

JOHNS HOPKINS COVID-19 RESEARCH PLAN FORM

Please thoughtfully complete the following form in collaboration with your co-investigators. Once completed, upload this document and email it along with your protocol and any other important study documents (i.e. Investigators Brochure, etc.) and email them to the COVID-19 Research Center at COVID19ResearchCtr@jhmi.edu.

For sections 1-6, feel free to cut and paste from your IRB application (thoughtfully) or refer to a _____ specific page of another document.

1. Concept Sheet Title

2. Abstract (Maximum 400 words)

3. Background (Maximum 400 words, not including references)

4. Specific Aims & Hypotheses (Maximum 200 words, not including references)

5. Pilot Data Summary (if available):

6. Approach (Maximum 400 words)

Please include a summarized study design(s), inclusion/exclusion criteria, analytical methods, & sample size calculations/statistical plan. Please discuss sample size and power with ICTR statistical team PRIOR to submission unless you are comfortable. If data are preliminary (not fully powered), then a strong case should be made for the scientific importance and likelihood of future funded research.

7. Description of requirements for JH patients, repository, or research/nursing staff (Maximum 400 words)

For patient specimens please provide details if your project will require additional patient contact including data or specimen collection or other new procedures which require a new informed consent. Please provide details if your project will require IRB submission, staff training, and/or coordinating/consenting /providing participant incentives.

8. Specimen Characteristics and Laboratory Methods

For projects that will use participant specimens, describe the criteria for selecting specimens, the lab testing methods, and the procedures for QA/QC.

9. Requires (select one):

- New IRB & new collection of data and/or biospecimens
- Existing IRB CIR and new collection of data and/or biospecimens
 - i. Existing IRB Number:
- Existing IRB CIR and new collection of data only or re-analysis of existing data
 - i. Existing IRB Number:
- NHSR Review

10. References