FAS-SEAS Human Subjects Research Resumption Form

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| Confirm plans fall under Phase HSR1.2 Criteria listed on website<https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1> |   |

Faculty/PI Information

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| **Name (Last, First)** |  |
| **Laboratory name** |  |
| **HUID** |  |
| **Department(s)** |  |
| **Email Address** |  |
| **Cell Phone No.** |  |

Human Subjects Research Studies List (list studies you are seeking approval to resume)

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|  | **IRB/ESTR #** | **TITLE**  |
| **Research Study 1** |  |  |
| **Research Study 2** |  |  |
| **Research Study 3** |  |  |

Peer Review (list other individuals who have peer reviewed approval request (incl. SOPs)

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| **Name** | **Affiliation** | **Email address** |
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Summary of SOP Attachments

* Experimental Method SOPs
	+ Summarize the details outlined in your attached SOPs for detailed experimental procedures or equipment used (including any cleaning and disinfecting).
* Location SOP
	+ Summarize the details outlined in your attached SOPs. Provide a copy of the facility-specific plan, if applicable. If the location is off campus (e.g. clinical site, or community), include details along with request.
	+ Describe how many people will be in the space where the study is performed and highlight how it meets [FAS-SEAS Phase2b guidelines](https://hu.sharepoint.com/%3Ab%3A/r/sites/FASLabRe-OccupancyPlanning/Shared%20Documents/FAS-SEAS%20Phase%202b%20V10%20FINAL.pdf?csf=1&web=1&e=Y8KWiP). Include information about the rooms used, their dimensions and configuration, airflow data, and plans for boosting airflow (HEPA, fan) if applicable.

Research Study 1 (copy and paste for additional studies)

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| **Who is the study population? What is the age range, and are there any enrollment considerations that will ensure individuals** [**that are known to be or may be at increased risk of severe illness due to COVID-19**](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html) **will be excluded.** **If the study involves a population on this list, describe any specific precautions will be taken to mitigate transmission risk? [Note in Phase HSR1.2 this would have to happen in a clinical setting or in the community).**  |  |
| **If participants are not affiliated with Harvard (i.e. do not complete Crimson Clear daily) describe what COVID screening procedures will be in place to screen participants 24 hours prior to the study visit.**  | *Suggest to review “Template Screening Procedures for Human Subjects” document linked to on CUHS site (link at top of document) that is based on Crimson Clear.*  |
| **What is the location where the research will be performed? Please reference Location SOP.** |  |
| **If the location of the research is not on Harvard campus, confirm that all study team members will still have to have approved Crimson Clear pass on day of research.**  |  |
| **Will any guardians, parents or other persons attend? What specific precautions will be taken to ensure that individuals accompanying participants are not at high risk for COVID-19 or what specific precautions will be taken to mitigate risk? In addition, please reference Specific Experimental Method SOP in place to maintain distancing in the presence of the additional accompanying individuals.** |  |
| **Will screening and consent take place remotely? If not, why?** |  |
| **Will close interactions (<6 feet physical distance) for greater than 15 minutes be required? If so, use the table below to summarize each instance of close contact, and reference Specific Experimental Method SOP on what additional safety precautions are in place.** |  |
| **Are any bio samples collected? If so, please reference Specific Experimental Method SOP on what safety precautions are in place.**  |  |
| **Will participants wear masks for the duration of the study visit? If not, please justify why masks cannot be worn continuously and reference the SOP for what safety measures can be put in place.** |  |
| **What equipment will be used as part of the visit? Reference Specific Experimental Method or Location SOPs highlighting cleaning protocols.**  |  |
| **What shared surfaces will be touched by participants or researchers as part of the visit? Reference Specific Experimental Method or Location SOP highlighting cleaning protocols.**  |  |
| **Does this research involve collaborations with any other institutions? If so, confirm the location where the research will take place and that it is approved by the overseeing IRB.** |  |
| **Will your study make use of any shared facilities? If so, please reference in Location SOP how scheduling will be handled.**  |  |
| **List study team members that will be involved in the resumption of human subjects research under this protocol.**  |  |
| **Describe the precautions that are in place to reduce exposure while participants/researchers are traveling to campus/study site.** |  |
| **List the person (or people) responsible for coordinating the study and confirm that this plan has been shared with them.**  |  |

Risk mitigation for close contact

If there will be close contact for >15 mins, please describe the nature of the close contact interactions, estimated duration for each type for each study and the specific risk mitigation procedures put in place.

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| **Research Study 1** |
| **Nature of Close Contact (with estimated distance)** | **Duration (minutes)** | **Risk mitigation (e.g. augmented ventilation, additional PPE)** |
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| **Etc** |  |  |

Number of Participants Estimated per Month (to estimate # surgical masks required)

For each study, make sure that the number of participants that interact with any given research team member does not exceed 10 people over a one week period.

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| **Research Study 1** |  |
| **Research Study 2** |  |
| **Research Study 3** |  |

Lab Safety Officer

Each lab must have a designated lab safety officer that will attend regular lab safety meeting and act as a liaison between the local safety committee and the laboratory.

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| **Name (Last, First)** |  |
| **Email** |  |

Study Team Isolation Contingency Plan

In the event a study team member or participant tests positive for COVID-19, PIs should outline their plans for personal isolation and safe shutdown plan.

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| **Form Completed By:** |  |
| **PI Signature (if form was completed by a delegate)** |  |

***For Admin Use***

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| **Dept/Area Chair(s) Approval:** |  |
| **School/Division Approval for Phase HSR1.2** |  |