RePORT International Concept Proposal

*Template v1.0, 07July2023*

Tracking Number (assigned by RICC): **ID\_\_**

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| **Title \***  |  |
| **Submission date \*** | Click or tap to enter a date. |
| **Proposing investigators \***Include affiliation, qualifications (e.g., MD, PhD Epi/Biostat/Bio) and email. |  |
| **Collaborating investigators \***Indicate the RePORT Investigators assigned from each participating Country / Location. |  |
| **Junior / Early stage investigator?**If applicable, indicate which proposing or collaborating investigators completed their terminal degree or end of post-graduate clinical training in the past 10 years. Include the year they obtained their final degree.  |  |
| **RePORT partner /** **Executive Committee correspondent \***For external investigators ONLY. If not known, RICC can help identify a RePORT investigator to work with you. |  |
| **Statistician(s) or person(s) performing statistical analysis**If known, include affiliation, qualifications (e.g., MD, PhD Epi/Biostat/Bio) and email. |  |
| **Data manager(s)**If known, include affiliation, qualifications and email. |  |
| **Brief summary of concept proposal \***The summary should be as concise as possible and ideally limited to 1–3 paragraphs. |  |
| **Cohort of interest \*** | [ ]  **Cohort A** (TB Cases)[ ]  **Cohort B** (Close Contacts) |
| **Location of interest \***Check all that apply |

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

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| **Study population and inclusion/exclusion criteria \***Briefly describe the participant population to be studied, including specific inclusion and exclusion criteria, according to the variables requested below. |  |
| **Study rationale**Describe importance of the study question as it relates to TB research and RePORT. Include background information to support the proposed study and other studies conducted in the field that address the proposed hypothesis. Cite relevant literature. Explain how this study will substantively contribute to, or differ from, the existing literature. |  |
| **Objectives / Hypotheses / Outcomes \***Include primary and secondary objectives and endpoints/outcomes.  |  |
| **Variables requested**Include the visits at which you want each variable being requested (e.g., baseline, M2, M6/EOT, etc.).(The list of harmonized variables is available at <https://bit.ly/reportdes>) |  |
| **Will specimens from the biorepository be needed?****If so, which specimens?**Include the specimen type, amount, and timing (e.g., study visit) of interest, expected assay to be run, and anticipated testing lab name and location.  |  |
| **Sample size/Power estimate**Provide an approximate target sample size. While not required, a table indicating sample sizes or power for a range of outcomes may be helpful. If the project is a data analysis (i.e., does not require the performance of assays on banked specimens) using all available data, provide power calculations for anticipated effect sizes. |  |
| **Analysis plan**Is this a cross-sectional study (only looking at one point in time) or prospective study? Define the main outcomes of interest, main exposures, and what type of analyses and model(s) will be used. Be specific about which comparisons they will be used for. Describe the variables that will be considered as confounders and how they will be used in the model(s). |  |
| **Structure / Logistics required from RePORT \***Specify RePORT resources being requested. Include any costs for which coverage by RePORT is being requested (assay costs, personnel costs, shipping costs, etc.). |  |
| **External support / Collaboration / Funding \***If known, discuss any anticipated collaboration with and/or funding support from industry or other programs or institutes outside of RePORT. Will a grant proposal be submitted to fund the work? |  |
| **Budget / Cost breakdown**Estimate the cost of completing the proposed work. Include a breakdown of the costs for each step (assay costs, personnel costs, shipping costs, etc.). |  |
| **Target conference (abstract)**If applicable, indicate the conference or meeting this data will be presented at, including the date and location. |  |
| **Target journal (manuscript)** |  |
| **Timeline \***Indicate a proposed timeline for completing steps such as data collection, data analysis, and manuscript draft. Include any dependencies such as award expenditure expiration dates that must be adhered to. |  |
| **Notes** |  |

**\*** Indicates fields which must be completed prior to submitting.

**Next Steps**

All RePORT International Concept Proposals are reviewed by the RePORT Scientific Review Committee, then the Executive Committee (EC). Here 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.
2. Please finalize the document to remove all edits and comments.
3. For concepts generated from within RePORT International, please ensure the PIs of the lead RePORT country have reviewed and approved the concept prior to submission.
4. For concepts that are developed within one or more RePORT International Working Groups, please circulate and obtain the approval of the Working Group prior to submission.
5. Once the document is ready for submission, please send it to tbricc@njms.rutgers.edu
6. The concept will be screened by coordinators at the RePORT International Coordinating Center for completeness and clarity.
7. If the document is missing information or sections need further clarification, the individuals listed under Proposing Investigators will be contacted to provide clarification.
8. You will be notified whether or not your proposal will move forward for review by the RePORT Scientific Review Committee and the Executive Committee. Each group may have additional questions about the concept proposal. Review by each group takes a minimum of two weeks.
9. You will be notified when your proposal has been approved or not, and if approved, the steps to coordinate delivery of data and specimens.
10. Please note that once approval is received from the RePORT Scientific Review Committee and the Executive Committee, additional approvals may be required before the concept can proceed. Each Country / Location may have additional regulations, approvals, DUA requirements, etc. that must also be obtained. The Report International Coordinating Center will assist to guide you through these additional processes.
11. If you have questions about the template or online submission form, contact tbricc@njms.rutgers.edu