**RePORT India**

**Concept Sheet Submission Form (Full)**

**STATEMENT OF AGREEMENT**

|  |
| --- |
| I hereby acknowledge and agree that: |
| * All information that I provide in this Concept Sheet is complete and correct as submitted. |
| * I have read the RePORT India Concept Sheet and Publication Policy and agree to follow all the guidelines and processes that are outlined therein. |
| * The submitting site PI or, for external investigators, a RePORT India liaison, has reviewed the completed Concept Sheet and approved the submission to the RePORT India Executive Committee (EC). (*If no liaison exists, email the RePORT India Administrative Coordinator, Daphne Martin-Gnanadason, dgnanadason@crdf.org).* |
| * If this proposal requests the use of genetics data and receives approval, I will submit the RePORT India Genetics Data Use Certification Agreement PRIOR to initiating any research activities. * If this proposal request incorporates data or specimens from other RePORT International sites outside of India, I will receive approvals from all participating RePORT International Consortia before any research activities are initiated. |
| * Use of specimens and/or data is restricted to the aims outlined in Section B3 of this Concept Sheet Submission Form. * I will submit a data file containing lab results of specimens received, as well as a codebook, to the central data repository (SAS-CHRD). |
| * Manuscripts or abstracts resulting from approved Concepts MUST be submitted to and approved by the RePORT India Publications Committee **prior to** submission to a journal or conference. |
| * Under no circumstances will I make the RePORT India study subject ID numbers public, whether in documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website. * It is my responsibility to ensure Concept Sheet compliance with all applicable regulations. If needed, I will ensure that all applicable institutional review boards (IRBs) / independent ethics committees (IECs) have approved the research prior to implementation. |
| * The lead investigator for each approved concept sheet must submit an annual progress report using the RePORT India Concept Sheet Annual Progress Report Template to the RePORT India Coordinator and by December 15 of each year. If no progress report is received after two email reminders, approval for the concept sheet will expire. A Progress Report will not be due until the next year for concept sheets approved less than six months prior to the December 15 deadline (i.e., after July 15). It is expected that regular interim updates about concept sheet progress may be provided to the EC throughout the year, upon request. |

My signature (PDF electronic signature) below indicates that I have reviewed, accept, and will adhere to the Guidelines for collaboration, publication, and acknowledgment as outlined in the attached Concept Sheet Guidelines and the RePORT India Publication Policy.

**Investigator e-Signature**

**SUBMISSION INSTRUCTIONS**

Email completed Concept Sheet Submittal Form mailing the RePORT India Coordinator, U.S. Secretariat and Executive Committee Chairs at dgnanadason@crdfglobal.org.

**A. GENERAL INFORMATION**

**1. Lead Investigator(s):**

Institution:

Address:

Telephone Number:

FAX Number:

Email:

**2. Study Title/Concept Sheet Title:**

**3. Topic** *(please select up to three from the following topics)***:**

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

**4. Contact Person**(*if different from lead investigator*)**:**

**5. Submission type**: Initial Date of submission:

Revised Date of **initial** submission:

Date of submission of this revision:

Amendment Date of **initial** submission:

Date of submission of this amendment:

Readme# of previously approved concept:

**6. Summary of Changes**: If submission is a revision (to a previously rejected) or an amendment (to a previously approved) existing concept sheet, please summarize all changes. (**NOTE:** In addition, please highlight all changes to previously submitted concept sheet.)

|  |  |  |
| --- | --- | --- |
| **Internal Use Only-DO NOT REMOVE** | | |
| Submission date: | | Approval Status:       Date: |
| REV &SCR end: | | DIST date: |
| PIR: | SCR: | PIR end: |
| BASIC SCI: | CLINICAL/EPI: | CS Number: |

**7. Consortia involved in the proposed study:**

|  |  |
| --- | --- |
| RePORT India | RePORT Brazil |
| RePORT South Africa | TRIPOD Indonesia |
| Other (Specify) \_\_\_\_\_\_\_\_\_\_\_ |  |

**7a. RePORT India sites involved in the proposed study:**

|  |  |
| --- | --- |
| BJGMC | BMMRC |
| NIRT | MVDRC |
| JIPMER | CMC |
| Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_ | Hinduja |

**8. Proposal includes (Mark all that apply):**

RePORT India Common Protocol Cohort A

RePORT India Common Protocol Cohort B

Other (specify):

**8a. 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):

**9. RePORT India Liaison (if lead investigator is not a RePORT India investigator):**

Name:

Institution:

E-mail Address:

Has the RePORT India liaison reviewed the completed Concept Sheet and approved the submission to the RePORT India EC?

Yes  No

**10. IRB/IEC& Human Subjects Issues:**

1. Does this project have IRB or IEC approval? Yes  No  NA

If “No”, please provide explanation and timeline for IRB/IEC submission:

1. Time period of IRB/IEC approval:     to
2. Local IRB/IEC reference #:

**11. Grant Information:**

1. Proposed study is related to an existing grant?

Yes (*please indicate the sponsor and, if NIH-supported, indicate the grant number*)

* + 1. NIH Sponsor:     Grant Number:
    2. Government of India Sponsor:      Grant Number:
    3. Other sponsor (*please specify*):

No

1. Proposed study is related to a pending grant submission?

Yes (*please indicate the sponsor and, if NIH-supported, the solicitation number*)

1. NIH Sponsor:      Solicitation Number:
2. Government of India Sponsor:       Solicitation Number:
3. Other sponsor (*please specify*):
4. Grant submission deadline:

No

1. Are RePORT India funds requested to support this proposed study?
   1. Yes, funds from the parent protocol budget will be used to support these efforts
   2. Yes, fund from the Common Protocol budget will be used to support these efforts
   3. Yes, discretionary funds from the RePORT Consortium will be requested
   4. No, a separate budget not related to RePORT will fund these efforts

If the answer was “yes” to any of the options in question 11c above, please submit a budget for the proposed study along with the concept sheet proposal.

1. If you answered “No” to 11a, 11b, and 11c, please indicate the source of funding for this proposed study:

**12. Conflicts of Interest Disclosure:**

1. Do any of the investigators have any financial conflicts of interest to disclose?

Yes  No

If “Yes” please explain:

**13. International Collaborations:**

Regardless of whether or not a subcontract is arranged, will this collaboration involve an institution or company that is not located in the United States or India?

Yes  No

***NOTE:*** *If yes, please keep in mind that collaborations with non-US investigators proposing to use specimens and/or data from NIH-funded awards cannot be initiated without prior NIH approval. Should this Concept Sheet receive Executive Committee approval, the lead investigator at each primary awardee institution involved with the collaboration should immediately contact the NIAID Program Official in order to receive further details for obtaining such approval.*

**14. Confidentiality:** Does this concept sheet include confidential or commercially sensitive information?

Yes  No

***NOTE:*** *If yes, the RePORT India Coordinator will share a confidentiality agreement template to be signed by the lead investigator and each concept sheet reviewer.*

**B. STUDY DESIGN** (*Use the following organization to present your study plan. Take whatever space is necessary to respond completely to each section.*)

**1.** **Summary** (*Provide a one paragraph summary of the study and its impact on participants.*)

**2. Background** (*Provide a brief description of the rationale for the study, including references.*)

**3.** **Specific Aims and Hypotheses** *(Specimens and data provided by RePORT India may only be used to complete the aims described in Section B3. Additional testing or use of data, including transfer to another investigator, outside the scope of the stated aims and not explicitly stated in the concept is not allowed.)*

**4. Relevance to the RePORT India** Common Protocol (*Discussion of consistency with Common Protocol core aims and scope and potential overlap/synergy with ongoing initiatives.)*

**5. Study Design** (*Summarize the type of study, study procedures, inclusion criteria, exclusion criteria, and sample size.*)

**5a.** Does this project involve additional participant burden**?**

Yes *(check all that apply below)*  No

New specimen collection needed

New questionnaire administered

New procedure (e.g., MRI, biopsy)

New or additional consent needed

Additional visit required

If “Yes” 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.

**5b.** Does this project involve additional RePORT India site staff burden (e.g., IRB submission, coordination of participant visits, administration of forms, data management, training etc.)?

Yes  No

If “Yes” detail any anticipated additional RePORT India staff burden (in terms of amount of time required, additional visits, specimens to be collected, etc.).

**6. Laboratory Methods** (*If applicable, summary of testing to be performed and how new studies will generate data, etc.*)

* 1. Where will laboratory testing be performed?

**7. Test Results**:

Will test results be returned to participants?

Yes No NA

a. If “Yes,” when and how?

b. If “No,” why not?

**8. QA/QC Procedures** (*For studies generating new laboratory data: summarize laboratory QA/QC procedures, participation in recognized programs, past publication, etc., relevant to the proposed investigations or testing.*)

**9. Data Analysis and Sample Size Calculations** (*Where appropriate, indicate which variables are needed from the RePORT India Common Protocol database. For Common Protocol variables, review Case report forms and data elements bank on the RePORT India web site or contact Daphne Martin-Gnanadason).*

a. Will analytic support be requested from the RePORT Consortium?

Yes No

b. If “No,” who will perform analysis?

c. Has analytic team reviewed the concept sheet/study prior to submittal?

Yes No

**10. Goals and Objectives** State the major goals and objectives of what you hope to accomplish with this concept sheet/study.

**10. Timeline** Provide a timeline with anticipated dates for all applicable milestones such as study planning, IEC and other approvals, staff training, study start, study completion, laboratory testing, data transfer, data analysis, manuscript write up and submission.

**11. Manuscript Will Be Completed by** (*Anticipated month and year in which the manuscript will be ready for submission to the Publications Committee for review.*)

     

Month Year

**C. 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.*)

**1. Repository Information:**

1. Will this project require the withdrawal of specimens from the NIRT Central Biorepository?

Yes No

Please indicate the date you will require specimens:

1. Will this project require the withdrawal of whole blood DNA from the NIRT Central Biorepository?

Yes No

Please indicate the date you will require specimens:

**NOTE**: At the time of concept approval, you will need to complete the RePORT India Genetics Data Use Certification Agreement.

In addition, once the concept is approved please complete the NIRT DNA Biorepository Sample Request Form.

**2. Sample Characteristics:** To protect the most valuable and irreplaceable specimens in the RePORT India Common Protocol, 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 India Specimen Allocation Committee.

1. 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 ATB treatment failure (number of requested participants \_\_\_\_\_\_\_)
   * Cohort ATB 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 No

If “Yes,” please explain:

1. Sample Type:**\*** PBMC Plasma PAXgene RNA Mtb isolate subculture

Sputum Urine Saliva Whole blood (DNA) QuantiFERON

Other (specify):

***\* 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 NIRT Central Biorepository without prior approval from the Repository Program Officer and the RePORT EC.*

1. Please refer to the Appendix for a list of Common Protocol samples and storage specifications. Indicate the quantity of sample that is being requested in the table below (next page):

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SAMPLES** | **VISITS** | | | | | | | |
| **COHORT A– DS TB and MDR-TB short course** | | | | | **COHORT B** | | |
| **BL** | **M1**  **(M3 for MDR-TB traditional tx)** | **M2**  **(M6 for MDR-TB traditional tx)** | **END OF TX** | **TX/F/W/R** | **BL** | **M4-M6 (Or) M12** | **TB ACTIVATION** |
| **WHOLE BLOOD**  (PAXGENE RNA) |  |  |  |  |  |  |  |  |
| **WHOLE BLOOD \*\*** (PLASMA) |  |  |  |  |  |  |  |  |
| **WHOLE BLOOD** (DNA) |  | - |  |  |  |  |  |  |
| **WHOLE BLOOD \*\*** (PBMCS) |  |  |  |  |  |  |  |  |
| **WHOLE BLOOD** (QFT NIL) 4th GEN | - | - | - | - | - |  |  |  |
| **WHOLE BLOOD**  (QFT MIT) 4th GEN | - | - | - | - | - |  |  | - |
| **WHOLE BLOOD**  (QFT-TB1) 4th GEN | - | - | - | - | - |  |  | - |
| **WHOLE BLOOD (**QFT TB2) 4th GEN | - | - | - | - | - |  |  | - |
| **SALIVA**  (DNA) |  | - | - |  |  |  |  |  |
| **URINE** |  |  |  |  |  |  |  |  |
| **SPUTUM** (storage) |  |  |  | - |  | - | - |  |
| **MTB ISOLATE** |  | - | - | - |  | - | - |  |

**NOTE: *A data file containing lab results of specimens received, as well as a codebook, must be submitted to CHRD-SAS prior to the release of visit data to you for analysis.***

**Appendix – RePORT India Central Biorepository Specimen List & Storage Specifications (Common Protocol)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SAMPLES** | **VISITS** | | | | | | | |
| **COHORT A– DS TB and MDR-TB short course**  (Tot. Vol of Specimen/Aliquot Vol./No. of Aliquot) | | | | | **COHORT B** (Tot. Vol of Specimen / Aliquot Vol./No. of Aliquot) | | |
| **BL** | **M1**  **(M3 for MDR-TB traditional tx)** | **M2**  **(M6 for MDR-TB traditional tx)** | **END OF TX** | **TX/F/W/R** | **BL** | **M4-M6 (Or) M12** | **TB ACTIVATION** |
| **WHOLE BLOOD**  (PAXGENE RNA) | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 | 2.5ml / 2.5ml\* / 1 |
| **WHOLE BLOOD \*\*** (PLASMA) | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 | 8-10ml / 200-500µl / 8 |
| **WHOLE BLOOD** (DNA) | 3-6ml/1ml/3-6 | - | 3-6ml/1ml/3-6 | 3-6ml/1ml/3-6 | 3-6ml/1ml/3-6 | 3-6ml/1ml/3-6 | 3-6ml/1ml/3-6 | 3-6ml/1ml/3-6 |
| **WHOLE BLOOD \*\*** (PBMCS) | 8-10ml**/**3-5x106cells/ml**/**1-4 | 8-10ml**/**3-5x106cells/ml**/**  1-4 | 8-10ml**/**3-5x106cells/ml**/** 1-4 | 8-10ml**/**3-5x106cells/ml**/**1-4 | 8-10ml**/**3-5x106cells/ml**/**1-4 | 8-10ml**/**3-5x106cells/ml**/**1-4 | 8-10ml**/**3-5x106cells/ml**/**1-4 | 8-10ml**/**3-5x106cells/ml**/**  1-4 |
| **WHOLE BLOOD** (QFT NIL) 4th GEN | - | - | - | - | - | 1ml/100µL/ 3 | 1ml/100µL/ 3 | 1ml/100µL/ 3- |
| **WHOLE BLOOD**  (QFT MIT) 4th GEN | - | - | - | - | - | 1ml/100µL/ 3 | 1ml/100µL/ 3 | - |
| **WHOLE BLOOD**  (QFT-TB1) 4th GEN | - | - | - | - | - | 1ml/100µL/ 3 | 1ml/100µL/ 3 | - |
| **WHOLE BLOOD (**QFT TB2) 4th GEN | - | - | - | - | - | 1ml/100µL/ 3 | 1ml/100µL/ 3 | - |
| **SALIVA**  (DNA) | 6ml / 1.5ml / 2-4 | - | - | 6ml / 1.5ml / 2-4 | 6ml / 1.5ml / 2-4 | 6ml / 1.5ml / 2-4 | 6ml / 1.5ml / 2-4 | 6ml / 1.5ml / 2-4 |
| **URINE** | 10ml /1.5ml/ 4 | 10ml /1.5ml/ 4 | 10ml /1.5ml/ 4 | 10ml /1.5ml/4 | 10ml /1.5ml/ 4 | 10ml /1.5ml/ 4 | 10ml /1.5ml/ 4 | 10ml /1.5ml/ 4 |
| **SPUTUM** (storage) | 3-5 ml/ 0.5-1ml / 1-4 | 3-5 ml/ 0.5-1ml / 1-4 | 3-5ml/ 0.5-1ml / 1-4 | - | 3-5 ml/ 0.5-1ml / 1-4 | - | - | 3-5 ml/ 0.5-1ml / 1-4 |
| **MTB ISOLATE** | Subcultured  & Stored/1ml/ 4 | - | - | - | Subcultured  &  Stored/1ml/ 4 | - | - | Subcultured  &  Stored/1ml/ 4 |

**Note –** Volume of Samples may vary from subject to subject based on availability.

**\* Paxgene tubes are stored as such in -80\*C. DNA:** 4ml tube is currently used.

**\*\* Plasma and PBMC separated from same Hep. Tube (8-10ml).** Repeat QFT & Biorepository samples will be collected forBaseline QFT negative subjects only either at M4-6 or M12, visit timepoint depends on the RePORT site involved. Baseline QFTpostive subjects, no further in person follow-up visit is conducted.