



COVID RESEARCH CHECKLIST FOR INPATIENT AND OUTPATIENT STUDIES

You may direct any questions to: COVID19ResearchCtr@jhmi.edu

A. Pre-IRB

1	<p>Prepare COVID Research Coordinating Committee (CRCC) application https://ictr.johnshopkins.edu/wp-content/uploads/JH-COVID-Research-Plan-Form-10132020-1.pdf Submit via Qualtrics: https://jhmi.co1.qualtrics.com/jfe/form/SV_6PULJbcadTae2Gx</p>
2	<p>CADRE Committee review (if your research will involve clinical data in CADRE database) https://ictr.johnshopkins.edu/wp-content/uploads/CADRE-Data-Request_v6.docx Send to: cadre_request@lists.johnshopkins.edu.</p>
3	<p>Biospecimen Committee review (if your research will involve existing serum or plasma specimens from patients with COVID sourced from CCPSEI protocol) https://ictr.johnshopkins.edu/wp-content/uploads/COVID19-Biospecimen-Request-Form-10122020.docx send request to cbenne31@jhmi.edu</p>
4	<p>Office of Research Administration – see table at link below with function and location of different ORA entities, including contracting. Identify your division/departmental contracting lead. https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/ Contact: ORA@jhmi.edu or (410) 955-3061</p>

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

1	<p>CRCC Letter (required for IRB review → load to IRB Section 20, Item 2) CADRE Approval and Biospecimen Approvals, as appropriate, also required for IRB Review and uploaded to Section 20 item 2.</p>
2	<p>Protocol</p> <ul style="list-style-type: none"> For secondary data use only using JH-CROWN as source registry: eFormS https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/eFormS_COVID-19_Secondary_Data.docx For secondary research with COVID19 related biospecimens +/- associated JH-CROWN data: eForm S https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/eFormS_COVID-19_Projects_involving_Data_and_Biospecimens.docx
3	<p>HEIC Checklist (aka Supplemental Form for COVID-19 research) https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/HEIC_checklist.docx Upload to Section 20, Item 2.</p> <p>Contact: Aaron Milstone at amilsto1@jhmi.edu, (443) 287 8932</p>

4	<p>Protocol Synopsis</p> <p>Protocol Synopsis Template for COVID-19 Related Interventional Research - A Draft Synopsis must be submitted with each COVID-19 application that involves a therapeutic intervention. Uploaded to Section 20, Item 2.</p>
5	<p>Department of Nursing review</p> <p>https://www.hopkinsmedicine.org/institutional_review_board/forms/jhhs_nursing.pdf</p> <p>Rachel Hampton will help you with this-- rhampto5@jhu.edu</p> <p>Updates to this form are in progress.</p> <p>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 hwatson7@jhmi.edu, (410) 614-8319 (JHHS), Jackie Lobein at jlobein1@jhmi.edu, (301) 896-3122 (HCGH, Sibley, Suburban)</p>
6	<p>Institutional Biosafety Committee (IBS review) IBC@jhu.edu</p> <ul style="list-style-type: none"> • 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: https://www.hopkinsmedicine.org/hse/training/ • Anyone organizing the packing and shipping for biospecimens will require Department of Transportation (DOT) and/or International Air Transportation Association (IATA) training: https://www.hopkinsmedicine.org/hse/training/ • Register your study with IBC: https://www.hopkinsmedicine.org/hse/biosafety/ht_p_t_registration.html <ul style="list-style-type: none"> → Studies with infectious agents, pathogens, or biological toxins: https://www.hopkinsmedicine.org/hse/forms/PathogenToxinRegistration.pdf → Studies with human tissues, cell lines, and/or body fluids https://www.hopkinsmedicine.org/hse/forms/HumanTissueRegistration.pdf • Note: For item 9 on both registration forms, templates with acceptable processes and language are in development. You can tailor these to your research. • PI will receive registration number (s). Enter number in Section 23, Item 7 of IRB application • Upload IBC Approval Letter to IRB Section 24, Item 2 <p>Contact: IBC@jhu.edu</p>
7	<p>Establish consent process. Guidance available at:</p> <p>https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/Informed_Consent_f_or_COVID19_studies.docx</p> <p>Contact: Liz Martinez at liz@jhmi.edu, (410) 614-6323</p>
8	<p>Site Selection (note: inpatient studies with outpatient f/u require a site designation for the outpatient visits)</p> <ul style="list-style-type: none"> • Greenspring station, choose ICTR-Other and fill in "Greenspring COVID CRU" • For Bayview, choose ICTR-Other and fill in "Bayview COVID+ CRU" • For ICTR (no longer infectious), choose the relevant ICTR CRU (JHH adult outpatient, Bayview adult outpatient) • Contact is Kim Kafka: COVID19ResearchCtr@jhmi.edu
9	<p>Enrollment at Sibley, HCGH, Suburban (Capital Region Research—CAPRES)</p> <ul style="list-style-type: none"> • Inpatient research only • Requires partnership with local PI (at site) • Additional checklist regarding CAPRES: https://ictr.johnshopkins.edu/wp-content/uploads/CAPRES-COVID-Inpatient-Studies-Checklist-02212021.docx <p>Contact: Jackie Lobien at jlobien1@jhmi.edu, (301) 896-3122</p>

10	<p>Recruitment (outpatient)</p> <ul style="list-style-type: none"> If you plan to recruit from HOPE registry say so. In doing so, in Section 13 Item 1, select the box next to “Prior Hopkins/Affiliates study participants”, describe their recruitment in Section 13 Item 2, and address Section 13 Item 4. As a note, if the HOPE registry will also be used as a data source, in Section 13, Item 8 select the box next to “JHM IRB approved studies or research databases” and answer Section 13, Item 9. All material used for recruitment must be uploaded it IRB Section 13, Item 7. The use of each material must be described in Section 13, Item 7. <p>Contact: Cassie Lewis-Land at clewis4@jhmi.edu, (410) 361-6467</p>
11	<p>Pharmacy</p> <ul style="list-style-type: none"> 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. 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.). FAQ Sheet: https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information/IDS_guidance_COVID19_pandemic.pdf <p>Contact: Megan Ossing at mossing1@jhmi.edu</p>
12	<p>Data risk tier calculator</p> <ul style="list-style-type: none"> 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 ITrisk@jhu.edu and obtain their approval. Their approval should be uploaded to Section 20, Item 2.

C. Implementation—inpatient/outpatient

1	<p>Orderset</p> <ul style="list-style-type: none"> See SOP for guidance on order set build (this is not just the IDS order): https://ictr.johnshopkins.edu/wp-content/uploads/OrderSet-SOP-02112021-Final.pdf <p>Contact: Tad Edwards at epicresearch@jhmi.edu, (667) 208-7986</p>
2	<p>Pharmacy</p> <ul style="list-style-type: none"> Notify IDS pharmacist of record for your study initial IRB approvals, as well as any subsequent amendments as soon as possible. <p>Contact: Megan Ossing at mossing1@jhmi.edu</p>
3	<p>SOPs (data management, reporting, specimen handling, etc)</p> <ul style="list-style-type: none"> Some study resources can be found on the ICTR website https://ictr.johnshopkins.edu/study_team/training-education/tools-and-resources/ If you don’t have these for your study, contact us for list of SOPs you should have, with templates for your use at COVID19ResearchCtr@jhmi.edu
4	<p>ICTR (for outpatient enrollment or follow-up visits)</p> <ul style="list-style-type: none"> Greenspring Station COVID-19 Outpatient CRU https://ictr.johnshopkins.edu/covid-research-center/greenspring-covid-19-outpatient-cru Bayview COVID-19 Outpatient CRU https://ictr.johnshopkins.edu/covid-research-center/bayview-covid-19-outpatient-cru/ <p>Contact: Kim Kafka at COVID19ResearchCtr@jhmi.edu</p>

5	<p>Request for Ranking (for inpatient studies)</p> <ul style="list-style-type: none"> • 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. • Slide Template at: https://ictr.johnshopkins.edu/covid-research-center/covid-johns-hopkins-clinical-research-coordinating-committee/ <p>Contact: Stephanie Swords at COVID19ResearchCtr@jhmi.edu</p>
6	<p>Enrollment logistics</p> <ul style="list-style-type: none"> • Alert attending and nurse of your interest in approaching potential participants (Epic Secure Chat) • Register participants in Clinical Research Management System (CRMS)- associates patient with your study in Epic https://cscop.jhmi.edu/confluence/pages/viewpage.action?pageId=39584072 • Document research encounters with research notes in EPIC (create dot phrases)
7	<p>Transportation</p> <ul style="list-style-type: none"> • ICTR coordinating institutional contract with service to oversee transportation. Check back with ICTR. • Alternative: Establish own contract with transportation company if you plan to transport patients to and from outpatient visits

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