**FAS-SEAS Phases for Resumption of Human Subjects Research**

The phased resumption of human subjects research were prepared by the Harvard University Resumption of Human Subjects Research Committee (HURHSRC) consisting of Randy Buckner (FAS), Dan Lieberman (FAS), Shannon Sewards (HU Area IRB Director) Maurice Smith (SEAS), Leah Somerville (FAS), Conor Walsh (SEAS) and in consultation with the Office of the Vice Provost for Research. PIs are strongly recommended to view the [Instructions for Returning to In-Person Human Subjects Research CUHS website](https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1) and [University Guidance for Human Subjects Research](https://provost.harvard.edu/files/provost/files/appendix_5_guidance_for_human_subject_research.pdf). A PI may submit an exemption request to the specific criteria outlined if they can show how they have minimized risk with a detailed plan. If any aspect of the study is being changed for which there is not already approval (including subject recruitment, experimental procedures, consent mechanisms or study personnel), PIs will need to seek IRB approval before proceeding with the research.

1. *Considerations for Phase HSR1.1*

Criteria for the first phase is outlined below. Additional guidance for resumption of other activities will be outlined as lessons are learned from Phase HSR1.1 and other institutions resuming human subjects research.

**Phase HSR1.1 – *June 8 – July 27, 2020***

* Only Harvard affiliated study participants for on-campus research
	+ - Only participants without known COVID-19 medical risk factors as per CDC guidelines
		- Continuous interactions <6ft for up to 15 mins only
		- Face shields, in addition to face masks, worn by study team members for times of close contact
		- Only participants who can wear face masks may participate in research
		- Outdoor testing where appropriate social distancing can be maintained
		- Maximum number of study team members (2, only 1 <6ft of participant)
		- Public transport strongly discouraged for participants
* Up to 10 participants to interact with a study team member in a week
1. *Considerations for Phase HSR1.2*

Criteria for this phase are to afford other human subjects studies requiring in-person interactions to resume. This includes research that requires continuous interactions > 15 minutes within close contact, research on populations who are not Harvard affiliates, study populations who cannot reliably wear masks (e.g. toddlers) and patient populations (e.g. stroke survivors), research in local clinical settings (e.g. inpatient rehab) and research off campus such as in community settings (e.g. community walking or home studies with detailed risk mitigation procedures). Note that this phase does not include bringing participants with known COVID-19 medical risk factors (as per CDC guidelines) on Harvard campus. In addition, in this next phase researchers who are regularly interacting with participants and in close contact are recommended to undergo frequent COVID-testing. [FAS-SEAS Phase 2b](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) guidelines all apply.

**Phase HSR1.2 – *July 28, 2020 - Present***

* Non-Harvard affiliated study participants for on-campus research
	+ - Only participants without known COVID-19 medical risk factors as per CDC guidelines on Harvard campus
		- Documentation of any close contact >15 minutes (i.e. nature and estimated time) in resumption request highlighting specific risk mitigation.
		- Face shields, in addition to ASTM rated face masks, worn by study team members for times of close contact
		- Maximum number of study team members (3, only 2 <6ft of participant)
* Frequent testing (at least weekly) of researchers engaged in human subjects research where there is close contact
* Research with subjects who cannot wear masks (e.g. toddlers) reviewed on case by case basis
* Up to 10 participants to interact with a study team member per week when close contact <6 feet
* Research in community settings reviewed on case by case basis

**Further guidance for PIs**

Time limit & PPE for close contact (see table in Human Subjects Resumption Request Document)

To enable studies that require longer durations of close contact, it is a combination of room size, local ventilation/filtration, specific PPE, and specific activities that factor into risk mitigation strategies. Human subjects research procedures will be reviewed on a case by case basis and PIs are encouraged to include:

* The precise nature of close contact (e.g. arm’s length placement of electrodes), highlight how close contact time is minimized, and provide estimate of time in close contact.
* Approaches that provide local augmentation of ventilation/filtration (e.g. location of experiment within room relative to room HVAC, local HEPA filter, local fan to direct air flow at boundary of close contact, etc.). EHS will be able to advise on best approaches and evaluate their potential effectiveness (e.g. test with particle generators). PIs are encouraged to consult with their local building manager and EHS when preparing their plans. EHS contact Shawna Marquis [shawna\_marquis@harvard.edu].
* Other measures that will be taken to minimize risk (e.g. limiting time when subject and researcher are face to face, limit talking to only that required for study procedures, use of physical (e.g., plexiglass) barriers).
* For any request for additional PPE considerations (e.g. N95 equivalent protection), PIs are encouraged to consult with EHS when preparing their plans.

Research with low-risk participants (those not defined as vulnerable) who cannot wear masks.

Given the importance of mask wearing in reducing the risk of COVID transmission, any procedures requesting resumption of research where masks cannot be worn must meet a very high bar. For research with non-vulnerable populations who cannot wear masks, PIs should consider how a combination of COVID testing, additional PPE (e.g. N95 equivalent), HVAC control, maintaining 6 ft of distance, barrier protection (e.g. plexiglass), tightly controlled space (e.g. easily accessible spaces that reduce exposure within common areas like elevators).

Research in community settings (see template location SOP)

For research to be held in community or home settings, PIs should pay attention to factors that would reduce risk for researchers and study participants. For example, having transportation that minimizes interactions with other people, procedures that minimize close contact, additional PPE where appropriate and documentation of environment where testing will occur including describing ventilation. Researchers need to ensure that any research study procedures (e.g. location of testing) are approved by the governing IRB.

**Research at other institutions** (see template location SOP)

As other local institutions resume their human subjects research, researchers may resume collaborations at other sites. As recommended in university guidelines on resumption of human subjects research, safety procedures and precautions to be followed are those at the site where the research is being performed. PIs should submit a document that details the nature of the research and where it will occur for local department/school review as part of their request to resume research. For off-campus research, you will need to abide by applicable site specific COVID-19 safety standards on social distancing, hygiene and equipment and space disinfecting, and any Harvard requirements relating to off campus activities including travel restrictions. Researchers need to ensure that any research study procedures are approved (e.g. local institutional approval) by the governing IRB.