**Brigham Health Clinical Trial Scientific Review Committee**

**for COVID-19 related studies**

**Date of Submission to Review Committee:**

**PI Name:**

**Department/Division:**

**Study Initiated by: \_\_** PI \_\_ Industry

**Study Protocol Title:**

**IRB Protocol Number (if existing):**

**Funding source:**

**If Industry initiated: If PI initiated:**

**\_\_\_\_ (y/n/NA)** CDA in place \_\_\_ **(y/n/NA)** IND filed/pending/exempt

**\_\_\_\_ (y/n/NA)** Investigator brochure

**\_\_\_\_ (y/n/NA)** IND filed/pending/exempt (describe)

**Patient population (Check the appropriate box/es):** \_\_ COVID patients

 \_\_ Healthy Volunteers

 \_\_ Health care workers

 \_\_ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study type (please check):** \_\_ interventional (direct patient contact)

\_\_ Interventional Treatment Study

\_\_ Interventional Prevention Study

\_\_ Screening

\_\_ Diagnostic

\_\_ Biorepository/Biospecimen request only

\_\_ Biospecimen and Survey study

\_\_ Survey study

\_\_Other: \_\_\_\_\_\_\_\_\_\_

 \_\_ observational (no patient contact)

\_\_ Chart Review

\_\_ Other: \_\_\_\_\_\_\_\_\_\_

**If Drug/Device, please name the drug/device:**

**Study objectives and hypothesis:**

**Location of study (check all applicable):**

 **\_\_\_ inpatient \_\_\_ outpatient \_\_\_ virtual (online only) \_\_\_ other (describe)**

**Please submit your protocol synopsis or full protocol and consent form. If these are not completed yet, please summarize your implementation plan (please include process for recruiting, resources needed including staff, and location, type and frequency of study visits, method of intervention):**

**(If applicable) biospecimen collection and plan:**

**Samples:** \_\_\_ Prospective (freshly collected) \_\_\_ Retrospective (discarded or banked)

**Can you use discarded samples?** **\_\_\_\_ (y/n)**

**Do you need identifiable samples (linked to patient name, MRN, etc)? \_\_\_\_\_\_ (y/n)**

**Do you need fresh (unfrozen) samples? \_\_\_\_\_ (y/n) If yes, please justify the need for fresh samples below:**

**Please fill in below the type of sample, number of each sample, and sample volume, tests you plan to run:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Sample** | **Total # of patients from which to collect each sample type** | **Number of samples per patient** | **Sample volume per sample** | **Tests to run / Tube needed** |
| **Blood** |  |  |  |  |
| **Urine** |  |  |  |  |
| **Stool** |  |  |  |  |
| **Other:** |  |  |  |  |
| **\_\_\_\_\_\_\_\_\_** |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

***Please attach your protocol synopsis or full protocol and consent form and email it to*** BWHCOVIDreview@partners.org ***for review prior to Partners IRB submission.***