**SAFE HUMAN SUBJECTS RESEARCH (HSR):**

 **PROTOCOL PLAN FOR IN-PERSON RESEARCH ACTIVITY**

Beginning March 2020, JHU paused most in-person human subjects research due to increased risks associated with the COVID-19 pandemic. COVID-related studies and limited therapeutic studies continued, as did study activities that moved to remote data collection.

Consistent with JHU Return to Research Guidelines, JHSPH researchers may seek approval to resume in-person data collection (See pp. 15-17 of the JHU Return to Research Guidelines at

<https://covidinfo.jhu.edu/assets/uploads/sites/10/2020/06/Research_Restart_Guidelines_Phase_1.pdf>.

The PI of each IRB approved study must submit for approval plans to protect study team members, research participants, community members, and fellow occupants of shared spaces. We must recognize that research participants are volunteers, and that there is often little or no direct benefit to their participation in the research; safety of research participants must be paramount in research resumption. Research teams must redesign their study workflow, including defining occupancy limits in research spaces, imposing physical distancing measures, providing PPE, establishing protocols for cleaning research spaces, and training study teams on all these procedures. JHSPH research activities extend around the world, with dramatic variation in the intensity of the COVID-19 pandemic and mitigation procedures implemented. Investigators must strongly consider their local context when planning to resume in-person research interaction.

All Principal Investigators of JHSPH IRB approved protocols (previously approved with paused activities and new applications) who wish to conduct in-person human subjects research activities must complete this form and upload into their study’s PHIRST2.0 application as an “Other Administrative Submission”. The PI and research team must develop a detailed plan to implement in-person HSR safely by describing protections from COVID-19 for study staff and study participants based on the risk of COVID 19 exposure associated with those in-person interactions, including the following considerations:

* How will staff/participants be screened prior to engaging in in-person research activities?
* Do the research staff have adequate PPE to minimize risk from the interaction?
* Are face coverings provided to study participants?
* Are the study participants members of a population particularly at risk of COVID-19?
* What is the proximity of study staff to study participants?
* What is the duration of the interaction between study staff and study participants?
* What is the setting of the in-person interaction (In a JHU managed facility? Outdoors? In a well-ventilated indoor facility? In a home setting?)
* What is the cleaning protocol associated with the site of the interaction?

Examples:

* Lower risk studies (protected participant interaction):
	+ Interactions outdoors with face coverings and 6 feet physical distancing
	+ Brief interactions in contained settings where both staff and participants are wearing face coverings and are physically distanced at least 6 feet apart
	+ Brief interactions where the 6 feet distance cannot be maintained but where staff wears appropriate PPE (face mask and face shield, at a minimum) and participants are masked, such as to collect biospecimens or perform brief clinical assessments like measuring blood pressure
* Medium risk studies (significant participant interaction):
	+ Potential aerosol generating procedures (e.g., spirometry, nasal swabs) among asymptomatic persons not suspected of having COVID-19
	+ Interview studies requiring close contact in contained settings for extended periods of time (>15 mins)
* Higher risk studies
* Significant participant interactions with multiple participants in contained areas (e.g., in-person focus group discussions)
	+ Potential aerosol generating procedures (e.g., spirometry, nasal swabs) among persons with COVID-19 related symptoms

This form includes questions covering the following content areas:

1. **Administrative**
2. **Research team**
* **COVID-19 Symptom Screening**
* **Contingency Plans for COVID-19 Exposure**
1. **Study participants**
* **COVID-19 Symptom Screening**
* **Contingency Plans for COVID-19 Exposure**
* **COVID-19 highly vulnerable participants**
1. **Study site**
* **Planned in-person interactions**
* **PPE requirements**
* **Workflow including physical distancing, scheduling, precautions**
* **Cleaning / Disinfection protocols**
* **Staff training**

Within each section, resources are provided to help guide investigators and research teams about appropriate protocols and procedures. Please use these resources to develop and describe your plans for each component.

**NOTE: If your plan is approved and later changes, YOU MUST SUBMIT A REVISED PLAN FOR REVIEW AS AN “OTHER ADMINISTRATIVE SUBMISSION” IN PHIRST2.0. You may submit a tracked version of this form with your changes and a clean version.**

1. **Administrative**

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| **PI Name:** |
| **IRB No.:** |
| **Study Title:** |
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| 1. **Is COVID-19 the primary focus of your in-person research study activities?**

[ ]  No[ ]  Yes |
| **Does your study require support services from JHM clinical departments, including the ICTR Clinical Research Units, Investigational Drug Service (IDS), Radiology, etc.?** [ ]  No[ ]  Yes**Does your study perform any in-person research activities in a JHM clinical setting involving either outpatient or inpatient Hopkins medicine patients?** [ ]  No[ ]  Yes |
| 1. **Identify the location(s) of site(s) where your study’s in-person research activities will occur (select all that apply).**

[ ]  U.S. only (Hopkins managed facilities)[ ]  U.S. only (non-Hopkins facilities)[ ]  International  |
| 1. ***For U.S. studies outside of Maryland and International studies:*** We need to understand the local context of your research site with respect to resuming in person research activities. Please describe the following:
* What research activities are permitted by local authorities at your site?
* What COVID-19 protections are required to permit in person activities to go forward?
* What guidance/requirements have been issued by local authorities (Health Departments, Ministries of Health, Government authorities, local IRBs, etc.)?
* What COVID testing capacity is available?
* Upload all documents associated with your responses with this form.

Response:      |

**B. Research Team**

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| **1.** | **COVID-19 Symptom Screening:** All research team members working in the research setting (U.S. and overseas) must affirm the absence of symptoms before interacting with study participants or others. Unprotected exposure to COVID-19 positive persons outside of a clinical or research setting must also be identified.***General Requirements and Resources for Study Staff:**** + *Before coming to work, staff must check themselves for COVID-19 symptoms: fever, cough, shortness of breath, or difficulty breathing (see full list of symptoms at:*[*https://www.hopkinsmedicine.org/coronavirus/covid-19-self-checker.html*](https://www.hopkinsmedicine.org/coronavirus/covid-19-self-checker.html)*)*
* *If staff experience unprotected exposure from someone with known or suspected COVID-19, staff must avoid spreading COVID-19 to others by self-isolating in accordance with the protocol procedures outlined in the guidance on the IRB COVID-19 webpage:*[**COVID 19 Isolation Procedure for Staff**](https://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/HSR%20Isolation%20Algorithm_2Mar2021.pdf)**,**

<https://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/HSR%20Isolation%20Algorithm_2Mar2021.pdf>**.*** + *Screening protocol:*  <https://covidsurvey.jh.edu/forced>
	+ *Transportation: Transport of study staff (and participants) for study purposes may pose additional risk for COVID exposure. Please address how you will minimize this risk.*

***JHU Employee-Specific Requirements in JHU Managed Facilities and Resources:**** + *University wide application/process for symptom checking using the Prodensity mobile app; keep up with changing requirements over time.*
	+ *If a team member has any symptoms they are required to stay at home and notify their supervisor/PI.*
	+ *University-provided COVID hotline should be utilized for further instructions.**Students should call the University Health Services at 410-955-3250 or Student Health & Wellness at 410-516-8270.  Employees may call the Employee COVID-19 Call Center at 833-546-7546 if they are experiencing symptoms or have had contact with someone who has been diagnosed as COVID-19 positive in the past 14 days.  The call center will evaluate the need for referral to care or for self-isolation.*
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| 1. **Describe the research staff who will interact with study participants and clarify your level of control or responsibility over that staff. Are they JHU-employed? If not, who has authority to determine the level of staff protections for this study? Please also address safe transport of study staff if applicable.**

Response:      |
| 1. **Describe your plan to implement staff screening, referral for care, and instructions for self-isolation*.***

Response:      |
| **2.** | **Contingency Plans for COVID-19 Exposure:** Provide a plan for managing a staff member who tests positive for SARS CoV-2 or who has unprotected exposure to a person with COVID-19. For JHU employees, plans need to be in place for contact identification and tracing that is consistent with human resources guidelines. Describe the following:* How will you respond to a positive test or unprotected exposure with respect to scheduling research study visits?
* What precautions will you take with respect to potentially contaminated research sites? Will you evacuate sites that are potentially contaminated? What are your return-to-work approaches?

***Resources:**** 1. [**https://intranet.insidehopkinsmedicine.org/heic/novel\_coronavirus/clinical\_resources.html**](https://intranet.insidehopkinsmedicine.org/heic/novel_coronavirus/clinical_resources.html)
	2. [**https://intranet.insidehopkinsmedicine.org/heic/\_docs/2019-nCoV\_patient\_discharge\_transfer.pdf**](https://intranet.insidehopkinsmedicine.org/heic/_docs/2019-nCoV_patient_discharge_transfer.pdf)
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| **Describe your contingency plan to address research team members who are COVID-19 positive or experience unprotected exposure to COVID-19:**Response:      |

**C. Study Participants**

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| **1.** | **Participant screening and triage methods**: Screen all study participants for elevated temperature and COVID-19 symptoms prior to entry into the research site.***Requirements and Resources:**** + *Screening protocol:*  <https://covidsurvey.jh.edu/forced>
	+ If you have no space in your site for screening, perform screening via phone the day before or day of the research study visit.
	+ If in-person temperature measurement and symptom screening is proposed, conduct triage outside or upon initial entry into the research space.
	+ If a participant screens as possibly COVID-exposed or has symptoms, provide information to that person about what to do next.
	+ Clarify referral procedures for study participants with fever or symptoms.
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| **Describe how and where you will screen, advise, and refer study participants who have COVID-19 symptoms:****If the study provides transport to participants to a study site, please address how to minimize transport risks.**Response:      |
| **2.** | **Contingency Plans for COVID-19 Exposure:** Provide a plan for handling a study participant who tests positive for SARS CoV-2 or has experienced unprotected exposure to COVID-19. Plans will need to be in place for contact identification and tracing that is consistent with human resources guidelines. Describe how research staff who interacted with study participants will be managed, including potential for testing, relief from duties, self-isolation, and return to work plans, if there was a breach in PPE during the contact.***Resources:**** + [*https://intranet.insidehopkinsmedicine.org/heic/novel\_coronavirus/clinical\_resources.html*](https://intranet.insidehopkinsmedicine.org/heic/novel_coronavirus/clinical_resources.html)
	+ [*https://intranet.insidehopkinsmedicine.org/heic/\_docs/2019-nCoV\_patient\_discharge\_transfer.pdf*](https://intranet.insidehopkinsmedicine.org/heic/_docs/2019-nCoV_patient_discharge_transfer.pdf)
 |
| **Describe your plan to address COVID-19 positive or exposed research study participants:**      |
| **3.** | **COVID-19 highly vulnerable participants**: It is recognized that some research studies require working with study populations or with specific study participants that may be at higher risk for adverse outcomes related to COVID-19. Consider whether the research aims/questions could be sufficiently addressed without in-person participation of those at greatest risk of COVID-19 disease. ***Resources:****See CDC guidelines for more information:* [*https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-athigher-risk.html*](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-athigher-risk.html)*Those that might be at higher risk for severe illness from COVID-19 include:* *o People of any age who have serious underlying medical conditions such as asthma, chronic lung disease, diabetes, high blood pressure, serious heart conditions, chronic kidney disease being treated with dialysis, metabolic syndrome, and liver disease;* *o Severe obesity;* *o People aged 65 years and older;* *o People in nursing homes or long-term care facilities;* *o Those that are immunocompromised.* *o Also consider those that may need to take extra precautions such as: people with disabilities, those that are homeless, or those that are pregnant.* |
| **If applicable, please justify the need for participation of highly vulnerable participants in in-person research activities. Clarify how vulnerable individuals will be identified and if special precautions will be taken to ensure their safety.**Response:      |

**D. Study Site Work Plan**

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| For each study site where you will perform in-person interactions with participants, you will need to provide the detailed information requested in this Section. If you have multiple sites that will all be using essentially the same procedures, you can simply list those sites under question number one and provide the documentation only once. If study procedures are different between sites, then please copy this Study Site Work Plan, Section D and complete for each site with procedures. |
| 1. List the address as appropriate. For community or home-based studies conducted outside

of the specific address, provide a description of the region(s) or communities involved. Add additional lines as needed. |
| Building name and floor / room numbers:       |
| Address:       |
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| Building name and floor / room numbers:                 |
| Address:       |
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| 2. | Briefly describe the physical environment of the building(s) or site and how those features affect your workflow plan. Response:      |
| 3. | For the site identified above:* Please justify the need for in person research activities at this site.
* What in-person interactions are proposed for this site?
* If biological specimens will be collected, describe how they will be collected, by whom, how they will be transported, where to, and by whom. What PPE will be used at each stage? Be clear about whether or not the specimens will be infectious or if there are aerosolizing risks.
* What is the risk of COVID-19 transmission based on these activities at this site?

Response:      |
| 4. | Document how safe distancing will be implemented for study team members and study participants at the site which limits potential contact and COVID-19 exposure. Consider ingress and egress to the study site, waiting areas, work/assessment stations, etc. As in-person research resumes, it is important to slowly ramp up study visits to ensure adequate physical distancing at the research site, including flow through common areas like lobbies, elevators, and waiting areas. ***Requirements and Resources:**** + *For Participants: Perform screening via phone the day before or day of the research study visit. If there is in-person temperature measurement and symptom screening, conduct triage outside or upon initial entry into the research space.*
	+ *For Research Staff: Before coming to work, employees should check themselves for COVID-19 symptoms: fever, cough, shortness of breath, or difficulty breathing (see full list of symptoms at:*[*https://www.hopkinsmedicine.org/coronavirus/covid-19-self-checker.html*](https://www.hopkinsmedicine.org/coronavirus/covid-19-self-checker.html)*)*
	+ *Use outdoor space for participant interaction when possible*
	+ *Infection Prevention Guidance for Non-Clinical Areas (detailed information relevant to many domains)*[*https://intranet.insidehopkinsmedicine.org/heic/\_docs/2019-nCoV\_non-clinical\_area\_guidance.pdf*](https://intranet.insidehopkinsmedicine.org/heic/_docs/2019-nCoV_non-clinical_area_guidance.pdf)
* **Physical distancing:** Provide plans for physical separation. This may include different working zones for investigators, different paths for participants, separation between the investigator’s and participant’s space, use of physical barriers, etc.

**NOTE - UPLOAD WITH THIS FORM**: Floor plan(s) with labels of different working zones, paths, and spaces are required for Hopkins managed facilities, and are highly desired for other sites.* **Temporal separation:**  Provide plans for temporal separation including participant scheduling and staggered work schedules for staff. All studies should initiate participant visits at 20 to 25% of maximal capacity for their initial week and gradually increase as appropriate.

**NOTE – UPLOAD WITH THIS FORM**: Timetables with labels of different working blocks with maximal number of study participants per day/week required for Hopkins managed facilities and are highly desired for other sites. * **PPE materials and supplies:** Specify the specific types of personal protective equipment (PPE) that will be required for both research staff as well as study participants. Address whether or not resources may be re-used, and if so, for how long or for how many participant interactions. Provide an estimate of the number and type of PPE required for the next six months. Describe the local availability and plan procurement of necessary PPE.
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| **Provide a workflow plan for Site 1 that will address the following three topics. If you do not have control over this site, please clarify what protections will be in place:*** Physical distancing
* Temporal separation
* PPE materials and supplies

Response:      |
| 5. | **Cleaning / Disinfection protocols:** Provide appropriate cleaning protocols for office and research spaces. Document in your office records who will perform the cleaning, what products will be used and the specific cleaning protocol to be implemented. This includes periodic/daily cleanings of common areas, interval cleaning of high-touch surfaces, and cleaning procedures to be performed between study participant visits. ***Requirements and Resources:**** <https://hub.jhu.edu/assets/uploads/sites/2/2020/05/Research_Restart_Guidelines_Phase_1.pdf> See Appendix D
* https://intranet.insidehopkinsmedicine.org/heic/\_docs/2019-nCoV\_asymptomatic\_screening\_precautions\_outpatient.pdf
 |
| 1. **Provide the routine cleaning protocol for this site.**

Response:      |
| 1. **Provide the plan for cleaning before and after each interaction with a study participant at the research site. Provide details about wiping down chairs, data collection tablets or pens, blood pressure machines, etc.**

Response:      |
| 6. | **Staff training:** Clarify your plan for implementation and documentation of staff training in safety and cleaning protocols, PPE use, etc. While some resources are provided below, you may need to develop your own training materials. ***Resources:**** Link to CITI training modules (appropriate for your study team) <https://about.citiprogram.org/en/series/covid-19-back-to-campus/>)
* Resources for staff well-being

<https://covid19.insidehopkinsmedicine.org/#faculty-support>* + *Infection Prevention Guidance for Non-Clinical Areas (detailed information relevant to many domains)* [*https://intranet.insidehopkinsmedicine.org/heic/\_docs/2019-nCoV\_non-clinical\_area\_guidance.pdf*](https://intranet.insidehopkinsmedicine.org/heic/_docs/2019-nCoV_non-clinical_area_guidance.pdf)
	+ *Keep up with changes in clinical guidance, safety precautions, and other information.*
 |
| **Please describe your staff training plan.**Response:      |

**E. Safe HSR Attestation**

***As PI, I certify to the following statements:***

[ ]  I have discussed the Safe HSR plan with all members of the research team.

[ ]  I understand that this plan will be reviewed by a School-level research restart committee and I will adhere to the specifics included in the plan.

[ ]  I have communicated with all research team members that they may speak with me directly or contact appropriate University resources regarding any concerns related to their work environment.

[ ]  The research team will follow prevailing guidelines regarding infection control, including not having staff come to work who have symptoms of illness, and following current JHU guidelines if members of the team test positive for COVID-19.

[ ]  I have discussed with my research team the importance of personal safety practices of daily symptom reporting, universal face coverings, physical distancing, and handwashing and ensured training in these areas.

[ ]  Research team members will wear face coverings at all times, with the exception of preapproved locations where not feasible (e.g. eating lunch in designated break room; dedicated office for sole individual use).

[ ]  Research staff will ensure that study participants undergo screening for symptoms and fever prior to entry into research space.

[ ]  Research staff will provide study participants a cloth face covering if they do not have one upon entering research space.

[ ]  The research team has developed a study work plan based on size and layout of research space for physical distancing to enable a 6-foot distance between all persons in the research environment, including both research staff and study participants.

[ ]  The research team will minimize the duration of time of in-person interaction with study participants and will continue remote research activities to the extent possible.

[ ]  I am providing appropriate personal protective equipment (PPE) for research team members and ensuring appropriate training per guidelines. Appropriate levels of PPE will be utilized when physical distancing is not possible due to performing research assessments.

[ ]  The research space has regular cleaning practices in place. The research team has developed protocols for use and cleaning of the research space, surfaces and equipment in between study participants.