**COVID-19 Secondary Data Reuse Research Study Summary for CADRE Review**

**Instructions**: Prior to your CADRE review we strongly recommend discussing your study design with an epidemiologist or biostatistician. These services are available via the BEAD Core (BEADCore@jhmi.edu) or the [Bloomberg School of Public Health Biostatistics Center](https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-biostatistics-center/). After that consult, email this completed form to cadre\_request@lists.johnshopkins.edu along with your draft IRB protocol and any other materials which may assist the reviewers, such as a detailed data variable list and, if appropriate, a de-identification plan. Someone will contact you promptly. After a pre-review of your materials, if your proposal is ready for review we will schedule a 15 minute review session. Available review sessions are Mondays 9-10, Wednesday 11-12, and Fridays 9-10. You will be provided with a written letter of CADRE findings 1-2 business days after your review.

In preparing your CADRE application, please bear in mind that the JH-CROWN registry is not a public-use dataset. Eventual data access will be prioritized by review of scientific merit and funding availability. The JH-CROWN registry has received large JHM/JHU resources with the expectation of cost recovery; you should plan for grant funding for data access.

**IRB Protocol # (if one exists):**

**Study name:**

**PI:**

**Submitter/Point of Contact (if different from PI):**

**Epidemiologist/Biostatistician:**

**Study question and aims:**

**Study design (check all that apply)**

\_\_ Descriptive

\_\_ Retrospective Observational Cohort

\_\_ Prospective Observational Cohort

\_\_ Intervention

\_\_ Case-Control

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

**Study Population Inclusion/Exclusion criteria:**

(e.g. All adult JHHS patients with a positive COVID-19 lab result)

**Expected number of patients in your study population:**

**Study Time Period (i.e. first and last date of patient data, may include prospective):**

**Outcome Variables (Primary, Secondary):**

**Anticipated Source of Data for the Study: (choose all that apply)**

\_\_ (1) Existing data set (please describe):

\_\_ (2) Manual chart abstraction

\_\_ (3) JH-CROWN COVID-19 Registry

\_\_ (4) Epic data extraction

\_\_ (5) Other (please describe):

**Data Elements Requested:**\* In the Source(s) of Data column, notate the relevant source(s) using the numbers in the “Anticipated Source of Data for the Study” (e.g. 2,3 would be a combination of manual abstraction and JH-CROWN)

|  |  |  |
| --- | --- | --- |
| **Source(s)****Of Data\***  | **Data Set** | **Additional Details** List specific fields here |
|  | Demographics |  |
|  | ED or In-Patient Encounters |  |
|  | Outpatient Encounters |  |
|  | Admission, Discharge, Transfer |  |
|  | Inpatient Encounter Dx |  |
|  | Outpatient Encounter Dx |  |
|  | Infections |  |
|  | Problem List |  |
|  | Lab Results |  |
|  | Organisms from sputum/blood |  |
|  | Card: ECG/EKG order & results |  |
|  | Imaging & Cardiology procedure narratives (results) |  |
|  | Medication Orders |  |
|  | Medication Administration |  |
|  | Blood Administration |  |
|  | Social history |  |
|  | Flowsheets | For oxygen saturation, intubation, ventilator use, ECMO, vital signs (temp), tracheostomy |
|  | Immunizations |  |
|  | Medical history |  |
|  | Clinical Notes – abstracted elements | Describe the elements you would like to glean from clinical notes. Will this be done via a manual chart abstraction, NLP, or in partnership with JH-CROWN investigators? |
|  | Clinical Notes – documents delivered to study | Note: this option requires Data Trust Review and is approved only in exceptional circumstances. Define which notes your study needs and where you would expect those notes to reside  |
|  | Research Study Enrollment |  |
|  | Geocode & Census | Select which of the following are desired: - 3-digit zip codes- Geocodes: longitude/latitude (truncated) - Census block group (LDS, more accurate than zip code)- Census tract (Safe Harbor de-identified) |
|  | Other |  |

Anticipated Format of Delivered Data

\_\_ SQL Database in PMAP (this is the default for larger data requests)

\_\_ Flat Files to SAFE (for small, simple requests)

\_\_ Other (Please describe):

Do you plan to share patient data with anyone outside of Johns Hopkins Medicine?

\_\_ No

\_\_ Yes (Please describe):

Note: In addition to a letter from CADRE documenting what was approved by CADRE, the IRB will ask you for a data spec sheet. If you intend to receive an extract of data from JH-CROWN or Epic you will need to get this spec sheet from the Core for Clinical Research Data Acquisition (CCDA) via a consult with Director Bonnie Woods or her staff. You may find it beneficial to have that CCDA consult prior to filling out this request form.

<https://ictr.johnshopkins.edu/ccda>