yes ☐ No

If "Yes," please explain:

a. **Sample Type**

**** NOTE:*** *Specimens previously thawed for other initiatives may be shipped. If unacceptable, give a reason below for requiring specimens not previously thawed. Leftover material cannot be returned to the Central Biorepository without prior approval from the Repository Program Officer and the RePORT EC.*

☐ PBMC	☐mtb isolate	☐ Saliva
☐ Plasma	☐Sputum	☐Whole blood (DNA)
☐PAXgene RNA	☐Urine	☐QuantiFERON
☐ Other:		

b. Sample Quantity:	Minimum:	Optimum:

PROJECT ABSTRACT
Should not exceed 350 words

PROJECT NARRATIVE
Should not exceed 20 pages. Text should be Arial font size 10 within 1-inch margins

REFERENCES CITED

This section must only include bibliographic citations and not be used to provide parenthetical information outside of the Project Narrative

PROJECT MILESTONE PLAN (TEMPLATE/ SAMPLE)
Copy template to complete for EACH Participating CRU. Text in red is an example. Information should match the proposal Project Narrative and Project Budget

Reporting Period (Complete for each semi-annual segment applicable top project duration.)		
Institute: <Enter>		
First Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s):
Training for five participants	*The project team will receive training in GIS technologies/methods used for disease surveillance.*	*Copies of all training materials, including power point slides, hand-outs; photographs, and video footage of the training*
Total Amount Requested for this Reporting Period:		$15000
Second Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)
Total Amount Requested for this Reporting Period:		$$ Total
Third Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)
Total Amount Requested for this Reporting Period:		$$ Total
Fourth Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)
Fifth Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)

Total Amount Requested for this Reporting Period:		$$ Total

Sixth Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s):
Training for five participants	*The project team will receive training in GIS technologies/methods used for disease surveillance.*	*Copies of all training materials, including power point slides, hand-outs; photographs, and video footage of the training*
Total Amount Requested for this Reporting Period:		$15000
Seventh Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)
Total Amount Requested for this Reporting Period:		$$ Total
Eighth Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)
Total Amount Requested for this Reporting Period:		$$ Total
Ninth Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)
Tenth Semi-Annual Reporting Period		
Milestone:	Description:	Associated Deliverable(s)

Total Amount Requested for this Reporting Period:		$$ Total

KEY PARTICIPANT INFORMATION FORM

Complete ONE for each participant on the collaborative team

Please copy this page as necessary.

TEAM MEMBER INFORMATION					
Last Name (surname)	Last	First Name (Given)	First	Middle (Patronymic)	Middle
Current Position	Full Title		Classification on Project		Choose Role…
Institute Name	Institute Name				
Complete Mailing Address	Building # and Street Name		City/State	Postal Code	Country
E-mail Address	Email		Telephone #		Country code + number
Highest Degree/ Year Awarded	Degree Type		Field/ Discipline		Year
Gender	Choose an option…				
Description of project role (responsibilities, expertise, level of effort on project):					
Enter description					

PROJECT BUDGET

Complete ONE for each Institution involved

Please refer to "Allowable Costs." Convert all amounts to USD

US Institute:			
CRU:			
Primary Participants			
Labor Participant Name (Add rows if necessary.)	**Hourly Rate**	**Total person hours[5]**	**$ USD**
1			
2			
TOTAL LABOR			
Equipment, Supplies, & Services (ESS) Item (Add rows if necessary.)	**Units**	**Unit Cost**	**$ USD**
1			
2			
TOTAL ESS			
Travel (Totals only, describe purpose and per person costs in detail in Budget Narrative.)			**$ USD**
Domestic Transportation			
Domestic Per Diem			
International Transportation			
International Living Allowance/Per Diem			
Other Travel Expenses (e.g. visa fees, conference registration fees, etc.)			
TOTAL TRAVEL			
TOTAL PRIMARY PARTICIPANT DIRECT EXPENSES			
Indirect Costs (IDC)of Primary Participant			
Must include a cost-share for IDC expenses exceeding 08% of total Modified Direct Cost.			
Secondary Collaborators (within individual team)			
Labor Participant Name (Add rows if necessary.)	**Hourly Rate**	**Total person hours[6]**	**$ USD**
1			
2			
TOTAL Labor			
Equipment, Supplies, & Services (ESS) Item (Add rows if necessary.)	**Units**	**Unit Cost**	**$ USD**
1			
2			
TOTAL ESS			
Travel (Totals only, describe purpose and per person costs in detail in Budget Narrative.)			**$ USD**
Domestic Transportation			
Domestic Per Diem			
International Transportation			
International Living Allowance/Per Diem			
Other Travel Expenses (e.g. visa fees, conference registration fees, etc.)			
TOTAL TRAVEL			
TOTAL SECONDARY COLLABORATOR DIRECT EXPENSES			
Indirect Costs (IDC) of Secondary Collaborators			
Must include a cost-share for IDC expenses exceeding 08% of Modified Total Direct Cost.			
TOTAL OF PRIMARY PARTICIPANT AND SECONDARY COLLABORATOR DIRECT EXPENSES			
TEAM SUBTOTAL (Total of direct expenses and IS)			
TOTAL COST-SHARING FROM NON-CRDF Global SOURCES (Including for-profit contributions. Describe in detail in Budget Narrative)			

[5]"Person-hours" = estimatedtotalnumberofhoursdevotedtotheprojectthroughoutthedurationoftheproject.
[6]"Person-hours" = estimatedtotalnumberofhoursdevotedtotheprojectthroughoutthedurationoftheproject.

PROJECT BUDGET

Complete ONE for each Institution involved

Please refer to "Allowable Costs." Convert all amounts to USD

US Institute:			
CRU:			
Primary Participants			
Labor Participant Name (Add rows if necessary.)	**Hourly Rate**	**Total person hours[7]**	**$ USD**
1			
2			
TOTAL LABOR			
Equipment, Supplies, & Services (ESS) Item (Add rows if necessary.)	**Units**	**Unit Cost**	**$ USD**
1			
2			
TOTAL ESS			
Travel (Totals only, describe purpose and per person costs in detail in Budget Narrative.)			**$ USD**
Domestic Transportation			
Domestic Per Diem			
International Transportation			
International Living Allowance/Per Diem			
Other Travel Expenses (e.g. visa fees, conference registration fees, etc.)			
TOTAL TRAVEL			
TOTAL PRIMARY PARTICIPANT DIRECT EXPENSES			
Indirect Costs (IDC) of Primary Participant			
Must include a cost-share for IDC expenses exceeding 08% of total Modified Direct Cost.			
Secondary Collaborators (within individual team)			
Labor Participant Name (Add rows if necessary.)	**Hourly Rate**	**Total person hours[8]**	**$ USD**
1			
2			
TOTAL Labor			
Equipment, Supplies, & Services (ESS) Item (Add rows if necessary.)	**Units**	**Unit Cost**	**$ USD**
1			
2			
TOTAL ESS			
Travel (Totals only, describe purpose and per person costs in detail in Budget Narrative.)			**$ USD**
Domestic Transportation			
Domestic Per Diem			
International Transportation			
International Living Allowance/Per Diem			
Other Travel Expenses (e.g. visa fees, conference registration fees, etc.)			
TOTAL TRAVEL			
TOTAL SECONDARY COLLABORATOR DIRECT EXPENSES			
Indirect Costs (IDC) of Secondary Collaborators			
Must include a cost-share for IDC expenses exceeding 08% of Modified Total Direct Cost.			
TOTAL OF PRIMARY PARTICIPANT AND SECONDARY COLLABORATOR DIRECT EXPENSES			
TEAM SUBTOTAL (Total of direct expenses and IS)			
TOTAL COST-SHARING FROM NON-CRDF Global SOURCES (Including for-profit contributions. Describe in detail in Budget Narrative)			

BUDGET NARRATIVE FORM

(Complete ONE for eachInstitution involved; include Secondary Institution costs explanation within each budget category.)

[7]"Person-hours" = estimatedtotalnumberofhoursdevotedtotheprojectthroughoutthedurationoftheproject.

[8]"Person-hours" = estimatedtotalnumberofhoursdevotedtotheprojectthroughoutthedurationoftheproject.

Describe and justify the expenses included in each budget line item. If a line item doesn't apply to your budget, please insert N/A for "not applicable "in the space provided.

Institute: _____
Labor Describe the level of effort projected for the PI and other team participants. Provide justification for pay rate and any fringe benefits included.
Enter Text….
Equipment, Supplies and Services (ESS) Justify the purpose and cost rationale of each ESS line item included in the budget. General or non-descript line items such as "supplies" or "services" are not acceptable. Please itemize.
Enter Text….
Travel Explain the need for travel - how the travel will benefit the project's aims - and your calculations of travel costs for domestic and foreign travel. Break down by airfare, hotel, per diem, etc.
Enter Text….
Institutional Support (IS) Justify indirect costs 08% of the total sub-team direct expenses requested. Indicate if a NICRA or other institutional IDC certification is applicable.
Enter Text….

PI OTHER SOURCES OF SUPPORT FORM
(Complete for EACH PI; replicate this page as necessary.)

PI Name	Last, First		
If no other sources of support, check "None." Otherwise, complete table below for each source (duplicate as needed).			☐**"None"**
Project/Proposal Title	Title	**Location of Research**	Region/Country
Support	☐ Current ☐Pending Submission Planned in Near Future		
Source of Support	Name	**Level of Effort (%)**	%
Award Amount	$ USD	**Period Covered**	MM/YY – MM/YY
Project/Proposal Title	Title	**Location of Research**	Region/Country
Support	☐ Current ☐Pending Submission Planned in Near Future		
Source of Support	Name	**Level of Effort (%)**	%
Award Amount	$ USD	**Period Covered**	MM/YY – MM/YY
Project/Proposal Title	Title	**Location of Research**	Region/Country
Support	☐ Current ☐Pending Submission Planned in Near Future		
Source of Support	Name	**Level of Effort (%)**	%
Award Amount	$ USD	**Period Covered**	MM/YY – MM/YY
Project/Proposal Title	Title	**Location of Research**	Region/Country
Support	☐ Current ☐Pending Submission Planned in Near Future		
Source of Support	Name	**Level of Effort (%)**	%
Award Amount	$ USD	**Period Covered**	MM/YY – MM/YY
Project/Proposal Title	Title	**Location of Research**	Region/Country
Support	☐ Current ☐Pending Submission Planned in Near Future		
Source of Support	Name	**Level of Effort (%)**	%
Award Amount	$ USD	**Period Covered**	MM/YY – MM/YY

Institutional Data Form
(Complete ONE for each Institution involved. Replicate as necessary)
The information requested below must be provided in full and signed by an authorized institutional signatory, certifying that the information is true to the best of their knowledge. CRDF Global cannot proceed with an award to the institute without this information.

Institution Name:	
Institutional Website:	
Type of Organization:	International Organization ☐ Government ☐Corporation ☐ University ☐
DUNS Number	

Organizations must have a DUNS number to receive federal funding. For help applying for a DUNS number and more guidance on completing this form, please click here.

US Organizations Only			
TIN/EIN			
Small Business Designations	Small Business ☐ SDB☐ HUB-Zone ☐ VOSB ☐ SDVOSB☐ N/A ☐		
Financial Controls, Audits, & Bioethics			
Did your organization expend more than US $750,000.00 in U.S. Government Federal Funding (Grants, Contracts, Subgrants, Subcontracts) in the previous fiscal year? If yes, please provide a copy of your single audit report, which is required under 2 CFR 200.		Yes ☐	No ☐
Have you been audited in the past 3 years? If yes, please send a copy of the report.		Yes ☐	No ☐
Were there any material or significant findings in the audit report?		Yes ☐	No ☐
Has your organization ever had a grant or contract terminated for cause?		Yes ☐	No ☐
Does your organization utilize a financial manual to authorize expenses?		Yes ☐	No ☐
Does your organization utilize an accounting system to track expenses?		Yes ☐	No ☐
Does your organization have an ethics policy?		Yes ☐	No ☐
Does your organization have a timekeeping system for labor such as timesheets?		Yes ☐	No ☐
Does your project involve: Human Subjects ☐ Animal Testing ☐ Recombinant DNA ☐ Not applicable/None ☐			
Executive/Management Reporting Requirements			
CRDF Global may be required to publicly report the names and total compensation of the five most highly compensate individuals at the awardees' institution. If you meet any of the criteria below, you are exempt from this requirement. Please fin and check any applicable exemption:			
In the previous tax year, institutional gross income from all sources was LESS than $300,000.			Exempt ☐
The institution received LESS than 80 percent of its annual gross revenues in U.S. federal funding (Contracts, Grants, Subgrants, Subcontracts or Loans).			Exempt ☐
The institution received LESS than $25,000,0000 in annual gross revenues from U.S. federal funding sources (Contracts, Grants, Subgrants, Subcontracts or Loans).			Exempt ☐
Executive compensation is publicly reported under section 13(a) or 15(d) of the Security Exchange Act or section 6104 of the Internal Revenue Code.			Exempt ☐
I do not meet any of the exemptions above. I will provide the names and total compensation of the five most highly compensated executives. Click here for more information.			Not Exempt☐
Past Performance			
Please list any applicable grants or contracts received from outside organizations. Successful completion is defined as zer suspensions or terminations for cause, audit findings or other discrepancies.			
Funding Source	Total Funding	Successful Completion?	Type of Project
World Bank	Ex. 50,000USD	Yes ☐ No☐	Research Grant
		Yes ☐ No☐	
		Yes ☐ No☐	

Signature	Name and Title	Date

CRDFGLOBAL INSPIRED BY PEOPLE | DRIVEN BY SCIENCE	Guidelines for Projects Involving Human and/or Animal Research Subjects

CRDF Global is committed to ensuring that projects involving human or animal research are conducted in accordance with all applicable regulations and ethical guidelines. All projects recommended for award that involve human or animal subjects will undergo bioethics review prior to award activation. Following are instructions for the documentation required at this proposal stage.

Human Subjects Activity
Human subject activity includes any activity that involves obtaining information about living individuals by an intervention or interaction with said individuals. Activities classified as human subjects range from the undertaking of clinical trials, to conducting verbal or written surveys of study participants.

Prior to award initiation by CRDF Global, all projects involving ***human subjects*** must submit:

1. Documentation of Institutional Review Board (IRB) registration and Federal wide Assurance (FWA) with the U.S. Department of Health and Human Services (HHS), Office of Human Research Protections[9] (OHRP). This information must be submitted to CRDF Global using the **Bioethics Review Form** found in Appendix A.
2. Written approval from each responsible IRB or equivalent ethics committee; **OR** Written research exemption from each responsible IRB, or equivalent. The written approval or exemption notice must clearly include the name of the project (that matches information provided to CRDF Global) and period for which the approval/exemption is valid.

Animal Subjects Activity
Animal subject activity is defined as any activity that involves handling and/or care of live, vertebrate animals for research, testing, experimentation or educational purposes.

Prior to award initiation by CRDF Global, all projects involving ***animal subjects*** must submit:

1. Documentation of certification by the Association for Assessment and Accreditation of Laboratory Animal Care International[10] (AAALAC International). This information must be submitted to CRDF Global, using Bioethics Review Form found in Appendix A.

OR

1. Submission of the CRDF Global Summary Protocol Form (PSF), which collects details specific to the proposed animal usage, including type of animal(s), necessity and role in proposed research, and other relevant details (how obtained, housed, post-study, etc.).
2. Written approval from each responsible Institutional Animal Care and Use Committee (IACUC), or equivalent ethics committee OR Written research exemption from each responsible IACUC, or equivalent.

CRDF Global reserves the right to request additional information to ensure compliance with US regulations. Awards will not be issued for any projects involving human or animal subjects until these requirements are satisfied. CRDF Global may consider exceptions to these requirements for documented extenuating circumstances, as permitted by US regulation.

Bioethics Review Form

CRDF Global is committed to ensuring that projects involving human or animal research are conducted in accordance with all applicable regulations and ethical guidelines. All projects recommended for award that involve human or animal subjects will undergo bioethics review prior to award activation. The Principal Investigator (PI) must submit this form to CRDF Global within 2 weeks of receipt.

Project Name:			
Principal Investigator (PI) Name:			
PI Contact Information:			
Institution Name:			
Institution Website:			
Does your project involve:	☐ Human Subjects	☐ Animal Subjects	☐ Recombinant DNA
If you checked the box for Human Subjects, you must submit the information below. ***To obtain these numbers (#), please visit OHRP website: https://www.hhs.gov/ohrp/irbs-and-assurances.html***			

[9] The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and well being of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

[10] American Association for Accreditation of Laboratory Animal Care (AAALAC) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

OHRP IRB#:		OHRP FWA#:	
If you checked off the box for Animal Subjects above, you must check one of the options below.			
AAALAC Accreditation:		☐ Yes ☐ No	
All projects with human or animal subjects must submit either approval or exemption notice from their IRB or IACUC (as applicable). *The notice must include project name and, period for which approval/exemption is valid.*			
IRB/IACUC Approval/Exemption Notice Attached:		☐ Yes ☐ No	
If you answered No above you <u>must</u> complete the following section, to the best of your knowledge			
Date by which IRB Approval/Exemption notice will be submitted to CRDF Global:		*MM-DD-YYYY*	

Submitted By:

Name and Title

Date

APPENDIX B:
Program Indirect Costs and Cost Share Guidelines for CRDF Global Administered Funds

Indirect Costs (IDCs)
Awardees (Primary Institutions[11] and Secondary Institutions[12]) may request indirect costs/overhead expenses on all direct costs except for equipment (over $5,000), capital expenditures, rent, student tuition, participant support costs[13] and Secondary Institution expenses (after the first $25,000) funded through sub-contracts under the Primary Institution award.* Total direct costs minus these items is considered the modified total direct cost (MTDC) amount for which the IDC rate should be applied. IDCs combined with the total direct costs cannot exceed the funding total allowed to request. Below are helpful calculations:

- **IDC $** = IDC% x MTDC $
- **Maximum Total Sub-Team budget** = total direct costs $ (including MTDC) + IDCs $

Institutions with a Negotiated Indirect Cost Rates Agreement (NICRA) may request up to their approved NICRA rate. Documentation for these rates should be provided in the budget narrative if the institution requires this payment.

Institutions without a NICRA may **not request more than 08%** in IDCs.
**Secondary Institutions may receive award funds either 1) through an award agreement directly with CRDF Global or 2) through a sub-contract under the Primary Institution award agreement. To reduce IDCs and administrative burden for Primary Institutions to sub-contract to Secondary institutions, CRDF Global highly encourages option 1.*

Cost Share Requirements
At the outset of each new RePORT activity, CRDF Global will determine whether to impose the following cost share requirement for awardees. This requirement will be communicated prior to the preparation of any proposal or issuance of any award agreement. Eligible cost shares must meet all of the following criteria:

- Are verifiable through appropriate documentation provided by the awardee
- Are not included as cost share contributions for any other award made from U.S. government funding
- Are necessary and reasonable for the accomplishment of project objectives
- Are allowable costs under this program
- Are not paid by the U.S. government under another award, except where the Federal statute authorizing a program specifically provides that Federal funds made available for such a program can be applied to matching or cost sharing requirements of other U.S. government-funded programs

Examples of cost shares that may be included in the proposal:

1. Salary (including fringe benefits) of any team member essential to the project. Salary and fringe rates should be listed separately for each team member in the cost share budget.
2. Consultant services: Labor and fringe rates for third parties providing volunteer services towards the project may be counted as cost sharing or matching if the service is an integral and necessary part of the project. Rates for third-party volunteer services must be consistent with those paid for similar work by the non-Federal entity. In those instances, where the required skills are not found with the awardee, rates must be consistent with those paid for similar work in the labor market.
3. Equipment/Supplies: Donated equipment, office supplies, or laboratory supplies. Value for these items must be assessed at fair market value of the property at the time of donation
4. Travel: For travel deemed necessary and reasonable to the project, the awardee may cost share appropriate travel expenses, including:
    a. Airfare – Lowest cost economy airfare and compliant with the Fly America Act
    b. Lodging – Not to exceed applicable domestic or international U.S. government per diem rates
    c. Meals and Incidentals - Not to exceed applicable domestic or international U.S. government per diem rates
    d. Ground Transportation – Necessary local travel, such as taxis, rental cars, or mileage reimbursement on use of personal vehicles in accordance with the U.S. government allowance for Privately Owned Vehicles (POV)

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[11] PrimaryInstitution" is a corporation, partnership, association, institutionorotherorganizationthatreceivesassistanceundertheawardAgreementandisresponsibleforcarryingoutthe Projectasspecifiedintheapprovedproposal.

[12] Secondary institutions are thoseotherthanthe PrimaryInstitutionthatwillparticipateintheproposedprojectandreceive financialsupportunder a CRDF Globalaward. SecondaryInstitutionsmayparticipateintheformofsub-contractedworkor direct award agreement from CRDF Global. All allowablecostsdescribedin the programapply.

[13] ParticipantSupportcostsincludestipendsorsubsistenceallowances, travelallowancesandregistrationfeespaidtooronbehalfofparticipantsortrainees (butnotemployees) inconnectionwithmeetings, conferences, symposiaortrainingprojects, scholarships/fellowships.

5. Unrecovered Indirect Costs: the difference between the amount charged to the award and the amount which could have been charged to award under the awardees federally-approved negotiated indirect cost rate (NICRA). Unrecovered indirect costs are only eligible as cost sharing for entities that currently have a NICRA with a cognizant U.S. government agency.