

PROCESS TO OBTAIN JHHS DATA FOR COVID-19 RELATED RESEARCH

Process: for COVID-19 research questions involving secondary data analysis of JHHS patient data, such as JH-CROWN COVID-19 PMAP registry or other Epic patient data, Investigator will need at a minimum 1) an approval or deferral by the [COVID-19 And Data Research Evaluation \(CADRE\)](#) to proceed and 2) IRB approval (see Figure 1). Other review/approvals may also be required.

- **CADRE review is not needed:** If studies are being conducted
 - with pre-existing data set and therefore are not asking for additional data;
 - by a manual chart review of < 20 patients;
 - during the time of COVID-19 but in which the research is not directly about COVID-19 patients.
- **CADRE review required:** If research involves
 - ~>10 patients, then prior to CADRE --> Strong recommendation from CADRE to seek epidemiological study design and biostatistical plan support - BEAD Core BEADCore@jhmi.edu or [BSPH Biostats Center](#). The [BEAD Core](#) has a special free consult service set up - COVID-19 Rapid Response (CRR) BEAD Core consult - for all investigators. Investigators in sponsoring areas such as the Departments of Medicine, Pediatrics, Gynecology/Obstetrics and the JHBMC will be eligible for 20 free hours annually.
- **Other reviews** by committees may be required and may occur at any time in the approval process:
 - IRB: Required approval before receipt of data. Special EMERGE IRB set-up reviewing COVID-19 related research protocols 2x weekly.
 - [Data Trust Research Subcouncil](#): Ensures the security and privacy of JHM patient data; triggers for review by this committee include the sending of identifiable patient data *outside* of Johns Hopkins or storing large amounts of patient data outside of pre-approved secured servers.
 - Clinical Research Coordinating committee: reviews and prioritizes clinical research protocols assessing: 1) Natural history and outcomes of patients with COVID-19; 2) Diagnostic tests for COVID-19; 3) Treatment trials for patients with COVID-19; 4) Requests for downstream basic science SARS-CoV-2 research questions.

STEPS FOR INVESTIGATORS WHO WOULD LIKE A BEAD CORE CONSULT

- **Request BEAD Core COVID-19 Rapid Response (CRR) Consult:**
 - 1) Email BEADCore@jhmi.edu and attach the following
 - a. draft of the [CADRE data request form](#),
 - b. draft IRB protocol (if applicable),
 - c. if post-CADRE, CADRE letter (note whether CADRE approved request),
 - d. any other relevant materials.
 - e. BEAD Core will send instructions for submitting an iLab intake form;
 - 2) Investigator will be assigned a BEAD Core Lead, and a one-hour consult will be scheduled. BEAD will provide as much team coverage as possible, to support the primary Lead and study team.
 - 3) After the one-hour consult, the Lead will provide the investigator with a written set of recommendations discussed during the consult. A main focus of the consult will be reviewing a draft of the CADRE data submission request form.
- **Next steps after BEAD Core CRR Consult:**
 - 4) **If pre-CADRE**, schedule CADRE meeting by emailing the completed CADRE request form to cadre_requests@lists.johnshopkins.edu. Meetings occur 3x weekly: Mon 9-10am, Wed 11am-12pm, Fri 9-10am. Review sessions are 15 minutes in length.

- 5) **If post-CADRE with approval**, obtain IRB approval (if hasn't been obtained already).
- 6) Submit materials to any other required committee reviews.
- 7) Contact the Core for Clinical Research Data Acquisition (CCDA) to proceed with patient data extraction.

Figure 1. Process to obtain JHHS Patient Data for COVID-19-related Research

