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

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 have changed.

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.
- As of June 1, 2021, **research reactivation plans approved by your college or equivalent academic unit are no longer required, nor is IRB approval of those reactivation plans.**
- **The guidelines for study participants are the same as for other visitors to campus**.
- **Face mask requirements on campus:** Public health requirements on campus depend on which COVID-19 Alert Level the Cornell Ithaca Campus is operating under at any given point in time. **Visit the Cornell COVID-19 Tracking Dashboard to see the current Alert Level, and scroll down the page to learn what each level means in terms of public health requirements (including wearing of face masks).** For example, **Alert Level Green requires that all** faculty, staff, students, and visitors—regardless of vaccination status—**must wear a mask when indoors on campus, unless alone in a private, non-shared space (e.g., office or dorm room), or when eating or drinking.** Unvaccinated individuals must maintain a six-foot distance from others when unmasked for eating or drinking indoors, as well as outdoors when physical distancing is not possible. Level Yellow extends the requirements so that all individuals, regardless of vaccination status, must also mask outdoors when physical distancing is not possible.

  Conditions can change swiftly, so regularly visit the Cornell COVID-19 Tracking Dashboard to see the current Alert Level. Also visit the Cornell COVID-19 Response: Face Masks webpage for more detailed information about masking requirements.
- **Any human participant research on campus that involves procedures that do not meet the current campus 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 participants should be screened for COVID-19 symptoms or exposure** prior to arrival on

[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.

campus. The IRB still recommends a self-screening procedure. **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.)

  - *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: 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.*
- **Keep a daily log of study participants** who come to campus and any research team members with whom they come in contact, in case needed for contact tracing purposes by local public health officials. 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. See Appendix C of this document for a sample contact tracing log.
- **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 unvaccinated 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. One example of a mitigation strategy could be that participants are required to be vaccinated in order to take part in the study.
- Any **modifications to IRB protocols** (beyond simply adding COVID-19 screening procedures) will require an amendment request to be submitted to the IRB (via irbhp@cornell.edu). 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.

- 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 the community. That is, the risk is no more than your risk when going to the grocery store or spending time inside another shared space outside the home, where everyone is wearing a face covering.

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. As of September 16, 2021, 96% of the Cornell Ithaca, Geneva, and Cornell Tech campus populations (students, faculty, and staff) have been fully vaccinated. Unvaccinated members of our community participate in regular surveillance testing in order to swiftly identify any SARS-CoV2 cases.
2. All individuals who come to Cornell's campus are required to have a face mask on their person. The specific requirements for when and where masks must be worn depend on the COVID-19 Alert Level on campus at any given time.
3. The researchers running this study will give you more information about masking requirements for 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.

Appendix C: Sample Study Participant Contact Tracing Form

- This is a sample contact tracing form to use for in-person research interactions during the COVID-19 pandemic. Researchers may choose to use another method of tracking contact information.
- This information must be stored securely and separately from study data, and destroyed after 30 days.
- If health department notification is required due to a COVID-19 exposure, the research team must not identify an individual as being a Cornell research study participant.
- Study participants must be told that their contact information will be provided to the local health department if a COVID-19 exposure occurs. They should also be informed of the protections put in place (listed above) to protect their privacy.

To be Completed by the Research Team:

Principal Investigator:	Date:
On-site Team Lead (if not PI):	Lab/Room number:

Name of research team members onsite	Student/Staff/Faculty	Time in	Time out

Participant Name	Phone Number	Time in	Time out