**RePORT International Concept Proposal**

**COMPLETION INSTRUCTIONS**

The RePORT International Scientific Review Committee (SRC) and then the Executive Committee (EC) review all RePORT International Concept Proposals. Below are the steps for submitting your concept:

1. Please fill in as many sections as possible, ensuring that all sections marked with **\*** have been completed. Concept sheets must be saved in MS Word for review.
2. For concepts generated from within RePORT International, please ensure the Principal Investigators (PIs) of the lead RePORT International country have reviewed and approved the idea before submission. There are checkboxes to indicate this.
3. For concepts developed within one or more RePORT International Working Groups, please circulate and obtain the approval of the Working Group before submission.
4. If you are external to RePORT International, the concept sheet’s LEAD submitter should be a RePORT investigator. You may also be listed as a second submitter and copied on any resulting review emails.
5. Once the document is ready for submission, please send it to the RePORT International Coordinating Center (RICC) at tbricc@njms.rutgers.edu. A RICC coordinator will screen the concept for completeness and clarity.
6. The submitter will be contacted if the document lacks information or sections need further clarification. The submitter will also be notified whether the proposal will move forward for review by the SRC and the EC. Each group may have additional questions about the concept proposal. Review by each group takes a minimum of two weeks.
7. If approved, you will be notified and communicated the steps to coordinate the delivery of data and specimens. You may also require a revised submission and/or a meeting with the SRC to address suggestions and clarifications.
8. Please note that additional approvals may be required once the SRC and the EC approve the concept note before it may proceed. Each country/location and collaborating network may also have additional regulations, approvals, data use agreement requirements, etc., that must be obtained. RICC (RePORT International Coordinating Center) can assist with guidance for these additional processes.
9. If you have questions about the template or online submission form, contact tbricc@njms.rutgers.edu.

RePORT International Concept Proposal

*Template v2.0, Mar 2025*

For RICC use only:

Tracking Number: **ID\_\_**

|  |  |
| --- | --- |
| **Scientific Review Committee** | **Executive Committee** |
| [ ]  Approved [ ]  Approved, with conditions [ ]  Disapproved [ ]  Review waived | [ ]  Approved [ ]  Approved, with conditions [ ]  Disapproved  |
| SRC Co-chair signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | EC Co-chair signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date: Click or tap to enter a date. | Date: Click or tap to enter a date. |

**INSTRUCTIONS**: Please complete this document to the extent possible. If you have questions about country contacts or other areas, please email tbricc@njms.rutgers.edu for assistance. **\***Indicates fields that must be completed before submitting.

|  |  |
| --- | --- |
| 1. **Title\***

Provide a detailed title similar to what you would use for a manuscript title. |  |
| 1. **Short title\***

For quick reference purposes. |  |
| **3. Initial submission date\*** | Click or tap to enter a date. |
| **3. Date of revised submission** If applicable. | Click or tap to enter a date. |
| 1. **Submitter’s information\***

Name, affiliation, and email address of the primary submitter for correspondence.**Are you external to RePORT International?**[ ]  Yes - please contact tbricc@njms.rutgers.edu before proceeding. Note: The primary submitter should be a RePORT International investigator. | Primary contact (RePORT International Investigator): Affiliation: Email:Secondary contact (optional):Affiliation: Email: |
| 1. **Proposing investigators\***

Provide each investigator’s specialty (e.g., epi, stats, microbiology), institutional affiliation (including RePORT country and site, if applicable), and email address. Ensure that all listed personnel have been informed and have consented to participate. At least one investigator must be affiliated with RePORT.If there are more than 5 investigators, please add additional rows or provide investigators’ information with a separate page. | **Investigator name and specialty** | **RePORT site and country and/or other affiliation** | **Email address** |
| **1.**[ ]  Consented to inclusion? |  |  |
| **2.**[ ]  Consented to inclusion? |  |  |
| **3.**[ ]  Consented to inclusion? |  |  |
| **4.**[ ]  Consented to inclusion? |  |  |
| **5.**[ ]  Consented to inclusion? |  |  |
| 1. **Collaborators\***

Indicate the investigators from each participating country/location. If there are more than 5 investigators, please add additional rows or provide them on a separate page. | **Investigator name and specialty** | **RePORT site and country and/or other affiliation** | **Email address** |
| **1.**[ ]  Consented to inclusion? |  |  |
| **2.**[ ]  Consented to inclusion? |  |  |
| **3.**[ ]  Consented to inclusion? |  |  |
| **4.**[ ]  Consented to inclusion? |  |  |
| **5.**[ ]  Consented to inclusion? |  |  |
| 1. **Junior/Early-stage investigator(s)**

If applicable, indicate which proposing or collaborating investigators completed their terminal degree or end of post-graduate clinical training within the past 10 years. Include the year they obtained their final degree. If the investigator is a medical or doctoral student, their RePORT mentor should submit the concept sheet.If there are more than 3 junior/early-state investigators, please add additional rows or provide them on a separate page. | Name: Affiliation: Email: |
| Name: Affiliation: Email: |
| Name: Affiliation: Email: |
| 1. **Statistician(s) or person(s) performing statistical analysis**

If applicable, include all requested fields.  | Name: Affiliation: Email: |
| 1. **Data manager(s)**

If applicable, include all requested fields.  | Name: Affiliation: Email: |
| 1. **Brief summary of concept proposal\***

Provide a concise summary in 1-3 paragraphs. The summary should clearly outline the proposed work's objective, significance, and expected impact.  |  |
| 1. **Cohort of interest\***
 | [ ]  **Cohort A** (TB Cases)[ ]  **Cohort B** (Close Contacts) |
| 1. **Location of interest\***

Check all that apply. |

|  |  |  |
| --- | --- | --- |
| [ ]  **Brazil**  | [ ]  **India**  |  |
| [ ]  **Philippines**  | [ ]  **South Africa**  | [ ]  **Other** *(describe)*Click or tap here to enter text. |

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| 1. **Study population and inclusion/exclusion criteria\***

Provide a brief description of the participant population being studied, including the specific inclusion and exclusion criteria, according to the variables requested below. |  |
| 1. **Study rationale\***

Describe the significance of the study question as it relates to TB research and RePORT International. Include background information, citing relevant literature and prior studies that support the proposed research. Clearly describe how this study will substantively contribute to existing knowledge or differ from the relevant previous research. |  |
| 1. **Objectives/Hypotheses/Outcomes\***

Include primary and secondary objectives, along with the corresponding endpoints/ outcomes. Clearly define the hypothesis being tested.  |  |
| 1. **Variables requested**

Specify the variables required for the study and indicate the study visits at which they should be collected (e.g., baseline, M2, M6/EOT, etc.).Reference: [Cohort A list of harmonized variables.](https://tbreportdes.org/) |  |
| 1. **Biorepository specimens**

If specimens from the biorepository are needed, specify the following: * Specimen type (e.g., blood, sputum, urine)
* Quantity required
* Study visit timing (e.g., baseline, follow-up visits)
* Expected assay to be performed
* Anticipated testing laboratory name and location.
 |  |
| 1. **Sample size/Power estimate**

Provide the approximate target sample size for the study. Include a table indicating sample sizes or power calculations for various outcomes if available. If the project is a data analysis (i.e., it does not require the performance of assays on banked specimens) using all available data, provide power calculations for anticipated effect sizes. |  |
| 1. **Study design\***

Indicate the type of study and provide relevant details.  | [ ] Cross-sectional – Examines data at a single point in time.[ ] Retrospective – Uses previously collected samples or data under the common protocol.[ ] Prospective – Involves collecting additional specimens/data beyond the standard RePORT specimens/data.**Additional details:** |
| 1. **Variables, outcomes, and analytic plan**

Define the main outcomes of interest, main exposures, and what type of analyses and model(s) will be used. Detail the comparisons that will be made and the statistical approach applied. Identify potential confounders and describe how they will be accounted for in the model(s). |  |
| 1. **Additional IRB approval**

Is additional human subjects (IRB) approval required for this specific study? | [ ]  Yes [ ]  No [ ]  Yes, pending approval |
| 1. **Structure/Logistics required from RePORT International\***

Specify any RePORT resources needed for this study, such as assays, personnel, shipping, regulatory, etc. |  |
| 1. **External support/Collaboration/ Funding**

If applicable, describe any anticipated collaboration with external institutions, industry partners, or research programs. Will a grant proposal be submitted to fund the work? If so, provide details.  |  |
| 1. **Budget/Cost breakdown\***

Provide an estimated budget for completing the proposed work. Break down costs for each step (e.g., assay, personnel, shipping, regulatory compliance, translation/interpretation services, etc.). Note: Do not list only the total amount. |  |
| 1. **Target conference**

If applicable, indicate the conference or meeting where this data will be presented, including conference name, date, and location. |  |
| 1. **Target Journal**

If applicable, specify the intended journal(s) for manuscript submission.  |  |
| 1. **Timeline\***

Provide a detailed timeline for completing key milestones, such as data collection, data analysis, and manuscript drafting. Include any important deadlines, such as award expenditure expiration dates. |  |
| 1. **Additional comments**

Include any other relevant details or considerations for this project.  |  |