Guidance on In-Person Research During the COVID-19 Pandemic

Last updated: September 2, 2022

The Cornell Office of Research Integrity and Assurance (ORIA) has developed guidance relevant to researchers planning for on-campus[1] human participant research operations. This guidance is updated periodically as New York State and Cornell University public health restrictions change.

Note: While this document is focused on in-person human participant research taking place on the Cornell Ithaca campuses (Ithaca, Geneva, and Cornell Tech[2]), many of the requirements and considerations listed below are also relevant to researchers interacting with study participants off-campus in Ithaca or elsewhere in the field. For off-campus research, other restrictions may also apply, depending on local, state, national or international policies.

Requirements for On-Campus Human Participant Research

- **Refer to the Coronavirus Research Continuity Guidance webpage** for the most up-to-date guidelines for Cornell researchers.
- **The guidelines for study participants are generally the same as for other visitors to campus**. The Cornell Tech campus has its own visitor policy, which you can review on this webpage.
- **Face mask requirements:** Masking and other public health requirements on campus change periodically and are communicated on the Cornell COVID-19 Response website. Campus face mask requirements, specifically, are described on their own webpage here.

  Human participant research activities similar to clinical exams or procedures should follow masking requirements used in Cornell healthcare facilities. As of August 2022, face masks are required in campus healthcare settings. Examples of such research activities include venipuncture, MRI, ECG/EKG, and use of any other devices that research staff have to place on a participant's body. **For all other indoor human participant research activities, the IRB strongly encourages use of face masks for participants and research staff, particularly in higher density situations or when participants are at higher risk of severe illness from COVID-19** (as indicated by the CDC).
- **Any proposed human participant research on campus that will not meet current masking requirements will need to be reviewed by Cornell Environment, Health and Safety.** IRB staff can help facilitate that contact as part of your IRB protocol review. Please call or email the IRB office if you have any questions about how the mask requirements may impact your research.
- **If your research requires study participants to be within six feet** of a researcher or other participant, **then the IRB recommends participants self-screen for COVID-19 symptoms or exposure** prior to arrival on campus **Researchers should not collect or record the answers to participants' screening questions.** Instead, participants can sign and submit an attestation, confirming they have self-screened. (See Appendix B of this document for a sample attestation.)

[1] This guidance applies to researchers on the Ithaca, Geneva, and Cornell Tech campuses.
[2] For researchers based at the Cornell Tech campus, please refer to Cornell Tech's Novel Coronavirus (COVID-19) Updates website for information about campus restrictions.

  - *Note: COVID-19 screening procedures do not require IRB approval as long as they are done for safety purposes and not for research data collection. No amendment is needed to add a COVID-19 screening procedure to an IRB-approved study.*

- You may require that study participants be vaccinated in order to participate in your research; however, you should *not record* proof of vaccination (e.g., photographing a vaccination card, writing down exact vaccination details, etc.). Instead, simply make a note that the participant was "cleared" to participate in the study.
  - *Note 1: If students in a specific class or academic program are the focus of your research, you cannot require that they be vaccinated. The university is implementing its own vaccination requirements—and exemptions—for students.*
- Keeping a daily log of study participants is not required, given that Cornell University and the local public health department are no longer conducting contact tracing. If your research group decides to continue keeping a log of participants for your own contact tracing purposes, to protect confidentiality, logs should not be stored with study data nor linked to a specific study, and they should be destroyed after 30 days.
- Keep abreast of Tompkins County Health Department and New York State COVID-19 guidelines that might impact movements or actions of researchers or study participants.
- Keep abreast of current guidelines for all activities on campus via the Cornell COVID-19 Response website, as well as the Cornell Environment, Health and Safety COVID-19 website.

Additional IRB Considerations

- Decisions about bringing volunteers to campus for in-person study visits should be more conservative for people at higher risk for severe illness from COVID-19 per public health guidance. Researchers should take this into consideration as they develop plans for in-person human participant research protocols. For research involving participant populations at higher risk for severe illness, study consent forms may need to include information about this added risk.
- If your study procedures involve use of any shared objects or devices (e.g., pen, computer keyboard, blood pressure cuff), please follow the IRB/EHS Guidance on Cleaning Devices/Objects.
- If your study involves a significant risk of viral transmission, (e.g., respiratory function testing, prolonged close contact between study participants and researchers without effective PPE, etc.), then you must include details in your protocol application about mitigation of risk of SARS-CoV-2 infection, and also include information in the study consent form about this risk and how it will be mitigated. Examples of mitigation strategies could include requiring a negative COVID-19 antigen test and/or vaccinations in order to take part in the study.
- Any modifications to IRB protocols (beyond simply adding COVID-19-related screening procedures) will require an amendment request to be submitted to the IRB (via RASS-IRB). If you previously amended your protocol to change all in-person activities to remote/virtual platforms and you would now like to shift back to in-person activities, an amendment request will be needed. If you want to keep both in-person and remote options open, that should be written into your protocol.

- The Cornell IRB still recommends that researchers **consider whether any in-person activities can be modified to use remote interaction** (e.g., online surveys, interviews using Zoom), thereby reducing risk of SARS-CoV-2 exposure to both researchers and participants. Such a change to study procedures would also require an amendment request.
- **Regularly visit the Cornell IRB COVID-19 FAQs webpage** to stay abreast of new and revised guidance.

Appendix A: Sample Study Participant COVID-19 Information Sheet

***Note to researchers**: The Cornell safety measures outlined below may change over time. Please regularly consult the Cornell IRB COVID-19 FAQs webpage for the most up-to-date version of this document.*

Thank you for volunteering to be a part of this research study. We want you to know that your safety is very important to us, and we also want to make sure that you are fully informed when you agree to be part of a study. We do this by obtaining your consent after informing you about the risks and benefits related to the research you will be participating in.

Presently in our community, there is still an existing risk: The novel coronavirus 2019 (called SARS-CoV-2), which causes the disease COVID-19. Unless otherwise noted in the specific consent form for the study you are participating in, we believe that the risk to you for contracting COVID-19 by participating in this research is no more than your risk for contracting this disease from going to another indoor public location in this community.

Please know that we are continuously monitoring the number of COVID-19 cases in our local community. In addition to adhering to local, state, and federal guidelines, Cornell is taking additional steps to ensure the safety of all visitors, students, faculty, and staff:

1. Cornell requires all students, faculty, and staff to receive a primary series of an approved COVID-19 vaccination, or obtain a medical or religious exemption.
2. At present, high quality masks are required when riding public transportation and in healthcare and COVID-19 testing facilities. Masks are strongly encouraged but not required in classroom settings. Please refer to the Cornell masking policy webpage for up-to-date requirements.
3. Visitors to the Cornell Ithaca, Geneva, and Tech campuses should stay home if they feel ill, and are strongly encouraged to take an antigen test in advance of visiting campus. The researchers running this study will give you more information about any vaccination, testing, and masking requirements before your visit to campus.

Appendix B: Sample Study Participant COVID-19 Self-Screening Attestation

I acknowledge that:

- I must comply with all set procedures to reduce the spread of COVID-19 while participating in this study.

I attest that:

- I do not have a temperature of 100.4°F or higher, or 2 degrees higher than my normal temperature.
- In the last 3 days, I have not experienced any symptom of illness linked to COVID-19, such as cough, shortness of breath or difficulty breathing, chills, muscle pain, sore throat, new loss of taste or smell, nausea, vomiting, or diarrhea.
- I do not believe I have had close contact* with someone with a suspected and/or confirmed case of COVID-19 in the past 2 weeks.
- I have not been diagnosed with COVID-19 and not yet cleared as non-contagious by state or local public health authorities.
- I do not have any other reason to think that I may have been exposed to COVID-19.

_____
Print name

_____
Signature

_____
Date

*Close contact is defined as contact closer than six feet for 10 or more minutes.