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 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.**
- **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 generally the same as for other visitors to campus.** As of mid-fall 2021, there are vaccination and COVID-19 testing requirements for all invited guests and visitors to the Cornell Ithaca campus who are 12 years of age or older. See the [Cornell COVID-19 Visitors Information page](#) for details on implementing this requirement. The Cornell Tech campus has its own visitor policy, which you can review on this webpage. If you believe your participant enrollment or retention will be severely negatively impacted by this visitor requirement, please contact your IRB Administrator for assistance.

- **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.

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\(^1\) 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.
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 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.)

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.

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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 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-related 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 October 28, 2021, 97% 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. All invited guests and visitors to the Cornell Ithaca campus who are 12 years old or older must present a photo ID, as well as proof of vaccination for COVID-19 or the results of a recent negative COVID-19 test. As of November 1, 2021, visitors to the Cornell Tech campus must show proof of vaccination; a negative test is not sufficient. The researchers running this study will give you more information about 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.
- (FOR ITHACA CAMPUS VISITORS 12 OR OLDER) I have been fully vaccinated for COVID-19 or received a recent negative COVID-19 test. Acceptable options include:
  - an FDA- or WHO-authorized vaccine; or
  - a negative FDA- or DOH-authorized PCR, rapid PCR, or NAAT COVID-19 test performed on a specimen collected within 72 hours of my campus visit; or
  - an FDA-authorized antigen test performed on a specimen collected within six hours of my campus visit.
- (FOR CORNELL TECH VISITORS 12 OR OLDER) I have been fully vaccinated with an FDA- or WHO-authorized vaccine.

______________________________
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:

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<td>On-site Team Lead (if not PI):</td>
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Last Updated: July 28, 2020