**IMPAACT NEW WORKS CONCEPT SHEET (NWCS)**

Submit the completed NWCS to the IMPAACT Operations Center for consideration by the Network using this email address: impaact.capsubmissions@fstrf.org. Upon receipt, the Operations Center will contact you to provide information concerning the next steps.

**Concept Submitted by:** [Name and email address]

**Date submitted:**

**Scientific Committee:** (please check all that apply)

|  |  |  |  |
| --- | --- | --- | --- |
| Complications/Coinfections  | ( ) | Tuberculosis | ( ) |
| HIV Treatment | ( ) | ART-Free Remissions | ( ) |

**Title:**

**Proposing Investigator(s):** Include name(s), institution, phone number(s), email(s).

**Rationale:**

**Primary objectives:**

**Secondary objectives:**

**Hypothesis:**

**Design and Methods:** Include outline of data analysis plan for each objective, and power calculations, if appropriate.

**Relevant IMPAACT studies:** List all IMPAACT studies that are pertinent to the research questions and from which data and/or specimens will be used.

**Data Management and Analysis:** Identify the responsible parties for both data management and analysis (e.g., IMPAACT SDAC, drug company, CRS/CTU), and identify specific variables and associated CRF(s) required for the analysis. If an SDAC statistician has already worked on this concept sheet prior to submission, e.g., by providing sample size calculations (which is NOT mandatory), please provide the statistician’s name.

**Resources Required:** Specify what IMPAACT resources are being requested, including funding, SDMC time, etc. If funding is to be provided through another source, identify the source and funding status. Note that IMPAACT Data Management Center time may be required for identification of specimens and preparation of data sets even if they are not carrying out the analyses, and this should be accounted for.

**Laboratory Samples Required:** Identify the number of samples required by sample type (i.e., serum, plasma); sample time points per protocol; sample quantity; and, the statistical rationale for these requirements.

**Existing Sample Inventory:** Identify where required samples currently reside (i.e., CRS, repository) and how many samples per location.

**Laboratory Testing:** Identify the laboratory(ies) that will perform the assays.

**Timeline for Completion:**

**Estimated Costs:** Specify any costs for which for coverage by IMPAACT is being requested (assay costs, personnel costs, shipping costs, etc.) and any costs to be covered by other sources and the status of the external funding.

**Indicate whether the Specimen Repository Website (**[**www.specimenrepository.org/home.html**](http://www.specimenrepository.org/home.html)**) was used to identify specimens for this project:** Yes \_\_\_ No \_\_\_

**References:**