

CRDF Global Request for Proposals (RFP)

Regional Prospective Observational Research in TB (RePORT) International and the Centers for AIDS Research (CFAR) Cross-Consortia Studies Elucidating the Role of HIV in TB Immunopathogenesis and Biomarker Discovery

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I. PROGRAM SNAPSHOT

Eligible Applicant(s)	Investigators from currently active RePORT and CFAR sites. See complete listing in Appendix A
RFP Opens	Friday, November 9 th , 2018 (23:59) U.S. Eastern Standard Time (EST)
Submission Deadline	Thursday, February 21 st , 2019 (23:59) U.S. Eastern Standard Time (EST)
Announcement of Results	May of 2019
Eligible Research Scope	To support ongoing projects by participating members of CFAR and RePORT consortia, to implement cross-cutting research activities, and to support hypothesis-driven research on TB bio-markers with translational potential to impact TB/HIV epidemic.
Project Duration	Up to 2 years
Award Amounts	Each award can be up to \$200,000 USD in total
Complete RFP & Application Forms	Download RFP and Word version of proposal forms and templates at: crdfglobal.org/funding-opportunities/2019-CFAR
How to Apply	All proposals must be submitted through the Electronic Proposal Submission (EPS) website: https://eps.crdfglobal.org/REPORT-CFAR E-mail attachments and hard copies will not be accepted. For more information and instructions please refer to Section VI. A Proposal Submission .
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II. BACKGROUND

CRDF Global is accepting proposals on behalf of the Division of AIDS at the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health to fund, collaborative global HIV/TB research projects across Regional Prospective Observational Research in TB (RePORT) International consortia (India, Brazil, Indonesia, South Africa, China and the Philippines) and the 19 Centers for AIDS Research (CFAR) allowing for work to extend across the 2 programs as well as sites and countries. The results of such research efforts will significantly impact HIV/TB clinical care and disease outcomes. Funding for this research award initiative is administered by CRDF Global, utilizing funds provided by U.S. National Institutes of Health (NIH).

RePORT International is a global network of observational cohorts and associated investigators with the goal of addressing local and global research priorities. RePORT International provides a platform for coordinated TB research by establishing a common set of standards and definitions; harmonized observational cohorts with well characterized populations; consolidated bio-specimen banks; and, integrated data collection and analysis

strategies. To this end substantial progress has been made with each participating country supporting local research teams that have established RePORT cohorts with ongoing studies. This goal has been accomplished through establishment of integrated multi-disciplinary teams of collaborative investigators that have planned and continue to plan and conduct research across the spectrum of clinical research in TB.

Similarly, the CFAR program is a trans-NIH program that provides administrative and shared research support to synergistically enhance and coordinate high quality HIV research projects. CFARs accomplish this through centralized core facilities that provide cutting edge expertise, specialized resources and innovative technologies in a cost-effective and efficient manner. The program emphasizes interdisciplinary and international collaboration across all areas of HIV research, including HIV/TB coinfection.

The Inter-CFAR HIV/TB Co-Infection Consortium was formed at the 2004 National CFAR Directors meeting to foster collaborations across the CFARs around HIV/TB research. The Consortium established three goals: 1) develop a shared research agenda around five areas of focus (molecular pathogenesis, immunology of coinfection, diagnostics, therapy and clinical trials, implementation science); 2) identify resources at individual CFARs that can be shared across CFARs; and 3) develop common or complementary research themes that could lead to joint inter-CFAR projects. The group published a supplement to the Journal of Infectious Diseases titled "[HIV/TB Coinfection: Current State of Knowledge and Research Priorities](#)" (15 August 2007, vol 196, S1).

Both groups are distinct but share complementary research goals and resources to enable successful collaborative research on biomarker discovery to inform TB treatment and prevention strategies in PLWH.

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. We 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.crdglobal.org>.

III. SCOPE

This supplemental funding is aimed at supporting ongoing projects by participating members of CFARs and the RePORT consortia, respectively to implement cross cutting research activities as detailed in the objectives below. All projects must address biomarker discovery research that is of special importance in TB/HIV co-infections. Eligible applicants must be investigators from currently active RePORT and CFAR sites (for complete list of eligible CFAR and RePORT sites provided refer to [Appendix A](#)). Additionally, details about each site; the research and research outputs, as well as the common protocol toolkit may be located here: <https://www.reportinternational.org/>

This solicitation will establish a new partnership between RePORT and CFAR investigators. It is anticipated that RePORT investigators will contribute their clinical expertise and samples from the established RePORT cohorts and will collaborate with CFAR investigators with fundamental research expertise and CFAR core facilities that can capitalize on the collected samples to address scientific objectives as described in this funding opportunity announcement.

Objectives

- Support hypothesis-driven research on TB biomarkers with translational potential to impact the TB/HIV epidemic.
- Encourage cross-consortium sharing of data and/or specimens and ideas inclusive of using bio-repository samples as needed.

Topics of interest include (but not limited to):

1. TB-specific immunologic mechanisms and/or markers in pediatric and adult populations that have been exposed to or infected with TB (inclusive of drug resistant TB).
2. Discovery or validation of prognostic immunologic signature(s) of TB progression and severity, including evaluation of how these biomarkers perform in the setting of HIV co-infection.
3. Vaccine-mediated mechanisms and/or correlates of protection against TB; host biomarkers that predict lack of vaccine protection in PLWH.

Scientific Justification

NIAID, DAIDS; together with in-country representation and support from National Health and Science ministries have jointly established Report to gain a comprehensive understanding of the pathogenesis of TB in TB/HIV co-infected populations. The purpose of RePORT International is to advance regional tuberculosis (TB) science that is also relevant in a global context; strengthen TB research capacity and infrastructure in high TB burden settings; and serve as an entity to foster research collaboration within each country and internationally, with the aim of carrying out a wide range of basic and clinical research that can lead to clinically important TB biomarkers, vaccines, drugs, and diagnostics. This goal has been accomplished through establishment of an integrated multidisciplinary team of highly collaborative investigators that have planned and continue to plan and conduct clinical research across a range of topics. Similarly, the overall mission of the CFAR program is to support multidisciplinary research aimed at reducing the burden of HIV both in the United States and around the globe. One-way CFARs accomplish this is by fostering inter-CFAR collaborations that bring together investigators with common scientific interests to share strategies, leverage resources and collectively identify significant research questions. The Inter-CFAR HIV/TB Co-Infection Consortium is one example of a group established to foster collaborations across the CFARs around HIV/TB research. It is anticipated that synergizing resources expertise and clinical samples of these 2 programs under this funding initiative will yield high quality collaborative research addressing research gaps that have been jointly identified.

TB remains a leading cause of infection-related death worldwide with the countries represented under RePORT carrying the largest proportion of this burden. In the collaborative workshop of CFAR and RePORT investigators, the potential for these collaboratives to contribute to the discovery, qualification, and validation of biomarkers of treatment response was emphasized. A major roadblock in developing biomarkers into validated surrogate endpoints of treatment response has been the lack of well-characterized repositories with biospecimens obtained from participants. The combined cohorts under RePORT offer participants who are exposed to a Tuberculosis index case (Contacts/Cohort B) as well as a cohort of newly diagnosed pulmonary TB cases; both cohorts include participants with or without HIV co-infection and other co-morbidities such as diabetes. TB disease in the contacts and treatment outcomes including failure and relapse in Cohort A are the outcomes of interest. The cohorts are well characterized inclusive of a a minimum set of data and biological specimens to permit a comprehensive and integrated biomarker discovery and validation program in the future. Additionally, cohorts of exposed contacts to index cases (the Cohort B of RePORT offers an opportunity to understand the immunological mechanisms underlying the acquisition of TB disease in the exposed enabling the discovery and validation of correlates of risk.

Elucidating TB-specific immunologic mechanisms; and determination of biomarkers of risk, progression and protection have been identified as requiring iterative, in-depth analyses across all or most sites within and between the respective consortia. This was not planned for in the initial funding cycle as all sites were not established and it was unclear at the time as to whether common themes would arise. Additionally, the cohorts have attained a level of maturity that lends for these additional and previously unbudgeted cross-consortia activities and analysis.

During the course of TB infection to TB disease; the human immune system for the most part keeps the progress to TB disease in check. The immune system challenged by co-infections such as HIV and diabetes alter the risk of progressing to active TB disease. The immunopathogenic mechanism are not fully understood. Expanded analysis of specimens collected cohorts under RePORT and CFAR are likely to elucidate these pathways.

Mtb has evolved numerous immune evasion mechanisms that disrupt the generation of protective immunity and facilitate pathogen survival within the host. Limited understanding of immune mechanisms capable of preventing Mtb infection, establishment and disease progression, as well as the mechanisms by which Mtb evades these responses, makes the selection of next generation TB vaccine candidates difficult. Although numerous animal and human studies have identified immunodominant Mtb antigens that trigger T cell responses and immune parameters that may be associated with some level of protection, none of these parameters alone appear to sufficiently provide long-term protective immunity against Mtb infection or prevent development of TB disease. Importantly, mechanisms necessary to prevent infection or establishment of disease may differ from those required to prevent transition to active disease. While non-human primate studies and imaging technologies have provided valuable insights into the dynamics of granuloma formation and maintenance during latency and disease reactivation, there is limited understanding of the immune mechanisms mediating these different disease stages. Additionally, mechanisms that confer a level of protection in extra-pulmonary sites may be distinct from those required in the lung. Finally, the specific mechanisms in children, the elderly and HIV-infected individuals that increase the probability of progression to active TB disease remain unclear.

Immunologic analyses, using pathogens other than Mtb, have described human immune gene expression profiles in blood that can distinguish respiratory infections of different etiologies, such as influenza A virus, Escherichia coli, Staphylococcus aureus, and Streptococcus pneumoniae. A number of studies also have used systems immunology approaches to characterize human immune signatures of different vaccines. Recently, immune profiles of response to the yellow fever vaccine were described that identify with, and could predict, the immunogenicity of the vaccine in humans. Similarly, signatures of the early response to influenza vaccination identified gene expression patterns that could predict the production of influenza specific antibodies at titers expected to induce protection. Importantly, these immunologic analyses of yellow fever and influenza vaccines provide valuable information regarding immunological mechanisms triggered by different types/forms of vaccines. In addition to detailed analyses of human blood, immunologists are examining tissue-resident immune responses to infections or vaccines using samples collected from organ donors, individuals undergoing surgical procedures, or through excision of lymph nodes or fine-needle aspirates of lymphoid and non-lymphoid tissues. The RePORT cohorts provide an opportunity to expand on these investigations as well. The application of such immunologic analyses to the TB field would dramatically enhance our understanding of immune mechanisms required for protection against Mtb infection/TB disease and provide foundational information to improve TB vaccine design.

Funds Available

This supplemental funding will support three or more RFAs to participating members of both consortia to implement cross cutting research activities as detailed in the objectives above. Grant awards will be made to research team institutions to support **projects up to two years in duration**. Each award can be **up to \$200,000 USD in total**. If justified near the end of the project, up to a six month no cost extension may be permitted.

CRDF Global will address all administrative related inquiries for the RFP, receive full proposals from applicants, coordinate a technical peer review of proposals, and communicate all results to applicants. Following these reviews, the program sponsors will determine meritorious proposals to receive awards administered through CRDF Global. The most meritorious applications will be awarded based on available funds and RePORT International priorities.

Duration and start date of the project:

- Upon announcement of award selection, **finalists may not begin any project activities or incur any project expenses** until an agreement has been signed by CRDF Global. This process can take 60-90 days from the time of award announcement. **Additionally, projects involving human subjects/animal subjects may not begin until all required bioethics documentation is approved by CRDF Global. This should be taken into consideration when preparing the proposal timeline.**
- The **start date of the project** shall be the date an award agreement is fully executed by CRDF Global.

- Research timeline is recommended to be prepared in terms of semi-annual segments, per the Milestone Plan. See sample plan included in [Appendix B](#)
- 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.

IV. ELIGIBILITY

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

1. Proposals for collaborative research projects should be submitted by a partnership of at least one RePORT and one CFAR investigator.
2. The grantee institution must have a currently funded RePORT or CFAR award. Collaborations are a requirement between RePORT Investigators and CFAR investigators but are also encouraged within these networks. A competitive application should be responsive to the scientific stipulation of the call and should include at least one RePORT and one CFAR investigator from currently funded sites.
3. The proposal must identify one of the investigators as the **Project coordinating Principal Investigator (PI)** (hereafter referred to as **Project PI**) who will serve as the main contact point, to administer and coordinate activities and represent the partnership. However, each institution represented by their respective investigators will receive a separate grant, and all investigators will share overall responsibility for the project and cooperate for project implementation and outcomes.
4. Investigators from institutions other than the Primary Institutions may be included as collaborators under each US and non-US site/CRU at the discretion of the Team co-investigators. This may include US-based RePORT counterparts as well as other RePORT and CFAR affiliated and/or non-affiliated collaborators. Collaborators whose institutions are requesting project funds should be designated as Secondary Institutions¹.
5. Funds may not be used to duplicate previously funded research goals or to simply augment enrollment numbers for currently funded studies or to support other previously funded activities from another source.
6. Each collaborative team can submit only one proposal for this competition. Furthermore, individuals can serve as primary investigator **on only one** proposal. A site may also participate in multiple applications but with different investigators.
7. **Cost-Share Requirements:** Awardees with a Negotiated Indirect Cost Rate Agreement (NICRA) from a U.S. federal cognizant agency exceeding 10% (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 10% 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.

¹ Secondary institutions are those other than the Primary Institution that will participate in the proposed project and receive support under a CRDF Global award. Secondary Institutions may participate in the form of sub-contracted work and may include any allowable costs described in this program.

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 cross-consortium 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 International and CFAR. Indication of a plan to disseminate research findings or describe successful cross-consortia data or specimen sharing.
- 4. Personnel Capacity and Budget:** The expertise of the Team co-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 International and CFAR:** Indication that the Team co-investigators and associated teams are committed to, and engaged in, research that adheres to RePORT's Common Protocol and CFAR's associated data and specimen standards. The project's likely contribution to the goal of cross-consortium research, data and laboratory harmonization, and lessons learned for future collaborative efforts.

CRDF Global will email each Team co-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, February 21st, 2019 (23:59) U.S. Eastern Standard Time (EST)**.

<https://eps.crdfglobal.org/REPORT-CFAR>

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

Once the proposal has been finalized, **the Project PI 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, each Team co-Investigator 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 PSF 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-CFAR

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 co-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 B](#) and 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:** Five (5) pages maximum, including any graphs, diagrams, or photos. Co-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:

- Project's relevance to both RePORT International and CFAR,
- Detailed methodology including a description of the study design, including the type of study, and whether the Common Protocol and CFAR 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 supplemental project as described in the Milestone Plan.
- Description of expected barriers and plans to overcome barriers to data and/or biological specimen sharing, including processes, procedures or agreements that will be developed. The investigators must acknowledge their plans to share such documents and findings with the RePORT International and CFAR Consortia.
- Key personnel: How the competencies of the Team co-investigators and team participants will enable the project to be carried out. How the Team co-investigators 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."

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 sub-team 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 additional team participants only, Team co-investigators do not need to complete a form with their own information
 - 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 Sub-Team Budget.** Complete ONE for each team co-investigator’s Primary 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 Team co-investigator’s Primary 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 Team co-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 or NSF, 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 a co-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 Team co-investigator’s Primary Institute.

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

1. **Team Co-investigator and Key Participant Biosketches in one file (Required)** Applicants must provide copies of all Team Co-investigators and key team participants’ biosketches 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 Team co-investigator's Primary 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

The maximum total award is up to **\$200,000 USD for no more than two years of support**. If justified near the end of the project, up to a six month no cost extension may be permitted.

- 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

The following costs are permitted under CRDF Global guidelines for this program:

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 costs² 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 Sub-Team budget = total direct costs \$ (including MTDC) + IDCs \$**

Non-US Institutions without a NICRA may **not request more than 08%** in IDCs.

Secondary Institutions. Secondary Institutions are institutions other than the Primary Institution that will participate in the proposed project and receive support under a CRDF Global award. Secondary institutions may participate in the form of sub-contracted work and may include any allowable costs described in this program. All secondary institution personnel and facilities must be specifically listed and described in the proposal. A separate budget justification for each secondary institution must be included in the Budget Narrative.

VIII. CRDF GLOBAL EXPECTATIONS OF GRANTEES

Awardees from this competition will be expected to:

- Have or provide 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 semi-annual progress reports for each six-month period (or fraction thereof) for the duration of the award, and one joint final project report.

IX. ADDITIONAL INFORMATION AND SUPPORT

² Participant Support costs include stipends or subsistence allowances, travel allowances and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with meetings, conferences, symposia or training projects, scholarships/fellowships.

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**

Roxana Rustomjee
5601 Fishers Lane, Rm 9E31A
Rockville, MD 20852
Phone: 240-627-3536
Email: Roxana.rustomjee@nih.gov

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

Candice Beaubien
5601 Fishers Lane, Rm 9G21A
Bethesda, MD 20892
Phone: 240-627-3098
Email: candice.beaubien@nih.gov

Elaine Wong
5601 Fishers Lane, Rm 9G34
Bethesda, MD 20892
Phone: 240-627-3100
Email: wongelai@niaid.nih.gov

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 Project Team co-investigator
 - Signed by Team co-investigators and Institute Representatives.
 - On institutional Letterhead
- Cover Sheet**
 - Project PI is designated among the Team co-investigators
 - All fields are completed
- Project Abstract**
 - Does not exceed 350 words
- Project Narrative**
 - All project criteria are addressed
 - Text is within five (5) 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
- References Cited**
- 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 (other than PIs) - 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
- Budget Narrative Forms**
 - One for EACH Team co-investigator Primary Institute – includes secondary institutions as well
 - 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 EACH Team co-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 team participants**
 - Uses NIH biosketch format
 - One for each co-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 Institution

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
 - Biosketches all team participants combined into a SINGLE PDF or Word file
 - Human and/or Animal Subjects research documentation combined into a SINGLE PDF or Word file

APPENDIX A

List of International Cohort Research Units (CRUs), CRU Sites, and U.S. Counterparts

RePORT India		
Cohort Research Units (CRUs)	International CRU Site PIs and Institutions	U.S. Counterpart PIs and Institutions
CMC	Devasahayam Christopher, D.N.B. Christian Medical College (CMC) Department of Pulmonary Medicine Ida Scudder Road Vellore, TN 632004	Lalita Ramakrishnan, MBBS, Ph.D. Department of Medicine, University of Cambridge, Cambridge CB2 0QH
JIPMER	Subhash Chandra Parija, M.D. Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Dhanvantri Nagar, Puducherry 605 006.	Jerrold Ellner, M.D. Rutgers New Jersey Medical School 185 S Orange Ave Newark, NJ 07103
MVDRC	Vijay Viswanathan, M.D., Ph.D. M.V. Diabetes Research Centre (MVDRC) No. 4, West Mada Church Street Royapuram, Chennai, TN 600013	Hardy Kornfeld, M.D. University of Massachusetts Medical School LRB-303 55 Lake Avenue North Worcester, MA 01655
BPHRC-LEPRA	Vijaya Valluri, Ph.D. Bhagawan Mahavir Medical Research Centre Mahavir Hospital, Mahavir Marg Masab Tank Hyderabad, TS 500004	Ramakrishna Vankayalapati, Ph.D. University of Texas Health Center 11937 US Highway 271 Tyler, TX 75708
BMMRC	Sumanlatha Gaddam, Ph.D. 10-1-1, Bhagawan Mahavir Medical Research Centre Mahavir Hospital, Mahavir Marg Masab Tank Hyderabad, TS 500004	
NIRT/BJMC	Padmapriyadarsini Chandrasekaran, M.D. Soumya Swaminathan, M. D. (previous PI) National Institute for Research in TB (NIRT) No. 1 Sathyamoorthy Road Chetput, Chennai, TN 600031	Amita Gupta, M.D. Johns Hopkins University 600 North Wolfe Street Phipps 540 Baltimore, MD 21287
	Vidya Mave, M.D. Byramjee Jeejeebhoy Medical College (BJMC) 1st Floor, Pathology Museum Jai Prakash Narayan Road Pune, MH 411001	

RePORT Brazil		
Cohort Research Units (CRUs)	International CRU Site PIs and Institutions	U.S. Counterpart PIs and Institutions
INI – Fiocruz (Rio)	Valleria Rolla, MD, PhD National Institute of Infectious Diseases Evandro Chagas 4365 Avenida Brasil, Manguinhos, Rio de Janeiro-RJ, 21040-900	Timothy Sterling, M.D. Vanderbilt University Medical Center A2209 Medical Center North, 1161 21st Avenue South, Nashville, TN 37232
Rocinha (Rio)	Betina Durovni, M.D. Clinica de Familia Rinaldo de Lamare 776, Niemeier Ave, Sao Conrado, Rio de Janeiro-RJ, 22450-221	
Caxias (Rio)	Afranio Kritski, M.D., PhD Universidade Federal do Rio de Janeiro (UFRJ) 255, 6th floor (TB Research Center), Prof Rodolpho Rocco, Ilha Fundao, Rio de Janeiro-RJ, 21941-913	
UFRJ	Afranio Kritski, M.D., PhD Universidade Federal do Rio de Janeiro (UFRJ) 255, 6th floor (TB Research Center), Prof Rodolpho Rocco, Ilha Fundao, Rio de Janeiro-RJ, 21941-913	
FMT / Manaus	Marcelo Cordeiro, M.D. Fundacao de Medicina Tropical (FMT) 25 Avenida Pedro Teixeira, Dom Pedro, Manaus-AM, 69040-000	
IBIT and IBR Salvador	Bruno Bezerril Andrade, M.D., PhD Instituto Brasileiro para Investigação da Tuberculose (IBIT), Fundação José Silveira Ladeira do Campo Santo, Federação, Salvador-BA, 40210-320	

RePORT South Africa		
Cohort Research Units (CRUs)	International CRU Site PIs and Institutions	U.S. Counterpart PIs and Institutions
SATVI	Mark Hatherill, M.D. South African Tuberculosis Vaccine Initiative (SATVI) University of Cape Town Faculty of Health Sciences, Room S2.11, IDM Anzio Road, Observatory, 7925	Jerrold Ellner, M.D. Rutgers New Jersey Medical School 185 S Orange Ave Newark, NJ 07103
Wits Health Consortium	Neil Alexander Martinson, M.D. Wits Health Consortium Perinatal HIV Research Unit Chris Hani Baragwanath Hospital Diepkloof, Soweto	Richard E. Chaisson, M.D. International Health Johns Hopkins Center for Tuberculosis Research and Center for AIDS Research 1550 Orleans St., 1M.08 Baltimore, MD 21231
UCT	Mark Nicol, M.D. Division of Medical Microbiology UCT Faculty of Health Sciences Observatory 7925, South Africa	Jeffrey Starke, M.D. Pediatrics-Infectious Disease Baylor College of Medicine Houston, TX, US
UCT	Keertan Dheda MBBCh (Wits),FCP (SA),FCCP, PhD (Lond), FRCP (Lond) Department of Medicine University of Cape Town Observatory South Africa 7925	Tawanda Gumbo, M.D. Baylor Institute of Immunology Research Baylor Research Institute 3434 Live Oak Street Dallas, TX 75204
K-RITH	Alexander Pym, M.D., PhD K-RITH Tower Building, level 3 Nelson R. Mandela School of Medicine 719 Umbilo Road, Durban, 4001, South Africa	Timothy Sterling, M.D. Vanderbilt University Medical Center A2209 Medical Center North, 1161 21st Avenue South, Nashville, TN 37232
RePORT Indonesia		

Cohort Research Units (CRUs)	International CRU Site PIs and Institutions	U.S. Counterpart PIs and Institutions
NIHRD	Karyana, Muhammad, M.Kes Gedung Laboratorium Terpadu (4) Lantai 5 Badan Litbangkes – Jl Percetakan Negara no 29 Jakarta	N/A
NIHRD	Mustika Indah, Retna Gedung Laboratorium Terpadu (4) Lantai 5 Badan Litbangkes – Jl Percetakan Negara no 29 Jakarta	N/A
INA-RESPOND	Kosasih, Herman, PhD Gedung Laboratorium Terpadu (4) Lantai 5 Badan Litbangkes – Jl Percetakan Negara no 29 Jakarta	N/A
RePORT China		
Cohort Research Units (CRUs)	International CRU Site PIs and Institutions	U.S. Counterpart PIs and Institutions
BCH	Yuhong, Liu China, Beijing, Tongzhou, Tongyan Expressway Side Rd, Beijing, China	N/A
BCH	Jingtao, Gao, PhD China, Beijing, Tongzhou, Tongyan Expressway Side Rd, Beijing, China	N/A
BCH	Liang, Li, MD China, Beijing, Tongzhou, Tongyan Expressway Side Rd, Beijing, China	N/A
RePORT Philippines		
Cohort Research Units (CRUs)	International CRU Site PIs and Institutions	U.S. Counterpart PIs and Institutions
UPM	Lopez, Anna Lena, MD, MPH University of the Philippines Manila-National Institutes of Health, Manila City, Philippines	N/A
UPM	Aldaba, Josephine University of Philippines Manila-National Institutes of Health, 623 Pedro Gil St. Ermita, Manila City, Philippines	N/A
UPM	Montoya, Jimmy University of Philippines Manila-National Institutes of Health, 623 Pedro Gil St. Ermita, Manila City, Philippines	N/A

List of eligible Center for AIDS Research (CFAR) Sites

Institution	Personnel	
<p align="center">CFAR at Case Western Reserve University/University Hospitals of Cleveland</p> <p align="center">Website: http://cfar.case.edu/</p>	<p>Director:</p>	<p align="center">Jonathan Karn, Ph.D. 216-368-3915 jonathan.karn@case.edu</p>
	<p>Co-Director:</p>	<p align="center">Michael M. Lederman, M.D. 216-844-8786 lederman.michael@clevelandactu.org</p>
<p align="center">District of Columbia CFAR George Washington University, American University, Children's National Medical Center, Georgetown University, Howard University, and Washington DC Veterans Affairs Medical Center</p> <p align="center">Website: https://dccfar.gwu.edu/</p>	<p>Director:</p>	<p align="center">Alan E. Greenberg, M.D., M.P.H. 202-994-0612 aeg1@gwu.edu</p>
	<p>Co-Director:</p>	<p align="center">Gary Simon, M.D., Ph.D., M.A.C.P. 202-741-2234 gsimon@mfa.gwu.edu</p>
<p align="center">Duke Center for AIDS Research</p> <p align="center">Website: http://cfar.duke.edu</p>	<p>Director:</p>	<p align="center">Kent Weinhold, Ph.D. 919-684-5572 kjw@duke.edu</p>
<p align="center">Einstein-Rockefeller-CUNY Center for AIDS Research</p> <p align="center">Website: https://www.einstein.yu.edu/centers/erc-center-for-aids-research/</p>	<p>Director:</p>	<p align="center">Harris Goldstein, M.D. 718-430-2156 Harris.goldstein@einstein.yu.edu</p>
<p align="center">CFAR at Emory University</p> <p align="center">Website: https://sph.emory.edu/departments/bshe/research/cfar/index.html</p>	<p>Co-Director:</p>	<p align="center">Carlos del Rio, M.D. 404-616-6779 cdelrio@emory.edu</p>
	<p>Co-Director:</p>	<p align="center">James W. Curran, M.D., M.P.H. 404-727-8720 jcurran@sph.emory.edu</p>
	<p>Co-Director:</p>	<p align="center">Eric Hunter, Ph.D. 404-727-9248 eric.hunter2@emory.edu</p>
<p align="center">CFAR at Harvard University</p>	<p>Director:</p>	<p align="center">Bruce D. Walker, M.D. 617-724-8332 bwalker@partners.org</p>

Website: http://cfar.globalhealth.harvard.edu	Co-Director:	Myron Essex, D.V.M., Ph.D. 617 432 0975 messex@hsph.harvard.edu
CFAR at Johns Hopkins University Website: http://hopkinscfar.org/	Co-Director:	Richard E. Chaisson, MD 443-287-1035 rchaiss@jhmi.edu
	Co-Director:	Chris Beyrer, MD, MPH 410 614-5247 cbeyrer@jhsph.edu
Providence/Boston CFAR Website: www.provboscfar.org	Director:	Susan Cu-Uvin, M.D. 401-793-4775 Scu-Uvin@lifespan.org
	Associate Director:	Larry K. Brown, MD 401-793-8808 lkbrown@lifespan.org
CFAR at University of Alabama at Birmingham Website: http://www.uab.edu/cfar/	Director:	Michael S. Saag, M.D. 205-934-7349 msaag@uab.edu
CFAR at UCLA Website: http://aidsinstitute.ucla.edu/	Director:	Jerome A. Zack, Ph.D. 310-825-0876 jzack@ucla.edu
	Co-Director:	Irvin S.Y. Chen, Ph.D. 310-825-4793 syuchen@mednet.ucla.edu
CFAR at UCSD Website: https://cfar.ucsd.edu	Co-Director:	Davey Smith, MD,MAS 858-552-7439 davey@ucsd.edu
	Co-Director:	Douglas Richman, M.D. 858-552-7439 drichman@ucsd.edu
CFAR at UCSF/GIVI Website: http://cfar.ucsf.edu	Director:	Paul A. Volberding, M.D. 415-750-2037 paul.volberding@ucsf.edu
	Director:	Warner C. Greene, M.D., Ph.D. 415-734-4805 wgreene@gladstone.ucsf.edu

<p>CFAR at University of Miami</p> <p>Website: http://cfar.med.miami.edu/</p>	<p>Director:</p> <p>Savita Pahwa, M.D. 305-243-7732 spahwa@med.miami.edu</p>
	<p>Co-Director:</p> <p>Mario Stevenson, Ph.D. 305-243-2689 MStevenson@med.miami.edu</p>
<p>CFAR at University of North Carolina</p> <p>Website: http://unccfar.org/</p>	<p>Director:</p> <p>Ronald I. Swanstrom, Ph.D. 919-966-5710 risunc@med.unc.edu</p>
	<p>Associate Director:</p> <p>Myron Cohen, M.D. 919-966-2536 mscohen@med.unc.edu</p>
<p>CFAR at the University of Pennsylvania, the Children's Hospital of Philadelphia, and the Wistar Institute</p> <p>Website: http://www.med.upenn.edu/cfar/</p>	<p>Director:</p> <p>Ronald G. Collman, M.D. 215-898-0913 collmanr@penntools.upenn.edu</p>
	<p>Co-Director:</p> <p>Robert Gross, M.D. 215-898-2437 grossr@penntools.upenn.edu</p>
<p>CFAR at University of Rochester</p> <p>Website: http://www.urmc.rochester.edu/dcfar/</p>	<p>Director:</p> <p>Steve Dewhurst, Ph.D. 585-275-3216 stephen_dewhurst@urmc.rochester.edu</p>
	<p>Co-Director:</p> <p>Michael C Keefer, M.D. 585-275-8058 michael_keefer@urmc.rochester.edu</p>
<p>CFAR at University of Washington/Fred Hutch</p> <p>Website: http://cfar.washington.edu</p>	<p>Director:</p> <p>Jared Baeten, MD, Ph.D. 206-520-3808 jbaeten@uw.edu</p>
	<p>Co Director:</p> <p>King K. Holmes, M.D., Ph.D. 206-744-3620 kkh@uw.edu</p>
	<p>Co Director:</p> <p>Ann Collier, M.D. 206-744-3293 phone acollier@uw.edu</p>

	Co Director:	Corey Casper, M.D., M.P.H. 206-667-4600 Corey.Casper@idri.org
Third Coast Center for AIDS Research Website: http://thirdcoastcfar.org	Director:	Richard T. D'Aquila, M.D. 312-503-6206 richard.daquila@northwestern.edu
	Co-Director:	Brian Mustanski, Ph.D. 312-503-6509 brian@northwestern.edu
Tennessee Center for AIDS Research Website: https://www.vumc.org/tncfar/	Director:	Simon A Mallal, M.B.B.S. 615-322-2035 simon.mallal@vanderbilt.edu
	Associate Director at Vanderbilt:	David W Haas, M.D. 615-936-8594 david.haas@vanderbilt.edu
	Associate Director at Meharry:	James E.K. Hildreth, Ph.D. M.D. 615-327-6904 jhildreth@mmc.edu

APPENDIX B: Application Forms

PROJECT TEAM COVER LETTER AND TERMS AGREEMENT

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

[INSTITUTE LETTER HEAD]

Re: [Full Proposal Title]

I, [co-Principal Investigator (PI) Name], hereby acknowledge that I have submitted a proposal to the **RePORT International/CFAR Supplemental Funding RFP** jointly with [co-investigator's Name(s)] of [co-investigator's institution name(s)].

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 Policy³. 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

Administrative/Sponsored Research Representative Signature⁴ Date

³ Please refer to CRDF Global's [Plagiarism and Policy Standards](#).

⁴ Administrative/Sponsored Research Representative is an administrative and financial personnel aware of the proposal content prior to submission.

COVER SHEET

GENERAL PROJECT INFORMATION				
Project Title <i>(not to exceed 25 words)</i>	Title			
Amount Requested <i>(not to exceed \$200,000 total)</i>	Total	Project Team #1	Project Team #2	Project Team #3 <i>(If Applicable)</i>
	\$Amount.	\$Amount.	\$Amount.	\$Amount.
Research Categorization ⁵	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

TEAM PROJECT PI						
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 <i>(Surname)</i>	Last	First Name <i>(Given)</i>	First	Middle <i>(Second/Patronymic)</i>	Middle	
Position/Title	Full Title					
PI E-mail	Email 1		Alternative E-mail <i>(optional)</i>	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					#	

⁵ Please reference the CRDF Global Research Areas document found here: http://www.crdfglobal.org/docs/default-source/cgp-competition-docs/crdf-global-research-areas_jan-2013.pdf?sfvrsn=0

TEAM CO-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					#

TEAM CO-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					#

PROJECT INFORMATION FORM

1. Topic (please select up to three from the following topics):		
<input type="checkbox"/> Host Immunology	<input type="checkbox"/> Other Co-morbidities	<input type="checkbox"/> Active TB Infection
<input type="checkbox"/> TB Epidemiology	<input type="checkbox"/> TB and Pregnancy	<input type="checkbox"/> TB Drug Resistance
<input type="checkbox"/> TB Treatment	<input type="checkbox"/> Pediatric TB Infection	<input type="checkbox"/> TB Social Factors
<input type="checkbox"/> TB and HIV Co-infection	<input type="checkbox"/> TB Diagnostics	<input type="checkbox"/> TB Vaccine
<input type="checkbox"/> TB and Alcohol	<input type="checkbox"/> TB Pathogenesis	<input type="checkbox"/> TB Infection Control
<input type="checkbox"/> TB and Diabetes	<input type="checkbox"/> TB Biomarkers	<input type="checkbox"/> Other (Specify)
<input type="checkbox"/> TB and Parasitic Co-infection	<input type="checkbox"/> LTBI	
2. RePORT International sites involved in the proposed study:		
<input type="checkbox"/> BJMC	<input type="checkbox"/> INI- Fiocruz (Rio)	<input type="checkbox"/> SATVI
<input type="checkbox"/> NIRT	<input type="checkbox"/> Rocinha (Rio)	<input type="checkbox"/> Wits Health Consortium
<input type="checkbox"/> JIPMER	<input type="checkbox"/> Caxias (Rio)	<input type="checkbox"/> K-RITH
<input type="checkbox"/> LEPRA-BPHRC	<input type="checkbox"/> UFRJ	<input type="checkbox"/> UCT – TB Biomarker-Targeted Interventions
<input type="checkbox"/> MVDRC	<input type="checkbox"/> FMT/Manaus	<input type="checkbox"/> UCT - NAA for diagnosis in children
<input type="checkbox"/> CMC	<input type="checkbox"/> IBIT and IBR Salvador	<input type="checkbox"/> UCT - Biomarkers of Treatment Response
<input type="checkbox"/> INA-RESPOND	<input type="checkbox"/> NIHRD	<input type="checkbox"/> Other (Specify)
3. CFAR sites involved in proposed study		
<input type="checkbox"/> Case Western Reserve	<input type="checkbox"/> UAB	<input type="checkbox"/> U. Wash
<input type="checkbox"/> DC CFAR	<input type="checkbox"/> UCLA	<input type="checkbox"/> Third Coast Center
<input type="checkbox"/> Duke	<input type="checkbox"/> UCSD	<input type="checkbox"/> VUMC
<input type="checkbox"/> Einstein-Rockefeller-CUNY	<input type="checkbox"/> U. Miami	<input type="checkbox"/> Other (Specify)
<input type="checkbox"/> Emory	<input type="checkbox"/> UNC	
<input type="checkbox"/> JHU	<input type="checkbox"/> U. Penn	
<input type="checkbox"/> Providence/Boston	<input type="checkbox"/> URMC	
4. Proposal includes specimens and/or data from (Mark all that apply):		
<input type="checkbox"/> RePORT International Common Protocol Cohort A (Active TB cohort)		
<input type="checkbox"/> RePORT International Common Protocol Cohort B (Latent TB Infection cohort)		
<input type="checkbox"/> CFAR		
<input type="checkbox"/> Other (specify):		
5. Proposal activities (Mark all that apply):		

<input type="checkbox"/> Request to analyze existing dataset(s) <input type="checkbox"/> Request use of current repository specimens for further testing <input type="checkbox"/> Request additional new protocol procedures and/or participant visits <input type="checkbox"/> Other (specify):	
6. Does this project involve additional <u>participant</u> burden?	<input type="checkbox"/> Yes <input type="checkbox"/> No
a. If “Yes” check all that apply below	
<input type="checkbox"/> New specimen collection needed <input type="checkbox"/> New questionnaire administered <input type="checkbox"/> New procedure (e.g., MRI, biopsy) <input type="checkbox"/> New or additional consent needed <input type="checkbox"/> 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.	
<hr/> <hr/>	
SAMPLE SPECIFICATIONS (<i>Specimens obtained may not be used for any purpose other than the approved project without prior consultation and permission from the Executive Committee.</i>)	
7. Repository Information:	
a. Will this project require the withdrawal of specimens from the RePORT Central Biorepository?	
<input type="checkbox"/> Yes <input type="checkbox"/> No If YES, list biorepository site	
8. Sample Characteristics: To protect the most valuable and irreplaceable specimens in the RePORT International 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 RePORT International 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.	
<input type="checkbox"/> Cohort A general (number of requested participants) <input type="checkbox"/> Cohort B general (number of requested participants) <input type="checkbox"/> Cohort A diabetic (number of requested participants) <input type="checkbox"/> Cohort A non-diabetic (number of requested participants) <input type="checkbox"/> Cohort B diabetic (number of requested participants) <input type="checkbox"/> Cohort B non-diabetic (number of requested participants) <input type="checkbox"/> Cohort A TB treatment failure (number of requested participants) <input type="checkbox"/> Cohort A TB early relapse (number of requested participants) <input type="checkbox"/> Cohort B TB activation cases (number of requested participants) <input type="checkbox"/> Cohort B TB activation cases who enroll in Cohort A (number of requested participants) <input type="checkbox"/> Pediatric Cohort A (active TB) aged 5 years or younger (number of requested participants)	

<input type="checkbox"/> Pediatric Cohort A (active TB) aged 6 - 14 years (number of requested participants) <input type="checkbox"/> Pediatric Cohort B (HHCs) aged 5 years or younger (number of requested participants) <input type="checkbox"/> Pediatric Cohort B (HHCs) aged 6 - 14 years (number of requested participants) <input type="checkbox"/> HIV co-infected Cohort A (number of requested participants) <input type="checkbox"/> HIV co-infected Cohort B (number of requested participants) <input type="checkbox"/> Other (specify (number of requested participants)		
a. Expected number of Person-Visits to be studied:		
b. Expected number of unique participants to be studied		
9. Will this project require serial specimens with explicitly stated comparisons?		
<input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," please explain:		
a. Sample Type <i>* 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.</i>		
<input type="checkbox"/> PBMC <input type="checkbox"/> Plasma <input type="checkbox"/> PAXgene RNA <input type="checkbox"/> Other:	<input type="checkbox"/> mtb isolate <input type="checkbox"/> Sputum <input type="checkbox"/> Urine	<input type="checkbox"/> Saliva <input type="checkbox"/> Whole blood (DNA) <input type="checkbox"/> QuantiFERON
b. Sample Quantity:	Minimum:	Optimum:

PROJECT ABSTRACT
Should not exceed 350 words

PROJECT NARRATIVE

Should not exceed 5 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. *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.)			Responsible Team		
First Semi-Annual Reporting Period			Mark all that apply		
Milestone:	Description:	Associated Deliverable(s):	Site Name	Site Name	Site Name
<i>Training for five participants</i>	<i>The project team will receive training in GIS technologies/methods used for disease surveillance.</i>	<i>Copies of all training materials, including power point slides, hand-outs; photographs, and video footage of the training</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total Amount Requested for this Reporting Period:		\$15000	\$10000	\$5000	
Second Semi-Annual Reporting Period			Mark all that apply		
Milestone:	Description:	Associated Deliverable(s)	Site Name	Site Name	Site Name
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total Amount Requested for this Reporting Period:		\$ \$ Total	\$ \$ USD	\$ \$ USD	\$ \$ USD
Third Semi-Annual Reporting Period			Mark all that apply		
Milestone:	Description:	Associated Deliverable(s)	Site Name	Site Name	Site Name
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total Amount Requested for this Reporting Period:		\$ \$ Total	\$ \$ USD	\$ \$ USD	\$ \$ USD
Fourth Semi-Annual Reporting Period			Mark all that apply		
Milestone:	Description:	Associated Deliverable(s)	Site Name	Site Name	Site Name
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Total Amount Requested for this Reporting Period:		\$ \$ Total	\$ \$ USD	\$ \$ USD	\$ \$ USD

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	<input type="text" value="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 Primary Institution involved
Please refer to "Allowable Costs." Convert all amounts to USD*

Sub Team:		Total Project Cost: \$200,000 USD Maximum		
Primary Participants				
Labor	Hourly Rate	Total person hours⁶	# of Days	\$ USD
Participant Name (Add rows if necessary.)				
1				
2				
3				
TOTAL Labor				
Equipment, Supplies, & Services (ESS)	Units	Unit Cost	\$ USD	
Item (Add rows if necessary.)				
1				
2				
3				
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				
Institutional Support (IS) of Primary Participant				
(No more than 08% of the total direct expenses)				
Secondary Collaborators (within individual team)				
Labor	Hourly Rate	# Hours per Day	# of Days	\$ USD
Participant Name (Add rows if necessary.)				
1				
2				
TOTAL Labor				
Equipment, Supplies, & Services (ESS)	Units	Unit Cost	\$ USD	
Item (Add rows if necessary.)				
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				
Institutional Support (IS) of Secondary Collaborators				
(No more than 08% of the total direct expenses)				
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)				

⁶ "Person-hours" = estimated total number of hours devoted to the project throughout the duration of the project.

BUDGET NARRATIVE FORM

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

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.

Sub-Team: _____

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 Team co- 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).			<input type="checkbox"/> "None"
Project/Proposal Title	Title	Location of Research	Region/Country
Support	<input type="checkbox"/> Current <input type="checkbox"/> 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	<input type="checkbox"/> Current <input type="checkbox"/> 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	<input type="checkbox"/> Current <input type="checkbox"/> 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	<input type="checkbox"/> Current <input type="checkbox"/> 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	<input type="checkbox"/> Current <input type="checkbox"/> 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

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 <input type="checkbox"/> Government <input type="checkbox"/> Corporation <input type="checkbox"/> University <input type="checkbox"/>
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 <input type="checkbox"/> SDB <input type="checkbox"/> HUB-Zone <input type="checkbox"/> VOSB <input type="checkbox"/> SDVOSB <input type="checkbox"/> N/A <input type="checkbox"/>	
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 <input type="checkbox"/>	No <input type="checkbox"/>
Have you been audited in the past 3 years? If yes, please send a copy of the report.		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Were there any material or significant findings in the audit report?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Has your organization ever had a grant or contract terminated for cause?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does your organization utilize a financial manual to authorize expenses?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does your organization utilize an accounting system to track expenses?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does your organization have an ethics policy?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does your organization have a timekeeping system for labor such as timesheets?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does your project involve: Human Subjects <input type="checkbox"/> Animal Testing <input type="checkbox"/> Recombinant DNA <input type="checkbox"/> Not applicable/None <input type="checkbox"/>			
Executive/Management Reporting Requirements			
CRDF Global may be required to publicly report the names and total compensation of the five most highly compensated individuals at the awardees' institution. If you meet any of the criteria below, you are exempt from this requirement. Please find and check any applicable exemption:			
In the previous tax year, institutional gross income from all sources was LESS than \$300,000.			Exempt <input type="checkbox"/>
The institution received LESS than 80 percent of its annual gross revenues in U.S. federal funding (Contracts, Grants, Subgrants, Subcontracts or Loans).			Exempt <input type="checkbox"/>
The institution received LESS than \$25,000,000 in annual gross revenues from U.S. federal funding sources (Contracts, Grants, Subgrants, Subcontracts or Loans).			Exempt <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/>
Past Performance			
Please list any applicable grants or contracts received from outside organizations. Successful completion is defined as zero 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 <input type="checkbox"/> No <input type="checkbox"/>	Research Grant
		Yes <input type="checkbox"/> No <input type="checkbox"/>	
		Yes <input type="checkbox"/> No <input type="checkbox"/>	

Signature

Name and Title

Date

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 a 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 Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services (HHS), Office of Human Research Protections⁷ (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 International⁸ (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.

⁷ The [Office for Human Research Protections \(OHRP\)](#) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

⁸ [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.

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 a bioethics review prior to award activation. The Principal Investigator (PI) must submit this form to CRDF Global within 2 weeks of receipt.

Project Name:	DETERMINATION OF EFFICACY OF XPRT PCR ULTRA AND TRANSCRIPTIONAL SIGNATURES IN THE DIAGNOSIS OF PLEURAL TUBERCULOSIS		
Principal Investigator (PI) Name:			
PI Contact Information:			
Institution Name:			
Institution Website:			
Does your project involve:	<input type="checkbox"/> Human Subjects	<input type="checkbox"/> Animal Subjects	<input type="checkbox"/> Recombinant DNA
If you checked the box for Human Subjects, you <u>must</u> submit the information below. To obtain these numbers (#), please visit OHRP website: https://www.hhs.gov/ohrp/irbs-and-assurances.html			
OHRP IRB#:		OHRP FWA#:	
If you checked off the box for Animal Subjects above, you must check one of the options below.			
AAALAC Accreditation:	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<i>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.</i>			
IRB/IACUC Approval/Exemption Notice Attached:	<input type="checkbox"/> Yes <input type="checkbox"/> 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:	<i>MM-DD-YYYY</i>		

Submitted By:

Name and Title
Date

APPENDIX C:

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

Indirect Costs (IDCs)

Awardees (Primary Institutions⁹ and Secondary Institutions¹⁰) may request indirect costs/overhead expenses on all direct costs except for equipment (over \$5,000), capital expenditures, rent, student tuition, participant support costs¹¹ 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

⁹ Primary Institution" is a corporation, partnership, association, institution or other organization that receives assistance under the award Agreement and is responsible for carrying out the Project as specified in the approved proposal.

¹⁰ Secondary institutions are those other than the Primary Institution that will participate in the proposed project and receive financial support under a CRDF Global award. Secondary Institutions may participate in the form of sub-contracted work or direct award agreement from CRDF Global. All allowable costs described in the program apply.

¹¹ Participant Support costs include stipends or subsistence allowances, travel allowances and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with meetings, conferences, symposia or training projects, scholarships/fellowships.

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)
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.