Human Subjects Research Resumption
Review Checklist Phase HSR1.2

* Have sufficient steps been taken to inform and discourage enrollment of individuals with known COVID-19 medical risk factors?
* Has the proposal demonstrated that remote procedures will be used when feasible, in order to minimize the participant’s time on campus and the amount of contact between participants and the study team?
* If close contact is required between the study team and participant (< 6 feet), have sufficient efforts been taken to:
	+ Minimize the total amount?
	+ Adopt outdoor testing when feasible?
	+ Instruct participants how to move about the space?
	+ Revise physical spaces (adding plexiglass barriers, etc) to reduce contact?
* If the research procedures may involve the temporary removal of face coverings, has this been justified and has sufficient effort been taken to put risk mitigation strategies in place?
* If there will be close contact, have the researchers fully described the appropriate additional PPE (e.g. face shields) that will be required?
* If biological samples will be collected and handled by the study team, have sufficient protections for the study team (PPE, physical handling) been described?
* Have the researchers adequately considered what physical surfaces/spaces will be used by participants and the study team, and made efforts to minimize them?
* Are the cleaning protocols described thorough and compliant with cleaning guidance?
* Have the researchers adequately considered by incorporating building-level guidance and guidance on the physical spaces that will be occupied? Has sufficient coordination been demonstrated within and across neighboring research teams to ensure that <50% person density is maintained even during experimental sessions?
* Where there are multiple studies, have the researchers considered having temporal separation and distinct groups of people, to minimize cross-transmission between different study groups?
* If any shared spaces or core facilities are used, is there sufficient consideration of the guidance and policy of that core facility?
* Have the researchers considered restroom usage and cleaning?
* Is the study team isolation plan sufficiently considered?
* Have the researchers adequately analyzed the ventilation capacity of the testing location and calculated the maximum occupancy limit (Available filtered or fresh airflow should always exceed 100 cfm per person)? Have the researchers considered this when designing protocols and described usage of HEPA filters if insufficient?

Guidelines for Phase HSR1.2 are listed below. If the proposed research aims to return in Phase HSR1.2, does it abide by the following constraints:

* 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

Review process:

1. Internal departmental review. If any of these factors are not sufficiently considered, departmental review should provide feedback to researchers and encourage them to revise-and-resubmit their plans, which can be re-reviewed at the department level.
2. Oversight committee. Plans that require exceptions outside of guidelines described above can be submitted to the *Harvard University Resumption of Human Subjects Research Committee* (HURHSRC) who will review the documentation and may seek guidance from the Office of the Vice Provost (OVPR). Department heads or departmental committee chairs can initiate this layer of review by emailing materials to:

 SEAS: Conor Walsh <walsh@seas.harvard.edu>

and Leigh Needleman <leigh\_needleman@harvard.edu>

 FAS Science Division: Leah Somerville <somerville@fas.harvard.edu>

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