*This document provides step-by-step instructions for each section of the eIRB application submitted for research extending beyond a pilot project drawing from biospecimens/data collected under at least one of the following biospecimen/data repositories:*.

* **IRB00248332: Remnant Biospecimens, “**Johns Hopkins COVID-19 Remnant Specimen Repository”
* **IRB00245545: Prospective Collection of Biospecimens, “**[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)”
* **RB00247569: Data only, “**The COVID Precision Medicine Analytics Platform (PMAP) Registry (JH-CROWN)”

**Please note:**

 \*Samples and data for these projects will only be provisioned with approval of the JHU COVID-19 Biospecimen Oversight Committee.\* This committee review will incorporate CADRE (COVID-19 And Data Research Evaluation) review; COVID prioritization committee review is not required for the secondary use of data/specimens collected under one or more of the repositories noted above.

<https://ictr.johnshopkins.edu/coronavirus/biospecimencommittee/>

**Section 1 – General Information**

Item 2 – Select “No”

Item 3 – Select “No”

Item 6 – Add “*Secondary research with COVID-19 related biospecimens/data.*” before the brief statement of research

 Item 7 – Select “Expedited” as the review type. Per DHHS regulations, use of biospecimens requires expedited review unless they are publically available.

Item 8 - Select “No”

Item 9 – Select “single-site study"

Items 12-19 – Select “No”

Item 23 - Add expected length of time to complete the project

Item 24 – Select “No”

Item 25 – Add all study team members who will be working on the project

**Section 2** – **Study Team Compliance Training**

Ensure that the PI and all study team members have completed the required compliance training courses.<https://www.hopkinsmedicine.org/institutional_review_board/training_requirements/index.html>

**Section 6 – Protocol Information**

Item 1 – Select JHM-IRB eForm

Item 2 - Upload a completed “eForm S for COVID-19 Project Involving Data and Biospecimens”, using the “Add” function (<https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/index.html>)

Item 5 – Provide any additional information about the project you believe will be helpful

Item 6 – Select “No”

Item 10 – Select “None of the above”

Items 11-14 – Select “No”

**Section 7 – Clinical Trials information**

Item 1 – Select “No”

**Section 8 – Conflict of Interest**

Answer all questions about COI

**Section 9 – Support Information**

Item 1 – Select type of support, if any, and complete support information. If your support source is not listed in the drop-down, email jhmeirb@jhmi.edu with a request to add the source

Item 3 – Select “No”

Items 9 - Select “No”

Items 10-11 – Answer depends on funding

**Section 10 – Study Location**

Item 1 – Add all locations and complete all PI contact information

Items 2 and 3 – Answer appropriately

**Section 11 – Sample Size**

Item 1 - Select “No”

Item 4 - Provide the number of individuals from whom biospecimens/data were obtained

Item 8 - Select “No”

**Section 12 – Participant Information**

Item 1 – Select “Yes”, as you will receive a limited data set

Item 2 – Provide age range

Item 3 - Select one or more of the first 4 options, (not the last 2)

Item 4 – Do not select any of the options; (these populations are not specifically targeted for this secondary research)

Item 5 – Select “No”

Item 6 – Select “Hopkins/Affiliates inpatients” and “Hopkins/Affiliates outpatients”. Also select JHH/JHBMC adult emergency department patients/records

**Section 13 – Recruitment Information**

Item 1 – Select “No intervention/interaction with participants”

Item 8 – Select “JHM IRB approved studies or research databases” and JHM Clinical Data any select any other data sources that apply

Item 9 – Enter “IRB00248332”, “IRB00245545”, “IRB00247569” and/or other JHM IRB application numbers as appropriate, then answer a and/or b accordingly

Item 11 – A HIPAA waiver is not required for projects using information/samples without identifiers or a limited data set. If you will only receive data/samples provisioned from one of the named repositories, this form is not required. If you will be pulling additional data [e.g. from a separate record review] or you will receive a dataset from JH CROWN that will include identifiers, a HIPAA waiver is required and a HIPAA Form 4 must be uploaded.

**Section 14 – Consent and Waivers**

Item 1 - Select “Waiver of Consent” if you are using data/biospecimens from IRB00248332, IRB00247569 or if you are using any other sources and consent was not obtained. Describe how each of the 4-5 criteria are met, as follows.

*“This research involves no more than minimal risk to the subjects. This research uses only data/biospecimens collected under approved IRB applications. There are no research related procedures that would affect patient care. For data usage, the PMAP platform accessed from the JHH Safe Desktop is protected HIPAA compliant research environments.*

*It would be impracticable to undertake this work without a waiver of consent. The population will include patients who have already died or who may not be healthy enough to return to the Hopkins system. Among those patients that are seen routinely within outpatient clinics, this will be across multiple clinical specialties and clinics and it would not be feasible to prospectively consent them. Were we to exclude these people, the database would have an inherent ascertainment bias.*

*The resource will contain a linking study ID that will be used in conjunction with the JH-Crown data and a linking table will be maintained by the resource study PI, lab PI, and repository program manager only, to ensure the protection of privacy.*

*Given that the data are previously collected in the course of routine clinical care under an approved IRB application that describes the HIPAA compliant environment in which data will be stored, the waiver of consent will not adversely affect the rights and welfare of the subjects.*

*It is not anticipated that information pertinent for sharing with subjects or their legally authorized representatives will be generated through this protocol.”*

Item 1 - Select “Consent was previously obtained which accounts for the activity proposed in this new submission and no new consent is required”, if you are prospectively collecting biospecimens obtained from 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)”

**Section 20 – Supplemental Documents**

Item 2 -

* Upload documentation of approval from the Biospecimen Oversight Committee.
* Upload a variable list outlining the data elements to be obtained with the provisioned specimens. This spec sheet will be provided by the CCDA.
* Upload a Use of Data Agreement, signed and dated by the PI

<http://intranet.insidehopkinsmedicine.org/privacy_office/additional_information/use_of_data_agreement.html>

**Section 22 – Devices**

Items 1 and 2 – Select “No”.

Items 1 and 2 – Select “Yes” if there are any assays that will used or studied in this research.

Mark item 1 “yes” if you are ***studying*** an assay in this research and indicate its FDA status in the items that appear. If the assay is FDA approved, or has 510 K marketing clearance, and it will be used according to the approved indications, list the device in item 3, providing the details and supporting document(s) where prompted. If the assay is investigational and is not yet FDA approved, list the assay in item 5 and provide the device details where prompted.

Mark item 2 “yes” if you will ***use*** any investigational assay (not yet approved by FDA, or used according to an indication not approved by FDA) in your research. List the assay in item 5 and provide the device details where prompted.

**Section 23 – Human Biological Samples**

Item 1 – Select “Yes”

Items 2-7 - Complete with study-specific information

**Section 24** **- Institutional Biosafety Committee**

Item 1 - Select ”Potential infectious agents or viral-based vectors”. Work with SARS-CoV-2 virus, derivatives thereof, and material derived from COVID-19 patients all need to be registered with the Biosafety Office and approved by the Institutional Biosafety Committee before obtaining these materials and commencing research. Provide responses to Items 2 and 3.

**Section 34 – SKCCC CRO**

Item 1 – Answer appropriately

**Section 36 – Data Confidentiality**

Item 1 – Complete and upload a Risk Tier Worksheet and select the assigned category

Item 2- Select “No”

 Select “Yes” if any person-level information, including de-identified data, limited data set, or personally identifiable information or protected health information will be sent outside of Johns Hopkins Health System or School of Medicine during the course of the study. Select or provide the name/entity of the receiving party.

Item 3 – If Item 2 is “Yes”, provide the number of individuals from whom biospecimens/data will be shared.

Item 4 – Answer appropriately

Item 6 – Select “Yes” only if you will use a source of data/biospecimens other than IRB00248332, IRB00245545 and/or IRB00247569 that is funded by NIH or CDC and if that study was active in 2016 and you are reviewing data that was funded by NIH.

<https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/certificates_of_confidential.html>

 Item 7 – If Item 6 is “Yes”, select "Hopkins Faculty". You need not respond to any of the additional items that will appear as a result nor upload any documentation.