**JHM IRB - eForm S–Secondary Research Protocol for COVID-19 Related Research---Data Collection only**

* **This form should be used for secondary COVID-19 research using identifiable private information only. Data are not required to be in existence at the time of the submission to the IRB.**
* **This form may be used for COVID-19 projects drawing data from an existing IRB-approved COVID-19 related registry. For a listing of currently approved COVID-19 related registries please see: https://ictr.johnshopkins.edu/coronavirus/cadre-analyses-2/.**
* **For projects seeking to use data from Protocol # IRB00247569 - The COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN), this form should only be submitted once approval from CADRE and a spec sheet from the CCDA have been secured. For more information about CADRE, please see:** [**https://ictr.johnshopkins.edu/coronavirus/cadre/**](https://ictr.johnshopkins.edu/coronavirus/cadre/)**. Approval from CADRE and the CCDA issued spec sheet should be uploaded in Section 20, Item 2 of the eIRB application.**
* **Please provide complete information for each item below. If an item is inapplicable to your study, explain why.**
* **When submitting JHM IRB eForm S (new or revised), enter the date submitted, the name of the PI, and the eIRB application number in the header at the top of the form.**

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*Please Note: This template uses the JH-CROWN: The COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN) (IRB00247569) as the basis for data projections. If your request for data will include projections from a different COVID-19 registry, references to the JH-CROWN registry may be replaced with that data source.*

*Instructional text is included in italics and should be deleted prior to submitting your eForm S. Pre-approved language appears in blue.*

1. **Research Question** (include all primary and secondary objectives)
2. **Background** (briefly describe relevant information to justify the research)
3. **Methods**
4. Describe the study design and the database(s) that will be utilized, including the specific sources from which you will collect data or samples. Include in your description whether you will use JHM clinical data [e.g. EPIC] or a research resource [provide IRB protocol number] Provide your inclusion/exclusion criteria and describe your method of case/patient/sample identification.

This study will use a PMAP projection from the JH-CROWN: The COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN) (IRB00247569) as its data source.

*If you will have additional data sources that you will combine with the projection from the JH-CROWN registry, please describe them here.*

I am working with the COVID-19 and Data Research Evaluation (CADRE) group to define my inclusion/exclusion criteria and data to be projected. Please see attached spec sheet provided by CCDA for detailed information.

1. If your study involves data from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies.  Please note:  Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016.  If this situation applies, Section 36, question 4 in the application will need to be answered “Yes” and “Hopkins Faculty” should be selected in question 7. No other documents are required.

*If you will link data from the JH-CROWN registry with data collected under an existing IRB approved protocol, list those protocol numbers here.*

1. Clarify whether there was an ethical review process for initial collection/derivation of data. If applicable, provide the determination of the ethics committee or IRB study number. Indicate whether consent was obtained and whether the consent covered the use as proposed in this research.

*If drawing data from the JH-CROWN registry only, please enter the following text:*

Data is drawn from protocol IRB00247569 which maintains current IRB approval. Data included in this registry was included under a waiver of consent.

1. Specify the targeted number of individuals from whom you plan to include data in this secondary use. Please be sure to specify the initial/largest cohort of eligible cases from which you will identify the final sample. Where applicable, please include an estimate of the time period that will be covered [e.g. will you include data within a certain range of dates?](You should contact the Johns Hopkins Center for Clinical Data Analysis (CCDA) if you need help to determine the number of individuals for whom your desired data is available (contact information: <https://ictrweb.johnshopkins.edu/ictr/connection/> ))

I am working with the CADRE group to define the number of individuals in the data projection and the time period covered. Please see attached spec sheet for detailed information.

1. Explain how your data are being extracted (manual chart review, bulk query). If you are planning to collect data from text documents (e.g., pathology/radiology reports) specify exactly how this will be accomplished. Are you planning to download text documents themselves? Storing copies of original documents from EPIC requires consultation with the CCDA and identification of an honest broker.

Data will be provisioned via a query performed by the CCDA of the JH-CROWN: The. COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN) (IRB00247569)

*If you will also be supplementing data provided from the registry with manual extraction [e.g. from a research database or EPIC, please describe that here].*

1. Explain how your data are being recorded (paper, laptop, etc.).

The registry data will not be recorded. They will be provisioned from the JH-CROWN registry *one-time, nightly, weekly, monthly, quarterly (pick one)*

*If you will be recording data separately as part of this project to combine with data provisioned from the registry, please describe the process for that separate recording here.*

1. Explain how the data are being moved to the final storage location.

Data will be moved to the SAFE Desktop by the CCDA. The study will not copy the data from the SAFE Desktop to any other location.  
  
*Note: if you are combining data from other sources, please describe your plan for merging these data with your data projection in SAFE.*

1. Provide the name and location of the server where the data will be housed.

The data will be housed on the SAFE Desktop associated with the Precision Medicine Analytics Platform.

1. Provide the name of the study team member responsible for data management and security.
2. Provide any plans for de-identification of the dataset. Identifiers (MRN, Name) should be stored in a separate file with the data file using unique IDs.

*If de-identification is needed, the CCDA will de-identify data from the JH-CROWN registry prior to delivering it to the study team’s SAFE Desktop and will perform any re-identification that is authorized by the IRB. Please state if this will occur.*

*Note: if you are combining data from other sources, please work with the CCDA in order to merge the data if de-identification is needed.*

1. Explain how access to the data will be controlled and whether the access is logged.

Data will be controlled and logged using the mechanisms described in the eFormR for The Johns Hopkins Precision Medicine Analytics Platform (PMAP) (IRB00201886)

1. List the computer programs being used to store and to analyze the data.

*Reference this* [***link***](https://ictr.johnshopkins.edu/programs_resources/programs-resources/i2c/secure-research-data-desktop/) *with the tools available on SAFE and list below the tools which you will use for your study.*

*If you are using data from several sources explain what variables will be used to merge files.*I am working with the CADRE group to define which variables will be used to merge files. Please see attached spec sheet provided by CCDA for detailed information.

1. Will the data set include any sensitive information (e.g., HIV status, psychiatric diagnosis)?

I am working with the CADRE group to define which variables if any are considered to be sensitive information. Please see attached spec sheet provided by CCDA for detailed information.

1. Will the data set include any genomic data?
2. Will the data be used in collaborative efforts with other institutions? If yes, will data leave Hopkins? If so, how will this be accomplished? What security measures are in place for the transfer? [Please contact the Office of Research Administration for details related to Data Use Agreements: <https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/>]

*Choose one:*

The data from the JH-CROWN registry will not leave Hopkins.

OR

*If you intend to share any data outside of Hopkins, describe your approach here.*

1. Provide an estimate of how long it will take you to complete the study, including the time for data analysis.
2. **Study Statistics**
3. Primary outcome variable.
4. Secondary outcome variables.
5. Statistical plan including sample size justification and any plans for interim data analysis.
6. **Risks**
7. Address the risk of loss of confidentiality.
8. Discuss the steps you are taking to minimize this risk.

Data will be stored in a JHED limited access on the SAFE Desktop. The PI will ensure that the access list will only include people who are approved as study team members on the IRB application.

1. Identify whether there are any additional risks and how you will minimize these risks.
2. Discuss your plan for reporting unanticipated problems or study deviations.
3. **Requested Variables** (Upload your data collection form in Section 20, Q 2 of the application. Do not use general terms, i.e. medical history. Be specific about what you plan to collect and indicate any coding scheme that will be used, e.g.  yes/no.)  
     
   Attach your CADRE spec sheet provided by CCDA, which will include a summary of the variables requested. \*Please also upload a data collection form as described here for any manual chart review or data collected from other sources not reflected on the spec sheet
4. **Agreement for Use of Data for COVID-19 related Research**

The COVID-19 PMAP databases are built from the experiences of patients, the documentation and care of providers and the skill and dedication of data scientists. To that end, research utilizing these databases must recognize the contributions of everyone and be part of a collaborative learning community. In recognition of this resource, we expect everyone who utilizes the data to be part of a learning community dedicated to timely and impactful discovery that improves patient outcomes. By submitting this eForm S you are agreeing to the following requirements for access to COVID-19 related data.

1. Any research team who utilizes the data has to propose a research question (independent and dependent variable) and post their plan for analysis on a COVID-19 PMAP database that is available to the Johns Hopkins community.
2. All teams need to abide by the requirement that data is analyzed within the SAFE Desktop and no data are downloaded or copied.
3. Teams must provide a three month progress report so that teams that are not making progress become known to other potential users
4. All findings and results must be shared with the Hopkins COVID research community, including analytic software, derivative variables, parameter estimates, and manuscripts.
5. Teams should consult clinicians and data scientists listed on the COVID-19 PMAP website who contributed to the COVID data resource design and collation. The contributions of all of them are expected to be recognized in publications.
6. All publications must include this statement “The data utilized for this publication were from the Johns Hopkins COVID-19 Precision Medicine Center of Excellence, officially designated by the Precision Medicine Analytics Platform (PMAP) leadership, and based on the contribution of many patients and clinicians.”