**JHM IRB eForm S – Secondary Research Protocol for COVID-19 Related Research with Biospecimens**

* **This form should be used for secondary research with COVID-19 related biospecimens.**
* **These studies will draw specimens from one of the following existing specimen repositories [IRB00248332 - Johns Hopkins COVID-19 Remnant Specimen Repository or Protocol # IRB00245545 -** [**Clinical Characterization Protocol for Severe Infectious Diseases (CCPSEI)**](https://e-irb.jhmi.edu/eirb2/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b7BD9CA491F7B694091B6F325DBB150FB%5d%5d)**] and will draw data from IRB00247569 - The COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN).**
* **Samples and data for these studies will only be provisioned with approval of the JHU COVID-19 Biospecimen Oversight Committee. Please do not submit this form prior to having obtained permission from the Biospecimen Oversight Committee.**
* **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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*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)

The biospecimens and associated meta-data available in this resource were collected prospectively under the “Clinical Characterization Protocol for Severe Infectious Diseases CCPSEI”, (IRB00245545, PI Sauer) and retrospectively under “The Johns Hopkins COVID-19 Remnant Specimen Repository”, (IRB00248332, PI Sauer). These repositories were developed with the intention to create an institutional resource available to all Johns Hopkins researchers to access for biospecimens with associated data in order to answer critical downstream research questions.

1. **Methods**
2. 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 the specific research resource [provide IRB protocol number] from which data/specimens will be drawn. Provide your inclusion/exclusion criteria and describe your method of case/patient/sample identification.

*Insert one or both of the following statements which applies to your study:*

1. This study will use the “Johns Hopkins COVID-19 Remnant Specimen Repository” (IRB00248332) as the source of biospecimens.

2. This study will use the “[Clinical Characterization Protocol for Severe Infectious Diseases (CCPSEI)](https://e-irb.jhmi.edu/eirb2/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b7BD9CA491F7B694091B6F325DBB150FB%5d%5d)” (IRB00245545) as the source of biospecimens.

*In addition, insert the one or both of the following statements:*

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

I have secured approval from the JHU COVID-19 Biospecimen Oversight Committee and CADREto use the data/specimens detailed in this eformS and provisioned for my project.

*If you will have additional data/specimen sources that you will combine with the data/specimens obtained from these COVID-19 related resources, please describe them here.*

1. Clarify whether there was an ethical review process for initial collection/derivation of data/biospecimens. 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.

*Please enter the following text that applies:*

Specimens are drawn from “Johns Hopkins COVID-19 Remnant Specimen Repository” (IRB00248332) that maintains current IRB approval. Specimens included in this repository were collected under a waiver of consent.

AND/OR

Specimens are drawn from “[Clinical characterization protocol for severe infectious diseases (CCPSEI)](https://e-irb.jhmi.edu/eirb2/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b7BD9CA491F7B694091B6F325DBB150FB%5d%5d)” (IRB00245545) that maintains current IRB approval. Specimens included in this resource were collected under a waiver of documentation of consent.

*Please also enter the following text:*

Data are drawn from “The COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN)” (IRB00247569) that maintains current IRB approval. Data included in this registry were included under a waiver of consent.

*If you will have additional data/specimen sources that you will combine with the data/specimens obtained from these COVID-19 related resources, please describe them here, including the relevant IRB protocol numbers and whether these protocols included a process for obtaining informed consent.*

1. If biological materials are involved please describe all the experimental procedures and analyses in which they will be used.

*Describe the experimental procedures and analyses for each type of biospecimens to be used.*

1. Specify the targeted number of individuals from whom you plan to include data/samples 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/> ))

*When submitting your request to access biospecimens and data from one of the COVID-19 approved repositories, please review the list of available data/specimens when developing your request. Your e-IRB application and this eform must align with the specimens/data approved to be provisioned, rather than what you may have originally requested. As COVID-19 related specimens are a precious resource, when requesting specimens, please consider the minimum amount of specimens needed to accomplish the research. Specimen requests with too high a volume may not be able to be accommodated.*

*Please enter the following text:*

I have secured approval from the JHU COVID-19 Biospecimen Oversight Committee and CADREto use the data/specimens provisioned for this research as outlined in the attached approved spec sheet.

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)*

*Describe your plans for recording data from analysis performed for this study.*

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.

*Describe your plans for combining data from analysis performed for this study with data provisioned by the CCDA.*

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 and/or CCPSEI.

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.

Unless otherwise requested using this eFormS and approved by CADRE, only a limited data set including the variables permitted by the Biospecimen Oversight Committee will be provisioned in association with the specimens.

*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) [or according to mechanisms described in the source repository].

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.*

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 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 Johns Hopkins.

OR

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

*Any data shared outside of Johns Hopkins through executed data use agreements will require approval from the PI of CCPSEI, the Remnant Repository, and/or JH-CROWN, as applicable.*

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 analysis plan
6. **Risks**
7. Address the risk of loss of confidentiality by discussing 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. Discuss your plan for reporting unanticipated problems or study deviations.

Any potential breaches of confidentiality will be reported to the JHM IRB in accordance with the IRB’s prompt reporting policy and to the PIs of the relevant source protocols, as well as the Biospecimen Oversight Committee.

1. **Requested Variables** (Upload your approved Spec Sheet in Section 20, Item 2.)
2. **Transfer of Materials**

Transfer of biospecimens from Johns Hopkins to another organization for research purposes and receipt of biospecimens from an outside organization for your research must adhere to JHU policies for material transfer (<https://ventures.jhu.edu/faculty-inventors/forms-policies/>) and biospecimen transfer (<https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_=0.622324232879>).

Please complete this section if your research involves transfer of biospecimens to an external entity.

1. Will you **transfer** biospecimens to an external entity as part of this research? [Yes/No]

 If “Yes”, please address each of the following:

1. Describe the nature of the research collaboration with the external entity and the rationale for the transfer. (Include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications.)
2. Please confirm you will secure an MTA through the appropriate office (JHTV or ORA) prior to transfer.

(See: <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>.)

1. If the biospecimens you intend to transfer were obtained through clinical or research procedures at Johns Hopkins and “Other” is selected in Item 4, Section 23, please submit the following items in that Section:
	1. A pdf version of a completed JHTV Online “Material Transfer Agreement Request Form for Outbound Material” <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/> **OR** a copy of the COEUS PD (Proposal Development Summary).
	2. A completed Biospecimen Transfer Information Sheet <https://www.hopkinsmedicine.org/institutional_review_board/forms/>.
	3. A signed and dated “De-identified Human Subject Certification” [https://livejohnshopkins-my.sharepoint.com/:w:/g/personal/sdamare1\_jh\_edu/ETANthXrGPVBmYs-\_UC59fUBu9b1An7tYUWh4GjiG2fH4Q?rtime=5kjTd-F410g](https://livejohnshopkins-my.sharepoint.com/%3Aw%3A/g/personal/sdamare1_jh_edu/ETANthXrGPVBmYs-_UC59fUBu9b1An7tYUWh4GjiG2fH4Q?rtime=5kjTd-F410g)
	4. Approval documents from recipient site, if applicable.
	5. Copies of the consent forms associated with the IRB protocols under which the biospecimens were collected, with language appropriate to this transfer highlighted.
	6. The name of the specialist you are working with in ORA to complete a contract/MTA.

Please see the following website for more information about transferring human biospecimens to outside entities: <https://www.hopkinsmedicine.org/institutional_review_board/news/announcement_transfer_human_biospecimens_outside_entities.html>.

1. **Agreement for Use of Data and Specimens 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 and specimen repositories must recognize the contributions of everyone and be part of a collaborative learning community. In recognition of this resource, we expect everyone who utilizes these resources 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/specimens.

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 areas of study that are not fruitful become known to other potential users
4. Teams must provide a summary analysis to CCPSEI study team to be shared with other CCPSEI investigators.
5. All findings and results must be shared with the Hopkins COVID research community, including analytic software, derivative variables, parameter estimates, and manuscripts.
6. Teams should consult clinicians and data scientists listed on the COVID-19 PMAP website who contributed to the COVID data resource design and collation. Their engagement and contributions are expected to be recognized in publications, either as authors (as appropriate) or acknowledged for study contributions.
7. All publications must include this statement “The data utilized for this publication were part of the Johns Hopkins COVID-19 Precision Medicine Analytic Platform which is based on the contribution of many patients and clinicians.”
8. For projects where specimens have been provisioned from Protocol # IRB00245545 - [Clinical Characterization Protocol for Severe Infectious Diseases (CCPSEI)](https://e-irb.jhmi.edu/eirb2/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b7BD9CA491F7B694091B6F325DBB150FB%5d%5d), publications must include the following statement: “The specimens and data utilized for this publication were collected under the Johns Hopkins COVID-19 Clinical Characterization Protocol for Severe Infectious Diseases (CCPSEI) which is based on the contribution of many patients and clinicians and the Special Pathogens Research Network.”
9. For projects where specimens have been provisioned from Protocol IRB00248332 – “Johns Hopkins COVID-19 Remnant Specimen Repository” publications must include the following statement: “The specimens and data utilized for this publication were collected under the Johns Hopkins COVID-19 Remnant Specimen Repository which is based on the contribution of many patients and clinicians from the Johns Hopkins Medical Institutions.”