



**COVID RESEARCH CHECKLIST FOR INPATIENT AND OUTPATIENT STUDIES**

You may direct any questions to: [COVID19ResearchCtr@jhmi.edu](mailto:COVID19ResearchCtr@jhmi.edu)

**A. Pre-IRB**

1	<p><b>CADRE Committee review</b> (if your research will involve clinical data in CADRE database)  <a href="https://ictr.johnshopkins.edu/wp-content/uploads/CADRE-Data-Request_v6.docx">https://ictr.johnshopkins.edu/wp-content/uploads/CADRE-Data-Request_v6.docx</a>            Send to: <a href="mailto:cadre_request@lists.johnshopkins.edu">cadre_request@lists.johnshopkins.edu</a>.</p>
2	<p><b>Biospecimen Committee review</b> (if your research will involve existing serum or plasma specimens from patients with COVID sourced from CCPSEI protocol)  <a href="https://ictr.johnshopkins.edu/wp-content/uploads/COVID19-Biospecimen-Request-Form-10122020.docx">https://ictr.johnshopkins.edu/wp-content/uploads/COVID19-Biospecimen-Request-Form-10122020.docx</a>            send request to <a href="mailto:cbenne31@jhmi.edu">cbenne31@jhmi.edu</a></p>
3	<p><b>Office of Research Administration</b> – see table at link below with function and location of different ORA entities, including contracting. Identify your division/departmental contracting lead.  <a href="https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/">https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/</a>            Contact: <a href="mailto:ORA@jhmi.edu">ORA@jhmi.edu</a> or (410) 955-3061</p>

**B. IRB application and related documents (do not wait for CRCC review and approval to start this)**

1	<p><b>Protocol</b></p> <ul style="list-style-type: none"> <li>For secondary data use only using JH-CROWN as source registry: eFormS  <a href="https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/eFormS_COVID-19_Secondary_Data.docx">https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/eFormS_COVID-19_Secondary_Data.docx</a></li> <li>For secondary research with COVID19 related biospecimens +/- associated JH-CROWN data: eForm S  <a href="https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/eFormS_COVID-19_Projects_involving_Data_and_Biospecimens.docx">https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/eFormS_COVID-19_Projects_involving_Data_and_Biospecimens.docx</a></li> </ul>
2	<p><b>HEIC Checklist</b> (aka Supplemental Form for COVID-19 research)  <a href="https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/HEIC_checklist.docx">https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/HEIC_checklist.docx</a>            Upload to Section 20, Item 2.             Contact: Aaron Milstone at <a href="mailto:amilsto1@jhmi.edu">amilsto1@jhmi.edu</a>, (443) 287 8932</p>
3	<p><b>Protocol Synopsis</b>  <a href="#">Protocol Synopsis Template for COVID-19 Related Interventional Research</a> - A Draft Synopsis must be submitted with each COVID-19 application that involves a therapeutic intervention. Uploaded to Section 20, Item 2.</p>
4	<p><b>Department of Nursing</b> review  <a href="https://www.hopkinsmedicine.org/institutional_review_board/forms/jhhs_nursing.pdf">https://www.hopkinsmedicine.org/institutional_review_board/forms/jhhs_nursing.pdf</a>            Upload form into IRB Section 11, Item 8.</p>

	<p><i>*Nursing approval is only needed if your research requires the use of Johns Hopkins Health System Departments of Nursing resources or if JHHS nursing staff will be study participants.</i></p> <p>Contacts: Heather Watson at <a href="mailto:hwatson7@jhmi.edu">hwatson7@jhmi.edu</a>, (410) 614-8319 (JHHS), Jackie Lobein at <a href="mailto:jlobein1@jhmi.edu">jlobein1@jhmi.edu</a>, (301) 896-3122 (HCGH, Sibley, Suburban)</p>
6	<p><b>Institutional Biosafety Committee</b> (IBS review) <a href="mailto:IBC@jhu.edu">IBC@jhu.edu</a></p> <ul style="list-style-type: none"> <li>• Anyone in your group who will handle or transport infectious pathogens (e.g. nasal swab for COVID19) must complete components of Health, Safety, Environment Training: <a href="https://www.hopkinsmedicine.org/hse/training/">https://www.hopkinsmedicine.org/hse/training/</a></li> <li>• Anyone organizing the packing and shipping for biospecimens will require Department of Transportation (DOT) and/or International Air Transportation Association (IATA) training: <a href="https://www.hopkinsmedicine.org/hse/training/">https://www.hopkinsmedicine.org/hse/training/</a></li> <li>• Register your study with IBC: <a href="https://www.hopkinsmedicine.org/hse/biosafety/ht_p_t_registration.html">https://www.hopkinsmedicine.org/hse/biosafety/ht_p_t_registration.html</a> <ul style="list-style-type: none"> <li>→ Studies with infectious agents, pathogens, or biological toxins: <a href="https://www.hopkinsmedicine.org/hse/forms/PathogenToxinRegistration.pdf">https://www.hopkinsmedicine.org/hse/forms/PathogenToxinRegistration.pdf</a></li> <li>→ Studies with human tissues, cell lines, and/or body fluids: <a href="https://www.hopkinsmedicine.org/hse/forms/HumanTissueRegistration.pdf">https://www.hopkinsmedicine.org/hse/forms/HumanTissueRegistration.pdf</a></li> </ul> </li> <li>• Note: For item 9 on both registration forms, templates with acceptable processes and language are in development. You can tailor these to your research.</li> <li>• PI will receive registration number (s). Enter number in Section 23, Item 7 of IRB application</li> <li>• Upload IBC Approval Letter to IRB Section 24, Item 2</li> </ul> <p>Contact: <a href="mailto:IBC@jhu.edu">IBC@jhu.edu</a></p>
7	<p><b>Establish consent process. Guidance available at:</b> <a href="https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/Informed_Consent_f_or_COVID19_studies.docx">https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/Informed_Consent_f_or_COVID19_studies.docx</a></p> <p>Contact: Liz Martinez at <a href="mailto:liz@jhmi.edu">liz@jhmi.edu</a>, (410) 614-6323</p>
8	<p><b>Site Selection (note: inpatient studies with outpatient f/u require a site designation for the outpatient visits)</b></p> <ul style="list-style-type: none"> <li>• For Bayview, choose ICTR-Other and fill in “Bayview COVID+ CRU”</li> <li>• For ICTR (no longer infectious), choose the relevant ICTR CRU (JHH adult outpatient, Bayview adult outpatient)</li> <li>• Contact: <a href="mailto:COVID19ResearchCtr@jhmi.edu">COVID19ResearchCtr@jhmi.edu</a></li> </ul>
9	<p><b>Enrollment at Sibley, HCGH, Suburban (Capital Region Research—CAPRES)</b></p> <ul style="list-style-type: none"> <li>• Inpatient research only</li> <li>• Requires partnership with local PI (at site)</li> <li>• Additional checklist regarding CAPRES: <a href="https://ictr.johnshopkins.edu/wp-content/uploads/CAPRES-COVID-Inpatient-Studies-Checklist-02212021.docx">https://ictr.johnshopkins.edu/wp-content/uploads/CAPRES-COVID-Inpatient-Studies-Checklist-02212021.docx</a></li> </ul> <p>Contact: Jackie Lobien at <a href="mailto:jlobien1@jhmi.edu">jlobien1@jhmi.edu</a>, (301) 896-3122</p>
10	<p><b>Recruitment (outpatient)</b></p> <ul style="list-style-type: none"> <li>• The HOPE Registry is an available Recruitment database for Outpatient COVID research.</li> <li>• If you would like to use the HOPE registry, or would like more information, please contact: Cassie Lewis-Land at <a href="mailto:clewis4@jhmi.edu">clewis4@jhmi.edu</a>, (410) 361-6467</li> </ul>
11	<p><b>Pharmacy</b></p> <ul style="list-style-type: none"> <li>• Contact IDS at JHH (5-6337) or Bayview (0-2747) if there is study specific drug, to obtain a budget estimate and begin logistic preparation.</li> <li>• For INDs, prepare an Investigational Drug Data Sheet for each product (upload in Section 21, Item 10, sub-item 13) and each study location (JHH, BMC, etc.).</li> </ul>

	<ul style="list-style-type: none"> <li>FAQ Sheet: <a href="https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/IDS_guidance_COVID19_pandemic.pdf">https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/IDS_guidance_COVID19_pandemic.pdf</a></li> </ul> <p>Contact: Megan Ossing at <a href="mailto:mossing1@jhmi.edu">mossing1@jhmi.edu</a></p>
12	<p><b>Data risk tier calculator</b></p> <ul style="list-style-type: none"> <li>If your study is a Risk Tier C, then data trust review will be required. The study cannot be approved without data trust approval. If your study is a Risk Tier B and you will send PII/PHI outside of Hopkins, then you must contact IT risk at <a href="mailto:ITrisk@jhu.edu">ITrisk@jhu.edu</a> and obtain their approval. Their approval should be uploaded to Section 20, Item 2.</li> </ul>

### C. Implementation—inpatient/outpatient

1	<p><b>Orderset</b></p> <ul style="list-style-type: none"> <li>See SOP for guidance on order set build (this is not just the IDS order): <a href="https://ictr.johnshopkins.edu/wp-content/uploads/OrderSet-SOP-02112021-Final.pdf">https://ictr.johnshopkins.edu/wp-content/uploads/OrderSet-SOP-02112021-Final.pdf</a></li> </ul> <p>Contact: Tad Edwards at <a href="mailto:epicresearch@jhmi.edu">epicresearch@jhmi.edu</a>, (667) 208-7986</p>
2	<p><b>Pharmacy</b></p> <ul style="list-style-type: none"> <li>Notify IDS pharmacist of record for your study initial IRB approvals, as well as any subsequent amendments as soon as possible.</li> </ul> <p>Contact: Megan Ossing at <a href="mailto:mossing1@jhmi.edu">mossing1@jhmi.edu</a></p>
3	<p><b>SOPs (data management, reporting, specimen handling, etc)</b></p> <ul style="list-style-type: none"> <li>Some study resources can be found on the ICTR website <a href="https://ictr.johnshopkins.edu/study_team/training-education/tools-and-resources/">https://ictr.johnshopkins.edu/study_team/training-education/tools-and-resources/</a></li> <li>If you don't have these for your study, contact us for list of SOPs you should have, with templates for your use at <a href="mailto:COVID19ResearchCtr@jhmi.edu">COVID19ResearchCtr@jhmi.edu</a></li> </ul>
4	<p><b>ICTR (for outpatient enrollment or follow-up visits)</b></p> <ul style="list-style-type: none"> <li>Bayview COVID-19 Outpatient CRU <a href="https://ictr.johnshopkins.edu/covid-research-center/bayview-covid-19-outpatient-cru/">https://ictr.johnshopkins.edu/covid-research-center/bayview-covid-19-outpatient-cru/</a></li> </ul> <p>Contact: <a href="mailto:COVID19ResearchCtr@jhmi.edu">COVID19ResearchCtr@jhmi.edu</a></p>
5	<p><b>Request for Ranking (for inpatient studies)</b></p> <ul style="list-style-type: none"> <li>Contact Stephanie Swords to alert her that your study has been IRB-approved, and prepare slide deck describing your study—you will present to CRCC for ranking once you have above logistics established.</li> <li>Slide Template at: <a href="https://ictr.johnshopkins.edu/covid-research-center/covid-johns-hopkins-clinical-research-coordinating-committee/">https://ictr.johnshopkins.edu/covid-research-center/covid-johns-hopkins-clinical-research-coordinating-committee/</a></li> </ul> <p>Contact: Stephanie Swords at <a href="mailto:COVID19ResearchCtr@jhmi.edu">COVID19ResearchCtr@jhmi.edu</a></p>
6	<p><b>Enrollment logistics</b></p> <ul style="list-style-type: none"> <li>Alert attending and nurse of your interest in approaching potential participants (Epic Secure Chat)</li> <li>Register participants in Clinical Research Management System (CRMS)- associates patient with your study in Epic <a href="https://cscop.jhmi.edu/confluence/pages/viewpage.action?pageId=39584072">https://cscop.jhmi.edu/confluence/pages/viewpage.action?pageId=39584072</a></li> <li>Document research encounters with research notes in EPIC (create dot phrases)</li> </ul>

More detailed information can be found at <https://ictr.johnshopkins.edu/covid-research-center/>