**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](https://ictr.johnshopkins.edu/coronavirus/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](https://app.scientist.com/providers/johns-hopkins-university-bsph-biostatistics-center-jhbc).
	The [BEAD Core](http://beadcore.jhu.edu/) 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 are 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](https://intranet.insidehopkinsmedicine.org/data_trust/data-trust-organization/research-data-subcouncil.html): 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
	1. draft of the [CADRE data request form](https://ictr.johnshopkins.edu/coronavirus/cadre/),
	2. draft IRB protocol (if applicable),
	3. if post-CADRE, CADRE letter (note whether CADRE approved request),
	4. any other relevant materials.
	5. 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:**
1. **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.
2. **If post-CADRE** **with approval**, obtain IRB approval (if hasn’t been obtained already).
3. Submit materials to any other required committee reviews.
4. Contact the Core for Clinical Research Data Acquisition (CCDA) to proceed with patient data extraction.

*Required*

IRB approval

*Strongly recommended*

Epidemiological/
Biostatistical Consult

Clinical research coordinating committee review

Other

*May be required*

Data trust committee review

COVID-19-related Research Question involving JHHS patient data (such as JH-COVID-19 CROWN registry or other Epic Patient data)

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

*For those requiring*

CADRE Approval

JHHS Patient Data Extraction by the CCDA