**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 Policy[[1]](#footnote-1). 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.

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| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  Principal Investigator Signature | Date |

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  Administrative/Sponsored Research Representative Signature[[2]](#footnote-2) | Date |

**COVER SHEET**

|  |
| --- |
| **GENERAL PROJECT INFORMATION** |
| Project Title (*not to exceed 25 words*) | Title |
| Amount Requested (not to exceed $200,000 total) | Total | Project Team #1 | Project Team #2 | Project Team #3(If Applicable) |
| $Amount. | $Amount. | $Amount. | $Amount. |
| Research Categorization[[3]](#footnote-3) | 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 |

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| **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 (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 | # |

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| --- |
| **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**

|  |
| --- |
| **Topic** *(please select up to three from the following topics)***:**  |
|

|  |  |  |
| --- | --- | --- |
| [ ]  Host Immunology | [ ]  Other Co-morbidities | [ ]  Active TB Infection |
| [ ]  TB Epidemiology | [ ]  TB and Pregnancy | [ ]  TB Drug Resistance |
| [ ]  TB Treatment  | [ ]  Pediatric TB Infection | [ ]  TB Social Factors |
| [ ]  TB and HIV Co-infection | [ ]  TB Diagnostics  | [ ]  TB Vaccine |
| [ ]  TB and Alcohol | [ ]  TB Pathogenesis  | [ ]  TB Infection Control |
| [ ]  TB and Diabetes | [ ]  TB Biomarkers | [ ]  Other (Specify)       |
| [ ]  TB and Parasitic Co-infection | [ ]  LTBI |  |

 |
| **RePORT International sites involved in the proposed study:**  |
|

|  |  |  |
| --- | --- | --- |
| [ ]  BJMC  | [ ]  INI- Fiocruz (Rio) | [ ]  SATVI  |
| [ ]  NIRT | [ ]  Rocinha (Rio) | [ ]  Wits Health Consortium |
| [ ]  JIPMER | [ ]  Caxias (Rio) | [ ]  K-RITH |
| [ ]  LEPRA-BPHRC | [ ]  UFRJ | [ ]  UCT – TB Biomarker-Targeted Interventions |
| [ ]  MVDRC | [ ]  FMT/Manaus | [ ]  UCT - NAA for diagnosis in children |
| [ ]  CMC | [ ]  IBIT and IBR Salvador | [ ]  UCT - Biomarkers of Treatment Response |
| [ ]  INA-RESPOND | [ ]  NIHRD | [ ]  Other (Specify)       |

 |
| **CFAR sites involved in proposed study**  |
|

|  |  |  |
| --- | --- | --- |
| [ ]  Case Western Reserve | [ ]  UAB | [ ]  U. Wash |
| [ ]  DC CFAR | [ ]  UCLA | [ ]  Third Coast Center |
| [ ]  Duke | [ ]  UCSD | [ ]  VUMC |
| [ ]  Einstein-Rockefeller-CUNY | [ ]  U. Miami | [ ]  Other (Specify)       |
| [ ]  Emory | [ ]  UNC |  |
| [ ]  JHU | [ ]  U. Penn |  |
| [ ]  Providence/Boston | [ ]  URMC |  |

 |
| **Proposal includes specimens and/or data from (Mark all that apply):** |
| [ ]  RePORT International Common Protocol Cohort A (Active TB cohort)[ ]  RePORT International Common Protocol Cohort B (Latent TB Infection cohort)[ ]  CFAR[ ]  Other (specify):       |
| **Proposal activities (Mark all that apply):** |
| [ ] Request to analyze existing dataset(s) [ ]  Request use of current repository specimens for further testing[ ]  Request additional new protocol procedures and/or participant visits [ ]  Other (specify):       |
| **Does this project involve additional participant burden?** | [ ]  Yes [ ]  No |
|  **If “Yes” *check all that apply below***  |
| [ ]  New specimen collection needed [ ]  New questionnaire administered [ ]  New procedure (e.g., MRI, biopsy) [ ]  New or additional consent needed [ ]  Additional visit required |
|  **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.**  |
|       |
|       |
| **SAMPLE SPECIFICATIONS** (*Specimens obtained may not be used for any purpose other than the approved project without prior consultation and permission from the Executive Committee.*) |
| **Repository Information:** |
| **Will this project require the withdrawal of specimens from the RePORT Central Biorepository?**  |
| [ ]  Yes [ ]  No If YES, list biorepository site      |
| **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.** |
| [ ]  Cohort A general (number of requested participants      )[ ]  Cohort B general (number of requested participants      \_)[ ]  Cohort A diabetic (number of requested participants      \_)[ ]  Cohort A non-diabetic (number of requested participants      )[ ]  Cohort B diabetic (number of requested participants      )[ ]  Cohort B non-diabetic (number of requested participants      )[ ]  Cohort A TB treatment failure (number of requested participants      )[ ]  Cohort A TB early relapse (number of requested participants      )[ ]  Cohort B TB activation cases (number of requested participants      )[ ]  Cohort B TB activation cases who enroll in Cohort A (number of requested participants      )[ ]  Pediatric Cohort A (active TB) aged 5 years or younger (number of requested participants      )[ ]  Pediatric Cohort A (active TB) aged 6 - 14 years (number of requested participants      )[ ]  Pediatric Cohort B (HHCs) aged 5 years or younger (number of requested participants      )[ ]  Pediatric Cohort B (HHCs) aged 6 - 14 years (number of requested participants      )[ ]  HIV co-infected Cohort A (number of requested participants      )[ ]  HIV co-infected Cohort B (number of requested participants      )[ ]  Other (specify      (number of requested participants      ) |
| **Expected number of Person-Visits to be studied:**  |       |
| **Expected number of unique participants to be studied** |       |
| **Will this project require serial specimens with explicitly stated comparisons?** |
| [ ]  Yes [ ]  NoIf “Yes,” please explain:       |
| 1. **Sample Type**

***\* NOTE:*** *Specimens previously thawed for other initiatives may be shipped. If unacceptable, give a reason below for requiring specimens not previously thawed. Leftover material cannot be returned to the Central Biorepository without prior approval from the Repository Program Officer and the RePORT EC.* |
| [ ]  PBMC[ ]  Plasma[ ]  PAXgene RNA[ ]  Other:       | [ ]  mtb isolate[ ] Sputum[ ] Urine | [ ]  Saliva[ ] Whole blood (DNA)[ ]  QuantiFERON |
| 1. **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 |
| *Training for five participants* | *The project team will receive training in GIS technologies/methods used for disease surveillance.* | *Copies of all training materials, including power point slides, hand-outs; photographs, and video footage of the training* |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
| Total Amount Requested for this Reporting Period: | $15000 | $10000 | $5000 |  |
| ***Second Semi-Annual Reporting Period*** | ***Mark all that apply*** |
| Milestone: | Description: | Associated Deliverable(s) | Site Name | Site Name | Site Name |
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
| 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 |
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [x]
|  |  |  |[ ] [ ] [ ]
| 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 |
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [x] [ ]
| 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 | 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: $200,000 USD Maximum** |
| **Primary Participants** |
| **Labor**Participant Name (Add rows if necessary.) | **Hourly Rate** | **Total person hours[[4]](#footnote-4)** | **# of Days** | **$ USD** |
| 1 |   |   |   |   |
| 2 |   |   |   |   |
| 3 |   |   |   |   |
| **TOTAL Labor** |   |
| **Equipment, Supplies, & Services (ESS)**Item (Add rows if necessary.) | **Units** | **Unit Cost** | **$ USD** |
| 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**Participant Name (Add rows if necessary.) | **Hourly Rate** | **# Hours per Day** | **# of Days** | **$ USD** |
| 1 |   |   |   |   |
| 2 |   |   |   |   |
| **TOTAL Labor** |  |
| **Equipment, Supplies, & Services (ESS)**Item (Add rows if necessary.) | **Units** | **Unit Cost** | **$ USD** |
| 1 |   |    |   |
| 2 |   |    |   |
| **TOTAL ESS** |   |
| **Travel** (Totals only, describe purpose and per person costs in detail in Budget Narrative.) | **$ USD** |
| Domestic Transportation  |   |
| Domestic Per Diem |   |
| International Transportation |   |
| International Living Allowance/Per Diem |   |
| Other Travel Expenses (e.g. visa fees, conference registration fees, etc.) |   |
| **TOTAL TRAVEL** |   |
| **TOTAL SECONDARY COLLABORATOR DIRECT EXPENSES** |  |
| **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) |  |

**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).** | [ ]  **“None”** |
|  |
| **Project/Proposal Title** | Title | **Location of Research** | Region/Country |
| **Support** | [ ]  Current [ ]  ­­­Pending Submission Planned in Near Future |
| **Source of Support** | Name | **Level of Effort (%)** | % |
| **Award Amount**  | $ USD | **Period Covered** | MM/YY – MM/YY |
|  |
| **Project/Proposal Title** | Title | **Location of Research** | Region/Country |
| **Support** | [ ]  Current [ ]  ­­­Pending Submission Planned in Near Future |
| **Source of Support** | Name | **Level of Effort (%)** | % |
| **Award Amount**  | $ USD | **Period Covered** | MM/YY – MM/YY |
|  |
| **Project/Proposal Title** | Title | **Location of Research** | Region/Country |
| **Support** | [ ]  Current [ ]  ­­­Pending Submission Planned in Near Future |
| **Source of Support** | Name | **Level of Effort (%)** | % |
| **Award Amount**  | $ USD | **Period Covered** | MM/YY – MM/YY |
|  |
| **Project/Proposal Title** | Title | **Location of Research** | Region/Country |
| **Support** | [ ]  Current [ ]  ­­­Pending Submission Planned in Near Future |
| **Source of Support** | Name | **Level of Effort (%)** | % |
| **Award Amount**  | $ USD | **Period Covered** | MM/YY – MM/YY |
|  |
| **Project/Proposal Title** | Title | **Location of Research** | Region/Country |
| **Support** | [ ]  Current [ ]  ­­­Pending Submission Planned in Near Future |
| **Source of Support** | Name | **Level of Effort (%)** | % |
| **Award Amount**  | $ USD | **Period Covered** | MM/YY – MM/YY |

Institutional Data Form

**The information requested below must be provided in full and signed by an authorized institutional signatory, certifying that the information is true to the best of their knowledge. CRDF Global cannot proceed with an award to the institute without this information.**

|  |  |
| --- | --- |
| Institution Name: |  |
| Institutional Website: |  |
| Type of Organization: | International Organization ☐ Government ☐ Corporation ☐ University ☐ |
| [DUNS Number](http://www.crdfglobal.org/sites/default/files/DUNS%20Number%20Guide_2.pdf)  |  |

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](http://www.crdfglobal.org/sites/default/files/Before%20You%20Receive%20Your%20Award_1.pdf).

|  |
| --- |
| US Organizations Only |
| TIN/EIN  |  |
| Small Business Designations  | Small Business ☐ SDB ☐ HUB-Zone ☐ VOSB ☐ SDVOSB☐ N/A ☐ |
| **Financial Controls, Audits, & Bioethics** |
| Did your organization expend more than US $750,000.00 in U.S. Government Federal Funding (Grants, Contracts, Subgrants, Subcontracts) in the previous fiscal year? If yes, please provide a copy of your single audit report, which is required under 2 CFR 200. | Yes ☐ | No ☐ |
| Have you been audited in the past 3 years? If yes, please send a copy of the report. | Yes ☐ | No ☐ |
| Were there any material or significant findings in the audit report? | Yes ☐ | No ☐ |
| Has your organization ever had a grant or contract terminated for cause? | Yes ☐ | No ☐ |
| Does your organization utilize a financial manual to authorize expenses? | Yes ☐ | No ☐ |
| Does your organization utilize an accounting system to track expenses? | Yes ☐ | No ☐ |
| Does your organization have an ethics policy? | Yes ☐ | No ☐ |
| Does your organization have a timekeeping system for labor such as timesheets? | Yes ☐ | No ☐ |
| Does your project involve: Human Subjects ☐ Animal Testing ☐ Recombinant DNA ☐ Not applicable/None ☐ |
| **Executive/Management Reporting Requirements** |
| CRDF Global may be required to publicly report the names and total compensation of the five most highly 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](http://www.crdfglobal.org/sites/default/files/Before%20You%20Receive%20Your%20Award_1.pdf) for more information. | [Not Exempt](http://www.crdfglobal.org/sites/default/files/Before%20You%20Receive%20Your%20Award_1.pdf) ☐ |
| **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 |
| \\crdf.org\crdfiles\DER\Communications\Organizational Use Folders and Files\CRDF GLOBAL LOGOS\LOGOS\CRDF Global_logo_Tagline_V1.jpg | Guidelines for Projects Involving Human and/or Animal Research Subjects  |

CRDF Global is committed to ensuring that projects involving human or animal research are conducted in accordance with all applicable regulations and ethical guidelines. All projects recommended for award that involve human or animal subjects will undergo 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 Protections[[5]](#footnote-5) (OHRP). This information must be submitted to CRDF Global using the **Bioethics Review Form** found in Appendix A.
2. Written approval from each responsible IRB or equivalent ethics committee; **OR** Written research exemption from each responsible IRB, or equivalent. The written approval or exemption notice must clearly include the name of the project (that matches information provided to CRDF Global) and period for which the approval/exemption is valid.

**Animal Subjects Activity**

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

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

1. Documentation of certification by the Association for Assessment and Accreditation of Laboratory Animal Care International[[6]](#footnote-6) (AAALAC International). This information must be submitted to CRDF Global, using Bioethics Review Form found in Appendix A.

OR

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

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

Bioethics Review Form

CRDF Global is committed to ensuring that projects involving human or animal research are conducted in accordance with all applicable regulations and ethical guidelines. All projects recommended for award that involve human or animal subjects will undergo 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 XPERT 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:  | [ ]  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***](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 and Title |  | Date |

**APPENDIX C:**

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

## Indirect Costs (IDCs)

Awardees (Primary Institutions[[7]](#footnote-7) and Secondary Institutions[[8]](#footnote-8)) may request indirect costs/overhead expenses on all direct costs except for equipment (over $5,000), capital expenditures, rent, student tuition, participant support costs[[9]](#footnote-9) and Secondary Institution expenses (after the first $25,000) funded through sub-contracts under the Primary Institution award.\* Total direct costs minus these items is considered the modified total direct cost (MTDC) amount for which the IDC rate should be applied. IDCs combined with the total direct costs cannot exceed the funding total allowed to request. Below are helpful calculations:

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

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

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

*\*Secondary Institutions may receive award funds either 1) through an award agreement directly with CRDF Global or 2) through a sub-contract under the Primary Institution award agreement. To reduce IDCs and administrative burden for Primary Institutions to sub-contract to Secondary institutions, CRDF Global highly encourages option 1.*

## Cost Share Requirements

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

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

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

1. Salary (including fringe benefits) of any team member essential to the project. Salary and fringe rates should be listed separately for each team member in the cost share budget.
2. Consultant services: Labor and fringe rates for third parties providing volunteer services towards the project may be counted as cost sharing or matching if the service is an integral and necessary part of the project. Rates for third-party volunteer services must be consistent with those paid for similar work by the non-Federal entity. In those instances, where the required skills are not found with the awardee, rates must be consistent with those paid for similar work in the labor market.
3. Equipment/Supplies: Donated equipment, office supplies, or laboratory supplies. Value for these items must be assessed at fair market value of the property at the time of donation
4. Travel: For travel deemed necessary and reasonable to the project, the awardee may cost share appropriate travel expenses, including:
	1. Airfare – Lowest cost economy airfare and compliant with the [Fly America Act](https://www.gsa.gov/portal/content/103191)
	2. Lodging – Not to exceed applicable [domestic](https://www.gsa.gov/portal/category/100120) or [international](https://aoprals.state.gov/content.asp?content_id=184&menu_id=81) U.S. government per diem rates
	3. Meals and Incidentals - Not to exceed applicable [domestic](https://www.gsa.gov/portal/category/100120) or [international](https://aoprals.state.gov/content.asp?content_id=184&menu_id=81) U.S. government per diem rates
	4. 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](https://www.gsa.gov/portal/content/100715) (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.
1. Please refer to CRDF Global’s [Plagiarism and Policy Standards.](http://www.crdfglobal.org/sites/default/files/Plagiarism%20Policy%20and%20Standards.docx) [↑](#footnote-ref-1)
2. Administrative/Sponsored Research Representative is an administrative and financial personnel aware of the proposal content prior to submission. [↑](#footnote-ref-2)
3. 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> [↑](#footnote-ref-3)
4. "Person-hours" = estimated total number of hours devoted to the project throughout the duration of the project. [↑](#footnote-ref-4)
5. The [Office for Human Research Protections (OHRP)](https://www.hhs.gov/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). [↑](#footnote-ref-5)
6. [American Association for Accreditation of Laboratory Animal Care (AAALAC)](https://www.aaalac.org/accreditation/index.cfm) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. [↑](#footnote-ref-6)
7. 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. [↑](#footnote-ref-7)
8. 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. [↑](#footnote-ref-8)
9. 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. [↑](#footnote-ref-9)