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**Concept Sheet to Perform a Study or Analysis in RePORT-Brazil**

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| **Title** |  |  | | | |
| **Submission date** |  |  | | | |
| **Proposing investigators/affiliation** |  |  | | | |
| **Collaborating investigators/affiliation** |  |  | | | |
| **Statistician(s)** |  |  | | | |
| **Data manager** |  |  | | | |
| **Will specimens from the biorepository be needed?**  **If so, which specimens?** |  |  | | | |
| **Who will perform the statistical analysis?** |  |  | | | |
| **Background/study rationale**  Please describe importance of study question as it relates to TB research and RePORT Brazil. Cite relevant literature. Include background information to support the proposed study and other studies conducted in the field that address the proposed hypothesis. Explain how this study will substantively contribute to, or differ from, the existing literature. |  |  | | | |
| **Objectives/hypotheses.**  Please be specific. Include primary and secondary objectives and endpoints/outcomes. Use the PICOT\* framework to help define your research question/hypothesis.  \*see below for more details |  |  | | | |
| **Variables requested:**  Include which visits you want each variable to be collected (i.e. baseline, M1, M2, M6, etc)  If you want the variable to be defined a specific way, please include that in the comments at the end of this document. | Variable |  |  |  |  |
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| **Length of follow-up**  Define how much follow-up you want participants to be able to have. For example, if you are interested in 6-month outcomes, all participants must have at least 6 months of follow-up. This can be started in terms of months/years of follow-up or enrollment prior to a certain date |  |  | | | |
| **Study population/inclusion and exclusion criteria**  A brief description of the participant population to be studied including specific inclusion and exclusion criteria, according to the variables requested above |  |  | | | |
| **Analysis plan**  Is this a cross-sectional (only looking at one point in time) or prospective study?  Define the main outcomes of interest and how they will be operationalized.  Define the main exposures and how they will be operationalized.  What type of analyses and model(s) will be used? Be specific about which comparisons they will be used for.  Describe what variables will be considered as confounders and how they will be used in the model(s). |  |  | | | |
| **Structure/logistics required from RePORT-Brazil:** |  |  | | | |
| **Timeline:** |  |  | | | |
| **Other:** |  |  | | | |

**PICOT**

*P = Patient, Problem, Population*: What population do you want to study? Think about age, sex, geographic location, or specific characteristics that are important for the question. To whom do you want to be able to generalize the results?

*I = Intervention, Prognostic Factor, Exposure:* What exposure(s) are you most interested in?

*C = Comparison*: What are you hoping to compare? Who is your referent group? Be as specific as possible.

*O = Outcome:* What are you trying to accomplish, measure, improve or affect? Outcomes may be disease-oriented or patient-oriented

*T = Time/type of study or question:* What time periods should be considered? What is your time period of follow-up? What study type is best suited to answer the question (i.e. cross-sections or cohort)