**Investigator Guidelines for In-Person Human Research during COVID-19 Pandemic**

*Note: HRPP Toolkit Materials and Guidelines are subject to frequent changes and updates as the COVID-19 health situation evolves.*

Conducting research during the COVID-19 public health crisis requires increased precautions to mitigate risk. Not all projects can be appropriately resourced so as to be conducted safely under current conditions. Investigators must exercise considerable judgment when deciding which projects they can fully and appropriately support with all necessary resources given stepped-up requirements.

These Guiding Principles – issued by the UGA Human Research Protection Program (HRPP) – provide a framework for PIs to assess the increased health safety processes required for appropriate risk mitigation. The IRB will assess protocols to ensure they include appropriate health safety processes, as PIs plan to begin or resume in-person human research.

1. COMMUNICATE RISK TO PARTICIPANTS. During recruitment, screening, visit scheduling, and consent, communicate risks of exposure and infection clearly to research participants. The HRPP has developed an Information Sheet that can be used for this purpose.
	1. Communicate risks before participants travel to research sites, including any risks associated with shared transportation modes such as public busses or ride share.
	2. Communicate risks during consent process and ensure comprehension – use [HRPP suggested consent language](https://research.uga.edu/hrpp/hso-2/#1598276075357-39046600-d4c7).
	3. Consider alternate signature collection methods such as digital signature or scanning or photographing signed forms.
	4. At all times, communicate the specific heightened risks of SARS-CoV-2 exposure and COVID-19 infection to high-risk participants based on CDC-identified categories – [People at Increased Risk](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html).
2. MITIGATE RISK TO PARTICIPANTS. When designing proposed processes to conduct research safely, thoroughly consider benefits to participants in relation to participant risk of exposure and infection, and incorporate risk mitigation strategies to the fullest extent possible. Significant mitigation efforts will be required when there is little or no medical or clinical benefit to participating subjects.
	1. Exclude and screen-out members of high-risk populations or provide strong justification for inclusion. Delayed enrollment plans may be considered if there is strong justification for inclusion.
	2. Use information about local conditions (e.g., case rates, prevalence) as criteria for assessing risk of exposure and infection.
	3. Conduct screening, visit scheduling, consenting, and post-session information/debriefing activities remotely.
	4. Change in-person research activities to remote activities, as feasible.
		1. Use email and electronic questionnaires (e.g., Qualtrics) and telephone and video conference technologies to replace in-person interviews and discussion.
		2. For identifiable personal or sensitive information, remote interfacing helps to mitigate health safety risks, but researchers must provide appropriately protective data security – see [EITS Data Classification and Protection Standards](https://eits.uga.edu/access_and_security/infosec/pols_regs/policies/dcps/).
	5. Eliminate as many commonly touched surfaces as possible. Use electronic communication to reduce shared handling of paper, clipboards, writing utensils.
	6. When designing processes to reduce likelihood of exposure and infection, consider: how physical spaces are used (including how researchers and participants travel through research spaces); the adequacy of ventilation (especially for activities where researchers or participants must be unmasked for a study procedure); whether outside spaces are available/feasible for any part of the research activity; and the impact of leaving interior doors open on HVAC efficiency.
	7. Use disposable materials to cover equipment, rather than materials that require laundering.
	8. Maintain a six-foot distance between researchers, and between researchers and participants, at all times except where absolutely unavoidable as necessary to perform the project.
	9. Reduce number of researchers with whom participants come into contact to the fullest extent possible.
	10. Limit the number of researchers and participants occupying the same physical space.
	11. Use PPE that is appropriate for the degree and duration of contact, respiratory activity, and participant risk factors. [CDC Standard Precautions](https://www.cdc.gov/infectioncontrol/guidelines/isolation/appendix/standard-precautions.html).
	12. When procedures require removing/replacing face coverings, incorporate guidance about safe techniques and handwashing/sanitizing, and replacing disposable masks. [How to Wear Masks](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wear-cloth-face-coverings.html).
	13. Clean and sanitize shared-use surfaces using approved cleaners/disinfectants between each participant. [EPA: Disinfectants for Use Against SARS-CoV-2 (COVID-19)](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19)
	14. Incorporate into the research protocol handwashing/disinfecting by researchers and participants.
		1. Consider availability of handwashing/disinfecting stations for researchers and participants.
		2. Train researchers and communicate with participants on the timing and method of hand washing/sanitizing.
	15. Assess risks and benefits to participants in the context of the study aims and procedures and the population, and in consideration of current community transmission rates and public health authority recommendations.

Note:

* If a PI is unable to make protocol modifications that adhere to these guidelines and the requirements in the HRPP Toolkit, then the request to begin or resume human research activities is more likely to be deferred or disapproved. This is particularly true for research that includes participants at high risk for severe COVID-19 related illness.
* If all the required Toolkit materials are not provided with the initial submission, they will be requested before the pre-review begins. This will impact the Submission Date for Full Committee Review, if applicable, and the overall estimated review time.
* Toolkit materials must be prepared for each project. Avoid trying to reuse previously approved versions as the context for each project will be considered separately. Be sure to proofread carefully prior to submission.