U.S. NIH – SAMRC
Request for Proposals (RFP)

Regional Prospective Observational Research in Tuberculosis in the Republic of South Africa
"RePORT South Africa Phase III"

Full Proposal Submission Deadline

Friday, December 1, 2023 (4:59 PM) U.S. Eastern Standard Time (EST)
Friday, December 1, 2023 (11:59 PM) South African Standard Time (SAST)

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I. COMPETITION SNAPSHOT

Eligible Applicant(s)	Investigators from all or a subset of currently active U.S. and South Africa RePORT sites, as well as U.S./South Africa collaborators. New research sites may work in collaboration with currently active U.S. and South Africa RePORT sites.	
Competition Opens	Monday, October 2, 2023 (4:59 PM) U.S. Eastern Standard Time (EDT) Monday, October 2, 2023 (11:59 PM) South African Standard Time (SAST)	
Full Proposal Submission Deadline	Friday, December 1, 2023 (4:59 PM) U.S. Eastern Standard Time (EST) Friday, December 1, 2023 (11:59 PM) South African Standard Time (SAST)	
Announcement of Results	Thursday, February 1, 2024 (4:59 PM) U.S. Eastern Standard Time (EST) Thursday, February 1, 2024 (11:59 PM) South African Standard Time (SAST)	
Eligible Research Scope	To support the establishment of a single RePORT South Africa-U.S. network RePORT consortium, consisting of multiple researchers and research sites to advance fundamental and clinical research in the areas of TB and TB/HIV in South Africa, by establishing longitudinal cohorts of TB patients and/or their contacts (or other high TB risk patients).	
Project Duration	Maximum of three (3) years	
Number of Awards	One (1) award	
Award Amounts	Up to 4.16 Million USD total which is comprised of funding of up to 21 Million ZAR (1.16 Million USD subject to rand-dollar exchange rate) contribution from SAMRC and up to 3 Million USD from NIH. The funding is for a period of three (3) years disbursed as per funding organization policies. For yearly distribution of costs, please refer to Section VII. Allowable Costs.	
Funding Agencies	National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) South African Medical Research Council (SAMRC)	
Complete RFP and ApplicationForms	A Microsoft Word version of the full proposal forms and templates are available for download here: https://www.crdfglobal.org/rfp/**report-south-africa-phase-iii/**	
Application Process and How to Apply	**Full proposals** will undergo eligibility checks and will be reviewed by the U.S. NIAID and SAMRC. All full proposals must be submitted electronically via email to **CRDF Global point of contact (POC)**: **Ms**. **Aisha Eiger**, aeiger@crdfglobal.org. Hard copies will not be accepted. For more information and instructions, please refer to Section VI.D. Proposal Elements.	
Condition for Application	Each research team should have at least one (1) Principal Investigator (PI) from South Africa and one (1) Co-PI from the U.S.	
Points of Contact	**Technical/Scientific Inquiries**	**Administrative Inquiries**
	U.S. NIAID Dr. Sudha Srinivasan sudha.srinivasan@nih.gov	**U.S. CRDF Global** Ms. Aisha Eiger aeiger@crdfglobal.org

II. BACKGROUND

The Regional Prospective Observational Research in Tuberculosis (RePORT) International consortium was established in 2013 with the mission of promoting and supporting tuberculosis (TB) research on the regional and global level to enhance research capacity in high burden countries. The RePORT International consortium consists of seven member countries, including: India, Brazil, South Africa, China, Indonesia, South Korea, and the Philippines. All member countries implement a common protocol and standardized laboratory manual which prescribes the collection of curated data and samples at specified time points, with centralized biorepositories and data management centers. The RePORT platform continues to serve as an important global resource for the TB research community which enables TB/HIV researchers to address critical research questions across a range of topics. The research priorities addressed by the consortia countries are aligned with the U.S. National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) priorities, as well as those of the participating host countries.

According to the 2022 World Health Organization (WHO) Global TB report, an estimated global total of 10.6 million people fell ill with TB in 2021, equivalent to 134 cases per 100,000 population. Among all TB cases, 6.7% were among people living with HIV and Africa had 23% of the TB cases. South Africa is among WHO's list of 30 high-burden tuberculosis countries and has one of the highest incidence rates of notified tuberculosis with an estimated TB incidence of 513/100,000 and an estimated TB/HIV co-infection rate was 59%. Among these 30 high burden TB countries, South Africa is among the 14 countries with the highest burden of TB, TB/HIV and multi-drug resistant TB (MDR- TB). TB remains the leading cause of death among people with HIV in South Africa. This problem is further compounded by the emergence of drug resistant strains of TB which are more difficult and very costly to treat.

A recent Lancet article in 2022 analyzed a prevalence survey conducted in 2018 in South Africa revealed that TB remains rampant, and that TB is more common in men and in people aged 65 years or older. The study also identified demographic groups, including younger men, who the TB program is seemingly failing to reach. Importantly, the survey also confirmed that people living with HIV in South Africa continue to have one of the highest burdens of TB globally. To this end, there is an urgency to develop new tools, diagnostics, therapeutics and intervention strategies to mitigate and alleviate the burden of TB/HIV disease in South Africa and on a global scale.

CRDF Global is accepting proposals on behalf of the NIAID at the U.S. NIH, and the South African Medical Research Council (SAMRC) to fund a single network of multiple clinical and laboratory research sites addressing an array of TB biomedical and clinical research of importance to South Africa and abroad. Funding for this network is provided by CRDF Global using funds provided by the U.S. NIH NIAID and the South African Medical Research Council.

III. SCOPE AND PURPOSE

This announcement invites application(s) from South African investigators working in partnership with one or more U.S. based investigators to submit research proposals for the establishment of the RePORT South Africa network 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 investigators that addresses an array of TB research questions of importance to South Africa in the global context.

This announcement will fund one (1) application for the duration of three (3) years 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 South Africa Network and administer the logistical 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 South African TB research network 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. The inclusion of previously disadvantaged sites/institutions is highly encouraged.

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.

A. Research Goals and Objectives

The intent of this initiative is to advance high priority TB and TB/HIV research including but not limited to:

- Identification and validation of novel biomarkers and biosignatures to aid in the diagnosis, treatment, and management of individuals with clinical, sub-clinical, and latent TB and who are at risk for progression toTB disease, and those who are being treated for different forms of TB disease in both pediatric and adult populations.
- Support research to develop, evaluate and/or validate diagnostic assays for TB infection including standardized specimen preparation, treatment monitoring, and drug resistance detection.
- Implementation science and development of implementation models to deploy new TB diagnostics applicable to the South African context.
- The diagnosis and clinical significance of sub-clinical TB and implications for clinical management and treatment.
- Identification of host (i.e., endocrine system, immune status, etc.) and microbial (i.e., strain type, antigen composition, etc.) factors that drive Mycobacterium TB (Mtb) pathogenesis, transmission, drug resistance, clinical management and epidemiology; and factors that influence dynamics of latent TB infection in pediatric and adult populations.
- Determine changes in the dynamics and drivers of TB transmission and disease over time in well-defined populations.

- Identification of host factors (genetic and other) that correlate with protective immunity or factorsassociated with failing to limit Mtb infection.
- Determination of the effect of HIV and HIV co-morbidities and co-infections (eg: diabetes mellitus) on the development and natural history of TB and individual response to treatment.
- Identification of pharmacokinetic (PK) and pharmacodynamic (PD) 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.
- Support research focused on improved or novel diagnostics and therapeutics for adult and pediatric populations.
- Support research to design and evaluate potential TB vaccine candidates.

B. Network Leadership

A proposal for a collaborative research network should be submitted by a consortium of investigators and institutes from South Africa and the U.S. The application must identify a lead South African institution ***which will serve as the Coordinating Center*** and a Principal Investigator (PI) who will be the central point of contact for the network and will lead and coordinate activities of the network. Designation of a secondary PI (aka Co-PI) is encouraged but left to the discretion of the applicant(s). Only one single network will be the recipient of the award. The application must include at least one collaborating U.S. investigator.

The consortium members must further organize themselves to form a single Leadership Group comprised of collaborating South Africa and U.S. investigators. The establishment of additional scientific and administrative groups that function under the direction of the Leadership Group is acceptable and encouraged. Equal numbers of South Africa and U.S. investigators in the Leadership Group is not required. However, the number of U.S. investigators should not exceed the number of South Africa investigators.

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

The Coordinating Center in South Africa shall budget for expenses required for executing the administrative and logistical functions required to manage the consortium and for the coordinating function of the RePORT South Africa consortium. This should include support of the leadership group and scientific working groups, organization and hosting of the Annual RePORT South Africa meeting and the Annual RePORT International meeting when South Africa hosts; and other RePORT consortium related scientific research activities.

C. Clinical Research Sites

The RePORT South Africa Leadership Group will provide oversight for the science of the network. It is expected that at least one U.S. investigator will be involved in the leadership group, but U.S. investigator involvement is not required at the site level.

It is expected that the clinical research sites will 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:

1. Investigators, nurses, site coordinator(s) and other clinical and technical personnel experienced in patient screening, recruitment and retention; adherence to applicable 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.
2. 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.
3. Access to appropriate Institutional Review Boards and or Ethics Committees to oversee and ensurethe ethical conduct of the proposed research at the institution.

The implementation of any clinical research at the Clinical Research Sites is the responsibility of the site PI but should be overseen by the leadership of the network.

D. 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 units (or previously collected under RePORT South Africa CRUs).

The application should include a description of relevant knowledge gaps or obstacles to address 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.

1. **Study Design**: The hypotheses and specific aims should be clearly stated. The study design should specify the data and/or type and volume of specimens required, the analyses planned, and protocols which will be used for these analyses.

2. **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.

3. **Impact**: A discussion of how the study will advance TB science should be included.

The research should utilize the research capacity existent in South Africa for the processing of samples. A central data management center should be utilized.

E. 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 or virtually central repository and data management center that will allow analyses and research beyond that proposed in the current application. 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 South Africa and the U.S. 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.

IV.ELIGIBILITY

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

A. For ALL Applicants

- The proposing investigators must possess the skills, knowledge, resources, and professional experience needed to carry out the proposed research and objectives of the initiative.
- Renewal applicants/sites must indicate how they will build upon previous efforts.
- Each PI should be experienced in research collaborations on clinical and/or biomedical studies in TB or HIV/TB.
- The proposed scope of work is not eligible to receive duplicative funding from another source during the same Period of Performance.

Institutions must:

- Be a legally incorporated institute within South Africa or United States.
- Not be a U.S. Federal Government agency.
- Agree to comply with applicable U.S. regulations on funding received from USG agencies.

The following are the criteria for **all Principal Investigators** (PIs):

- Be legally employed at an eligible institution.
- Must not be a Graduate or PhD student.
- Researchers employed by the U.S. federal government are not eligible under this opportunity.

It is the responsibility of the PI from each country to ensure that all named co-investigators and project staff are eligible. Applications involving ineligible applicants from the U.S. or South Africa will result in the application being withdrawn.

The U.S. institutions named in approved full proposals will be awarded based on the full economic costs as described in the U.S. NIH Guidance for Applicants.

B. Clinical Research Sites

Proposed clinical research sites and principal investigators must document the following capabilities:

- **Access to and ability to recruit individuals with the following characteristics**
  - Adults with pulmonary TB (drug susceptible and drug resistant)
  - People living with HIV infection and those without HIV infection
  - Individuals with recent exposure to active pulmonary TB
  - Persons with prevalent co-morbidities that may affect TB or HIV pathogenesis
  - Healthy individuals who can serve as controls

- **Access to and ability to enroll the following populations are not required but will be considered advantageous**
  - Individuals with extra pulmonary TB
  - Pediatric patients with and without active and/or latent TB including paucibacillaryand non-pulmonary cases
  - Pregnant women with active TB

- **Experienced clinical care capabilities with up-to-date training on Good Clinical Practice(GCP), Good Laboratory Practice (GCLP) standards**

- **Readily available experienced investigators and study staff**
    - Experience in basic data management
    - Access to a qualified mycobacteriology and clinical laboratory
    - Ability to collect, catalog and store human specimens and mycobacterial isolates at own unit (independent of repository)
    - Access to ethical and other medical review boards for review and approval of humanresearch
    - Experienced financial and administrative management staff
    - Existing adequate infection control to protect staff and study subjects from TB
    - Available basic equipment for biomedical and clinical studies
    - Access to or plans for establishing community engagement activities

- **Inclusion of previously disadvantaged institutions as part of the network is encouraged and viewed favorably.**

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 AND EVALUATION 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. A peer-based panel review will take place through a scientific panel of experts appointed by CRDF Global and approved by NIAID and SAMRC.

CRDF Global's panel of external reviewers will use the following criteria in the evaluation of the full proposals for this program:

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 South Africa**: Indication that the team investigators are committed to, and engaged in, research that adheres to RePORT Africa'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 address all program-related inquiries, receive/review applications and communicate all results to applicants. CRDF Global will also coordinate the joint peer review. Following these reviews, the most meritorious applications will be awarded for implementation.

CRDF Global will email the lead Investigator(s) 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 and reviewed.

A. Proposal Submission

CRDF Global reserves the right to deem a full proposal ineligible based on the failure of the team to submit by the deadline. All proposals must be submitted electronically by the **Principal Investigator (PI) on behalf of the entire collaborative team** via email to the CRDF Global point of contact (POC): **Ms. Aisha Eiger**, aeiger@crdfglobal.org, no later than:

- **Friday, December 1, 2023 (4:59PM) U.S. Eastern Standard Time (EST)**
- **Friday, December 1, 2023 (11:59PM) South African Standard Time (SAST)**

Proposals should be submitted only once. After the email submission process, the lead Principal Investigator will receive a confirmation of receipt message from CRDF Global's main POC, Aisha Eiger.

Proposal application materials submitted to CRDF Global must be prepared in **English** and **compiled** in the following document files for submission. Acceptable file formats are Microsoft Word (.doc) or Adobe Acrobat (.pdf). Please see Appendix B for a checklist of full proposal submission requirements.

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:
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 the proposal, applicants should review all documents and policies on the CRDF Global Applicant Resources page.

C. Proposal Formatting

Please observe the preferred proposal format:

- Typed
- Single-spaced
- One-inch margin on ALL sides
- Font size no less than Arial 10pt (Times New Roman, 10pt is not acceptable)
    - **A font size of less than 10pt 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. Please be reminded that the text must still be readable*.

D. Proposal Elements

(Required unless otherwise noted)

Detailed information for all of the necessary elements of the proposal is listed below. Appendices **may not** be included. Any proposal submitted without **ALL** of the 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.

Applicants are required to follow instructions and use the electronic forms and templates downloadable in a fillable format here: https://www.crdfglobal.org/rfp/**report-south-africa-phase-iii/**

The following sections must be compiled into and submitted as a single proposal document with pages numbered consecutively. Please refer to Appendix C for the complete package of full proposal forms and templates.

FULL PROPOSAL PACKAGE

D.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 Principal Investigator Partnership and Terms Agreement Statement in Appendix C.7. and include a scanned copy in the proposal document.

D.2: Cover Sheet

One per proposal including:

- Project title and basic information about the project
- Information on the South African and U.S. Project PIs
- Information on the South African and U.S. Primary Signatories (individuals who would be responsible for negotiating contractual and financial terms in the case of an award)

Please note that CRDF Global requires that the Cover Sheet in Appendix C.1. be signed by **both** the PI and Institution Leadership Representative. This applies to both the U.S. and South Africa. Please include a **scanned** copy of the signed document.

D.3: Project Abstract

One concise paragraph summarizing all relevant aspects of the project, with particular emphasis on the objectives, methods, and potential results (not more than 350 words).

D.4: Project Narrative

A maximum of thirty (30) pages, including any graphs, diagrams, or photos. 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 must be described in the Project Narrative:

- Specific Roles and responsibilities of South Africa-U.S. 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. Please also delineate a process by which any conflicts among investigators will be resolved, as needed for a multi-PI project.

- 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.

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

- Detailed methodology including a description of the study design, including the type of study, and a detailed plan of how 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.

- 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

- For U.S. institutions only, 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. Cost shares must meet the eligibility criteria outlined in the Uniform Administrative Requirements, Cost Principles, And Audit Requirements for Federal Awards §§200.306-Cost Sharing or Matching. U.S. applicants are highly encouraged to cost-share unrecovered indirect costs as part of their proposal budgets, per §§200.306(c).

- 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."*

D.5: References Cited

Reference information for the Project Narrative. 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. Identify the website address if the document is available electronically. While there is no page limitation for the References Cited, this section must only include bibliographic citations and not be used to provide parenthetical information outside of the Project Narrative.

D.6: Project Milestone Plan

A milestone plan must be submitted, describing specific milestones to be accomplished by the network during project implementation. Applications are advised to submit unique milestone plans for each individual research aim if individual sites are only participating in a certain research aim. If all the sites are participating in all of the research aims, then an overall research milestone plan maybe submitted. A sample milestone plan is included in Appendix C.5.

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.

- 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.

D.7: Key Participant Information 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.

D.8: Budget Narrative

Complete **ONE** form for each associated Institute inclusive of any Secondary Institutions. The form should match the associated budget sheets in the Project Budget explaining all included proposal request items. The budget should also cover the entire award period. PIs should refer to “**Allowed Costs**” in Section VII for information to be listed in the budget.

D.9: Statement of Other Sources of Support of Key Personnel

One for **each** PI listing 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**.

D.10: Institutional Data Form

This document is a **requirement** for **projects funded by CRDF Global**.

D.11: Plagiarism Policy and Standards Agreement

A CRDF Global plagiarism policy and standards document that is included herein, submitted as a signed **scanned** copy by **each** of the U.S. and South African PIs.

CRDF Global will not provide funding to an application in which plagiarism exists.

- **Plagiarism** is defined as: *the incorporation of published writing or another person's original writing into your document without clear formatting and accurate attribution of the source. Academic writing such as a funding proposal must be original work, written by the stated applicant(s).*

ADDITIONAL SUPPORTING DOCUMENTATION

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

D.12: Curricula Vitae (CV) or NIH Biosketch

Combine affiliated personnel CVs or biosketches from each institution into **ONE** file. Applicants must provide copies of all PIs, Co-PIs and key team participants' CVs/biosketches in a file separate from the main proposal file. PIs and Co-PIs must use the Biosketch format.

- PI/Co-PI biosketches should be no more than five (5) pages.
- Team member's CV/Biosketch should be no more than two (2) pages
- Please ensure you have provided a full CV/Biosketch for each team member listed in the consortium Key Participant Information form in the main proposal file.
- Each CV/Biosketch should include the individual's name, title, educational background, current and previous institutional affiliations with dates, area of expertise, and his or her scientific publications of relevance to the project. Please visit the following sites for writing a CV/Biosketch:
    - https://grants.nih.gov/grants/forms/biosketch.htm
    - https://owl.purdue.edu/owl/job_search_writing/resumes_and_vitas/writing_the_cv.html

D.13: Special Documentation

(As applicable)

Project Budget

(*Use Excel templates*)

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.

Research Involving Human/Animal Subjects

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 and funded by CRDF Global that involve human or animal subjects will undergo review by the CRDF Global Bioethics Review Committee (BRC) prior to award request. Grant recipients will not be authorized to begin work until institutional review board (IRB) approval is provided to CRDF Global. Activation of a grant Agreement is contingent on submission of complete IRB documentation and approval to CRDF Global. South African and U.S. PIs should apply to their IRBs for necessary bioethics approvals, as soon as feasible. Investigators will be required to submit proof of their institution's IRB approval **within six weeks** of award selection notice.

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

DURATION AND PROJECT IMPLEMENTATION

The activities of the approved full proposal must be carried out jointly between the collaborative consortium members. The start date of the project per consortium member shall be the same date, which will be mutually coordinated between the consortium members during the agreement negotiation period.

The total duration of the project shall be **up to 36 months (three years)** from the date the award agreement is fully executed. CRDF Global may grant up to **one year no-cost extension** of the project with strong justification and sponsor approval.

Awards are anticipated to start in **April 1, 2024**. Consortium finalists **may not begin any project activities or incur any project expenses** associated with the awards until an **award agreement** has been **signed** with their respective awarding agencies. A CRDF Global award start date is subject to change, pending timely submission by PIs of all documentation as required by U.S. government (USG) grant regulations.

A **research timeline** is recommended to be prepared in terms of semi-annual segments, per the Milestone Plan. Please see sample plan included in Appendix C.5.

CRDF Global will address all program and administrative related inquiries, serve as the point of contact for the RFP, and communicate all results to applicants. CRDF Global will also receive the full proposals from applicants and will coordinate a technical peer review of full proposals. Following these reviews, the program sponsors will collectively determine meritorious proposals to receive awards administered through CRDF Global.

VII. ALLOWABLE COSTS

One consortium proposal will be supported through this RFP. The total amount awarded will be approximately 4.16 million USD, which includes a contribution of up to 3 million USD from NIH/CRDF and 21 million ZAR from SAMRC. Institutions that receive funding approval from this RFP will be granted portions of the 4.16 million USD administered by SAMRC or CRDF Global on behalf of NIH/ NIAID. CRDF Global will support all U.S. institutions using NIAID funds.

SAMRC will primarily support the South African institutions, however some funding for these teams may come from CRDF Global using NIAID funds. South African institutes may also receive awards from both SAMRC and NIH via CRDF Global, with a separate portion of their budget to be represented in each award. **All projects funded by NIH via CRDF Global must comply with relevant U.S. federal regulations, and projects funded by SAMRC must comply with relevant South African regulations. In the case of an award, project budgets may be subject to revision to ensure compliance according to their sponsor's requirements.** All institutions funded by CRDF Global will be awarded a U.S. Dollar amount based on the currency rate at the time of proposal, and will be tracked in U.S. dollars, regardless of currency rate fluctuations after awarding.

Consortium members' combined budget percentage allocations must total one hundred percent (100%), up to 4.16 million USD. Fifty percent (50%) or more of the total proposal budget should go towards South African institutions. Applicants should allocate roughly one-third of the total budget towards each of the three years, to coordinate with the project's expected milestone and needs. After the three-year period of performance is over, awardees may be eligible for no-cost extensions of up to six months at a time at the discretion of CRDF Global, NIAID, and/ or SAMRC.

Consortium members should refer to the instructions below for submitting all documentation necessary:

Milestone Plan

The Project Milestone Plan should identify and describe specific milestones to be accomplished by the consortium members during project implementation, with budget estimates provided for each. CRDF Global staff and external peer reviewers will evaluate the plan to ensure that milestones are directly relevant to the overall research project; can be delivered in accordance with the timeline; and can be supported by appropriate documentation.

Budget

Consortium members must also submit a line-item project budget as seen in Appendix C.11 (using the Excel template). If selected for an award, CRDF Global staff may request additional information or supporting documentation before finalizing an award agreement. Project budgets should be calculated in accordance with the guidelines outlined in Section VII.A. or Section VII.B. depending on the funding body (SAMRC or NIH).

All budget submissions should be in U.S. Dollars and estimate currency conversions rates for the anticipated Period of Performance.

Budget Narrative

- Justification/support for requested costs should be provided in the budget narrative.
- Any equipment valued over $1,000 USD includes an additional detailed justification.
- For travel expenses, all trips are justified with description of who is traveling, to where, and for how long.
- Airfare, lodging and per diem costs for each trip are clearly stated.
- Please include receipts, quotes, or website links to support calculations for equipment, supplies, and services.
- After proposal selection, budgets will be subject to revision based on the cost allowability guidelines of the awarding agency that will be managing their institution's award.

A. Projects Funded by SAMRC

SAMRC will distribute funds to South African teams on a cost-reimbursable basis. The total funding distributed to South African sites by SAMRC will **not exceed ZAR 7.0 million per year during the 3 years** of the award. Should the awarded proposal allocate more funding per year to South African sites, additional funding may be provided through NIH/ CRDF, and would be subject to the allowability guidelines incorporated in Section VII.B.

SAMRC FUNDING BY YEAR	
Year 1	7.0 million ZAR
Year 2	7.0 million ZAR
Year 3	7.0 million ZAR
Total: 21 million ZAR	

The following allowable costs are permitted under SAMRC guidelines for this program:

Labor Costs

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

- The SAMRC will reimburse participants for labor costs associated with work on the project as permittedby the participants' institutions and based on their current salaries. **Labor expenses will be reimbursed for actual hours worked** on the project. 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.
- Student stipends are permissible and may include fringe benefits or tuition remission. For plannedstudents not yet identified, clearly indicate their participation and request for support in the ProjectBudget and Budget Narrative.
- Labor should also include the cost of a project coordinator to manage activities for the consortium.
- No more than 2.2 million ZAR per year of the proposed budget should comprise labor and student salaries.

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 20,000 ZAR, or other lower threshold consistent with the policy established by the proposing institute. Any item of requested equipment valued at more than 20,000 ZAR 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.
- ESS should comprise no more than 2 million ZAR per year of the proposed budget.

Biorepository Costs

- Defined as those costs associated with storage and curation of specimens. The SAMRC is not prescriptive regards whether a central repository is established or if investigators in the consortium store specimens on site.
- Biorepository costs should not exceed 1.4 million ZAR per year of the proposed budget.

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, annual RePORT International meetings, as well as for domestic travel, if applicable. Unclear travel expenses on proposals selected to award will undergo remediation that may cause activation delays.

Travel Allowances: applicants should refer to the following travel allowance guidelines when preparingtheir 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 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.

A budget for hosting the annual RePORT South Africa meeting should also be included and one budget to host the RePORT International meeting should be included.

Travel should not exceed 0.7 million ZAR for Years 1-3.

Data Management Costs

- These costs relate to **centralized** storage of data in the form of a datamanagement center. The purpose of this effort is to coordinate data storage and provide monthlyreports.
- Data management costs should not exceed 0.8 million ZAR for Years 1-3.

Indirect Costs (IDCs)

- The SAMRC will not cover any indirect costs for local South African institutions.

B. Projects Funded by CRDF Global

CRDF Global will support expenses for all U.S. institutions from universities and non-profits. **South African institutions may be funded through both SAMRC and NIH/CRDF Global. All NIH/CRDF Global awards must be compliant with U.S. federal regulations including 2 CFR 200.** U.S. federal government agencies, including their employees, **are not permitted** to receive funding under this program. CRDF Global will distribute support as a **cost-reimbursable** grant upon receipt of invoices and documentation reflecting expenses incurred. 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 awarded institutions for any financial resource issues that may arise from the cost-reimbursable policy.

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

Labor

- Personnel costs are defined as payments made to individual team participants for work performed on the project (i.e., labor costs). Include all benefits and fringe costs within the labor rate. They may not exceed the applicant institute's rates and must be documented in the proposal's budget narrative.
- 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 Budget Narrative.
- Investigators may not have a total LOE that is greater than 100% when their NIH and CRDF grant awards are combined.

Equipment, Supplies and Services (ESS)

- This 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 $5,000 USD, or other lower threshold consistent with the policy established by the proposing institute. Any item requested 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.
- Funds may also be requested for the costs of documenting, preparing, publishing or otherwise making available to others the findings and products of the work conducted under the award.

Travel

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

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, visit: https://www.gsa.gov/policy-regulations/policy/travel-management-policy/fly-america-act.

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/category/21287
- For non-U.S. travel, refer to: https://aoprals.state.gov/content.asp?content_id=184&menu_id=78

These are the maximum allowances for covering 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: applicants may use travel funds to cover the cost of visa fees.

Indirect Costs (IDCs)

Applicants 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 sub-awardee expenses (after the first $25,000). Total direct costs minus these items are 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 Consortium Member budget = total direct costs $ (including MTDC) + IDCs $

U.S. Institutions may request indirect costs up to **10%** of their Modified Total Direct Costs. Institutions **outside of the U.S.** may request indirect costs up to **8%** of their Modified Total Direct Costs.

[1] 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.

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 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

- **Aisha Eiger, Project Lead**
- **Cate Chisholm, Project Associate**

APPENDIX

APPENDIX A: Timeline and Application Process

October 2, 2023: **Opening of the Call**

December 1, 2023: **Proposal Submission Deadline**

- Proposals should be submitted to CRDF Global point-of-contact (POC): **Ms. Aisha Eiger**, aeiger@crdfglobal.org

December 3, 2023 to January 15, 2024: Evaluation of Proposals

- Proposals will be reviewed for their alignment to the call priority areas, eligibility of the applicants and collaborators, and expected outputs.
- Proposals will also undergo a joint review and evaluation from the U.S. NIAID and SAMRC panel.

January 15, 2024 to January 20, 2024: **Technical Review**

- A joint peer review and evaluation, involving U.S. and SAMRC reviewers, will be conducted to assess the merit of the submitted full proposals.

February 1, 2024: **Announcement of Approved Proposals**

- Approved proposals may start project implementation in April 2024.

APPENDIX B: Checklist for Full Proposals

(Documents/information must be combined into a SINGLE PDF or Word file.
All documents submitted to CRDF Global MUST be via email to the appropriate POC.)

I. Proposal Narrative

- **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
- **C.1. Cover Sheet**
  - All fields completed
  - Signed by Project Leaders and Institutional Leadership Representatives
- **C.2. Project Abstract**
  - Does not exceed 350 words
- **C.3. Project Narrative**
  - All project criteria are addressed
  - Text is within thirty (30) page limit
  - Formatted properly (typed, single spaced, one-inch margins, page numbers, font no smaller than Arial 10 pt)
  - Authors names are included at the end of section
- **C.4. References Cited**
- **C.5. Project Milestone Plan**
  - Written based on the instructions in Section VI and sample in Appendix C.11.
  - Should include clear, discrete, verifiable milestones; deliverables must be associated with each milestone
- **C.6. Key Participant Information Form**
  - One for each team participant – all fields completed; does not exceed one (1) page limit
- **C.7. PI Partnership & Terms Agreement Statement**
  - One for EACH collaborating investigator and their institution
  - Signed by Investigators and Institute Representatives
  - On institutional letterhead
- **C.8. Plagiarism Policy and Standards Agreement**
- **C.9. Statement of Other Support of Key Personnel Form**
  - One form for each co-investigator
  - If no other support reported, the form is completed with the co-investigator's name and the "non" box checked at the top of the page
- **C.10. Previous CRDF Global Awards** *(if applicable)*

II. Proposal Budget

- **C.11. Line-Item Budget** *(use Excel template)*
  - One budget document for each Institution
  - Follows allowable cost guidelines in Section VII
  - Cost-shares (if applicable) reported as monetary value
- **C.12. Budget Narrative**
  - One for each 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.

III. Bioethics Review Form

- **C.13. Bioethics Review Form**

IV. Institutional Data Form

- **C.14. Institutional Data Form**

V. Personnel List/ Curriculum Vitae (CV)/Biosketch

- **C.15. CV/Biosketch for All Team Participants**

- CVs/biosketches for South African and U.S. Project Leaders and all team participants
    - PI/Co-PI biosketches no more than five (5) pages
    - Team participant CVs (or biosketches) no more than two (2) pages
    - Each form has a corresponding detailed CV/Biosketch compiled as a separate document which is submitted separately from the proposal
    - Please visit the following sites for writing a CV/Biosketch:
        - https://grants.nih.gov/grants/forms/biosketch.htm
        - https://owl.purdue.edu/owl/job_search_writing/resumes_and_vitas/writing_the_cv.html

APPENDIX C: Full Proposal Forms and Templates

*(Complete for **each** applicable U.S. and South African team.)*

C.1. COVER SHEET

GENERAL PROJECT INFORMATION				
Project Title *(Not to exceed 25 words)*			Projected Length of Project (Months)	
Amount Requested	Total	U.S. Team	South African Team	
Research Categorization	Research Area	Sub-Research Area	Research Focus	
Research involves use of Human/ Animal subjects	☐ Human ☐ Animal ☐ None			

SOUTH AFRICAN PRINCIPAL INVESTIGATOR					
Last Name		First Name		Middle	
Position/ Title					
Institute Name					
Complete Mailing Address					
Institution type	☐ University/ Academic ☐ Research Institution ☐ Government ☐ Non-profit/ non-governmental ☐ Other: _____				
PI E-Mail			Alternative Email		
Telephone #			Gender	☐ Male ☐ Female	
Highest Degree Earned/ Field of Degree			Year Awarded		
			Citizenship		
Name of Institution Director			E-mail		
Institutional Director Address			Telephone #		
Total number of South Africa team members, including South Africa PI and graduate students					

SIGNATURES *(scanned, signed copies of this cover sheet are required for applicants)*			
South African Principal Investigator Signature		Date	
South African Institution Leadership Representative (Primary Signatory) Signature		Date	

U.S. CO-PRINCIPAL INVESTIGATOR					
Last Name		First Name		Middle	
Position/ Title					
Institute Name					
Complete Mailing Address					
Institution type	☐ University/ Academic ☐ Research Institution ☐ Government ☐ Non-profit/ non-governmental ☐ Other: _____				
Co-PI E-Mail			Alternative Email		
Telephone #			Gender	☐ Male ☐ Female	
Highest Degree Earned/ Field of Degree			Year Awarded		
(Must Check One) ☐ U.S. Citizen ☐ Permanent Resident ☐ non-U.S. Citizen with legal visa status					
Are you employed by the U.S. government?					
Name of Institution Director			E-mail		
Institutional Director Address			Telephone #		
Total number of U.S. team members, including U.S. PI and graduate students					
SIGNATURES *(scanned, signed copies of this cover sheet are required for applicants)*					
U.S. Principal Investigator Signature			Date		
U.S. Institution Leadership Representative (Primary Signatory) Signature			Date		

C.2. PROJECT ABSTRACT

(Abstract should not exceed 350 words.)

C.3. PROJECT NARRATIVE

(Narrative should not exceed 30 pages and text should be Arial font size 10 within 1-inch margins.)

C.4. REFERENCES CITED

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

C.5. PROJECT MILESTONE PLAN

(Text in red font is an example. Please copy the template to accomplish this. Information should match the proposal Project Narrative and Project Budget.)

FIRST SEMI-ANNUAL REPORTING PERIOD			Responsible Team *(Mark all that apply)*	
Milestone	**Description**	**Associated Deliverable(s)**	**South Africa**	**U.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 PowerPoint slides, hand-outs, photographs, and video footage of the training	N/A	NO
Total Amount Requested for the Period:		**$30,000**	$20,000	$10,000
SECOND SEMI-ANNUAL REPORTING PERIOD			Responsible Team *(Mark all that apply)*	
Milestone	**Description**	**Associated Deliverable(s)**	**South Africa**	**U.S.**
Completion of data analysis	Team X will conduct analysis on data collected at the field site.	Final Report	N/A	YES
Total Amount Requested for the Period:		**$10,000**	$5,000	$5,000
THIRD SEMI-ANNUAL REPORTING PERIOD			Responsible Team *(Mark all that apply)*	
Milestone	**Description**	**Associated Deliverable(s)**	**South Africa**	**U.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 PowerPoint slides, hand-outs, photographs, and video footage of the training	N/A	NO

Total Amount Requested for the Period:		**$30,000**	$20,000	$10,000
FOURTH SEMI-ANNUAL REPORTING PERIOD			**Responsible Team** ***(Mark all that apply)***	
Milestone	**Description**	**Associated Deliverable(s)**	**South Africa**	**U.S.**
Completion of data analysis	Team X will conduct analysis on data collected at the field site.	Final Report	N/A	YES
Total Amount Requested for the Period:		**$10,000**	$5,000	$5,000
FIFTH SEMI-ANNUAL REPORTING PERIOD			**Responsible Team** ***(Mark all that apply)***	
Milestone	**Description**	**Associated Deliverable(s)**	**South Africa**	**U.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 PowerPoint slides, hand-outs, photographs, and video footage of the training	N/A	NO
Total Amount Requested for the Period:		**$30,000**	$20,000	$10,000
FINAL SEMI-ANNUAL REPORTING PERIOD			**Responsible Team** ***(Mark all that apply)***	
Milestone	**Description**	**Associated Deliverable(s)**	**South Africa**	**U.S.**
Completion of data analysis	Team X will conduct analysis on data collected at the field site.	Final Report	N/A	YES
Total Amount Requested for the Period:		**$10,000**	$5,000	$5,000

C.6. KEY PARTICIPANT INFORMATION FORM

*(Complete **one for each** South African and U.S. team participant involved.*
Please copy this page as necessary.)

TEAM MEMBER INFORMATION				☐ South African Team Participant ☐ U.S. Team Participant	
Last Name (surname)		First Name (Given)		Middle	
Current Position					
Institution Name					
Complete Mailing Address					
E-mail Address				Telephone #	
Highest Degree/ Year Awarded				Gender	☐ Male ☐ Female
Classification on Project *(please check one)*	☐ Researcher/ Engineer ☐ Administrative		☐ Technical/ Scientific Support ☐ Student		
Duties and Responsibilities on the Project *(responsibilities, expertise, level of effort on the project)*					

C.7. PRINICIPAL INVESTIGATOR PARTNERSHIP AND TERMS AGREEMENT STATEMENT

(Each U.S. and South African team must complete using this Template/Sample. Please use Institute Letterhead. Document must be signed and scanned.)

[INSTITUTE LETTERHEAD]

Re: [Full Proposal Title]

I, [Principal Investigator (PI) Name], hereby acknowledge that I have submitted a proposal to the **U.S. NIH – SAMRC Regional Prospective Observational Research in Tuberculosis in the Republic of South Africa** jointly with [collaborating PI Name(s)] of [collaborating PI institution name].

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 understood CRDF Global's policies and standards outlined within the Regional Prospective Observational Research in Tuberculosis (RePORT) South Africa Phase III RFP, including CRDF Global's Plagiarism Policy. 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 Name and Signature Date

C.8. PLAGIARISM POLICY AND STANDARDS AGREEMENT

Provide a copy signed by each team Project Leader on the proposal.)

CRDF Global and SAMRC will not provide funding to an application in which plagiarism exists.

All applications for funding submitted to CRDF Global will be thoroughly screened for plagiarism against a large number of sources including published research papers, books, conference abstracts, and websites.

When plagiarism is detected, the program within CRDF Global that is overseeing the funding opportunity will determine the specific action to be taken. Action taken may include but is not limited to:

- informing the applicant that plagiarism has been discovered.
- excluding the applicant from the funding opportunity.
- informing the applicant's institution.
- informing reviewers.
- informing organizations collaborating with CRDF Global on the funding opportunity; and
- barring the applicant from participation in future funding opportunities.

Standards

Definition: **Plagiarism** is the incorporation of published writing or another person's original writing into your document without clear formatting and accurate attribution of the source. Academic writing such as a funding proposal must be original work, written by the stated applicant(s). Any text derived from another published source, or from an author not named in the proposal, must be formatted to clearly indicate that it is not the original writing of the applicant(s), and the correct citation to the original source must be given. Proper formatting is either the use of quotation marks around all of the borrowed text or indentation of the borrowed text to clearly set it off from your own writing.

Examples of plagiarism include, but are not limited to, the following cases.

- Using your own previously published text in the proposal without proper formatting and attribution. This is a common error. Even if you wrote the text, you cannot re-use text that you have published in any publicly available form, such as in a research paper, on a website, or in a conference abstract. Even your own previously published text must be formatted and a correct citation to the source must be given.

- Making minor alterations to previously published text and presenting it without proper formatting and citation. Simply changing some of the words within previously published text does not make it your original writing. To avoid plagiarism, the writing must be your original words, sentence structure, and organization. This is another common error.

- Presenting the original writing of another person, even if it hasn't been previously published, as the work of the applicant(s). If someone contributes writing to your proposal, that person must be one of the listed participants (principal investigator or named team member) in the proposal. Even if another person agrees to write text for your proposal and agrees not to be named in the proposal, the use of that person's writing as if it is your own is plagiarism.

- Copying a sentence or obviously unique phrases from another source without formatting and attribution. Stealing a little bit is still stealing. If the text is clearly recognizable as derived from a previously published source, then it must be formatted with proper attribution.

- Giving the correct attribution (citation) at the end of copied text but not formatting the text to clearly indicate that it is taken from the cited source. In the sciences and engineering, it is not sufficient to simply give the citation—if the text is from another source, it must be clearly formatted to show that.

I affirm that I have read and understand the above policy and standards for plagiarism, and I agree to adhere to them.

_____ _____

Principal Investigator Name and Signature Date

C.9. OTHER SOURCES OF SUPPORT OF KEY PERSONNEL

(For Principal Investigators only, please copy this page as necessary.)

☐ **"None" – Check here if no other sources of support. List names of South African Investigators below.**

Principal Investigator			
Support	☐ Current ☐ Pending Submission Planned in Near Future		
Project/ Proposal Title			
Source of Support		**Level of Effort (%)**	
Award Amount		**Period Covered**	
Location of Research			

Principal Investigator			
Support	☐ Current ☐ Pending Submission Planned in Near Future		
Project/ Proposal Title			
Source of Support		**Level of Effort (%)**	
Award Amount		**Period Covered**	
Location of Research			

C.10. PREVIOUS CRDF GLOBAL AWARDS

*(Please copy the form as necessary for each award. Individual forms should not exceed **one page**.)*

CRDF Global Award Number			
Title of Previous Project			
Start Date (MM/YY)		**End Date (MM/YY)**	
Please briefly describe the previous research project. Be sure to provide specific information regarding results and objectives. Were all objectives of the research plan achieved? If not, what prevented you from doing so? Please list scientific publications and conference reports that were published as a result of the CRDF Global award.			
How will the work accomplished during this project contribute to the proposed research? Please address specific project results (data, models, methods) that the proposed project will further develop and/or build upon.			

C.11. LINE-ITEM BUDGET

*(**Complete Excel template.** Complete **one for each** institute involved. Please refer to Section VII. Convert all amounts to USD.)*

Proposal Title:				
Institute Name:				
Project Personnel Labor Compensation Participant Name	**Hourly Rate**	**Total person hours**	**# Of Days**	**$ USD**
1				
2				
TOTAL LABOR COMPENSATION				
Equipment, Supplies, & Services (ESS) Item	**Units**	**Unit Cost**		**$ USD**
1				
2				
TOTAL ESS				
Project Personnel 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 DIRECT COSTS				
Indirect Cost (IDC) of Institute				
(Up to 10% for U.S. institutions/up to 8% for non-U.S. institutions)				
TOTAL INDIRECT COSTS				
CONSORTIUM TEAM SUBTOTAL (Total of direct expenses and IS)				
TOTAL COST-SHARING FROM NON-CRDF GLOBALSOURCES *(Describe in detail in Budget Narrative)*				

C.12. BUDGET NARRATIVE

*(Complete **one for each** institute involved.*
Please include secondary collaborative costs explanation within each budget category.)

Describe and justify the expenses included in each line item, e.g., the purpose and duration of each travel, the number of travelers, destinations, and how costs were determined. If a line item doesn't apply to your budget, please insert N/A for "not applicable" in the space provided.

Team: ☐ U.S.
☐ South Africa

Individual Financial Support (IFS) Describe the level of effort projected for the PI and other team participants – the time to be devoted by team members to the project and their hourly rate, and a total number of person-hours.
Equipment, Supplies and Services (ESS) List and justify in detail, requested equipment items with a value over $1,000 and a use life greater than one year, and all equipment, supplies and services with per unit costs. Explain the necessity of the ESS to the project, and how these items will be used in the proposal. For equipment, supplies, or service orders greater than $10,000 please describe the process that will be undertaken to ensure the order meets U.S. federal competitive selection requirements.

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.
Indirect Costs (IDC) Calculate an allowance for indirect costs of up to 8% of the total individual team modified total direct costs for foreign grantees. U.S. teams may receive up to 10%.

C.13. 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 Co-Investigator must submit this form to CRDF Global within 2 weeks of receipt.

Project Name:			
Principal Investigator (PI) Name:			
PI Contact Information:	**Telephone**:		**E-Mail**:
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**			
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 must 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, Title, and Signature Date

C.14. 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 ☐ Government. ☐ Corporation. ☐ University
UEI Number	

U.S. ORGANIZATIONS ONLY		
TIN/ EIN		
Small Business Designations	☐ Small Business ☐ SDB ☐ HUB-Zone ☐ VOSB ☐ SDVOSB ☐ N/A	
Financial Controls, Audits, & Bioethics		
Did your organization spend 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 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 ☐
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 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 ☐ No ☐	Research Grant
		Yes ☐ No ☐	
		Yes ☐ No ☐	

_____ _____ _____

Signature Name and Title Date

C.15. CURRICULA VITAE (CV) OR NIH BIOSKETCH

(Please visit the following sites for writing a CV/Biosketch: https://grants.nih.gov/grants/forms/biosketch.htm; https://owl.purdue.edu/owl/job_search_writing/resumes_and_vitas/writing_the_cv.html*)*