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

In response to the heightening risk of transmission of COVID-19—the disease caused by the 2019 novel coronavirus (also called severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2)—Cornell reduced laboratory research and other nonessential research activities in mid-March 2020, including the elimination of on-campus, in-person human participant research. As research on campus has started to resume, the Cornell Institutional Review Board on Human Participants (IRB) has developed guidance and identified other University requirements relevant to researchers planning to restart their on-campus human participant research operations.

Note: While this document is focused on in-person human participant research taking place on the Cornell Ithaca campuses (Ithaca, Geneva and Cornell Tech2), 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 Guidelines for Reactivating Human Subjects Research, developed by the Committee on Human Subjects Research Reactivation, for requirements that must be met in order to reactivate any human subjects research on campus. Note that there are additional requirements for research procedures considered to present moderate or higher risk of viral transmission between study participants and researchers (“COVID-19 risk”). See Appendix A of the guidelines for a flow chart to help determine COVID-19 risk for a given study.

• Submit a research reactivation plan to your college or equivalent academic unit.

• Contact the IRB (irbhp@cornell.edu) to obtain concurrence of COVID-19 risk level determination, submit a new protocol application form for new projects, and/or confirm whether an amendment is needed to an existing protocol. This can be done concurrently with the review of your research reactivation plan by your college/unit. IRB sign-off is required for any in-person, on-campus human participant research project, whether it is a new study or an existing study being “reactivated.”

• Prior to arrival on campus, study participants must complete a self-screening process for exposure to COVID-19 or symptoms of illness. See Appendix B of the Guidelines for Reactivating Human Subjects Research for a sample self-monitoring health check procedure that can be used. 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.)

  o Note: COVID-19 screening procedures do not require IRB approval as long as 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.

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.
• **All individuals on campus must have a face covering on their person.** The research team must have extra face masks on hand in case a study participant arrives without one. (See instructions on purchasing face coverings and other critical supplies from Procurement and Payment Services.)

• **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 New York State COVID-19 guidelines** that might impact movement of researchers or study participants (e.g., the COVID-19 Travel Advisory).

• **Keep abreast of current guidelines for research and other activities on campus** via the Cornell COVID-19 and Reactivation Planning 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 to reactivate in-person human participant research protocols. For research involving participant populations at higher risk for severe illness, study consent forms should 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 review the IRB/EHS Guidance on Cleaning Devices/Objects that Contact Intact Skin.

• **If your study involves a higher risk of viral transmission**, per the Guidelines for Reactivating Human Subjects Research, then you must include details in the consent form about this risk and how it will be mitigated, in addition to any other risks of participation that may be unrelated to COVID-19. For study procedures with lower or moderate risk of viral transmission, the consent form may or may not need to be updated (to be determined by the IRB), though information about risk of viral transmission should be communicated to study participants in some way (e.g., as part of a pre-visit information sheet—see Appendix B for an example).

• Any **modifications to IRB protocols** (beyond simply adding COVID-19 screening procedures) will require an amendment request to be submitted to the IRB (irbhp@cornell.edu).

• The Cornell IRB 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 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 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. Prior to coming to campus, all Cornell University researchers (and other faculty and staff on campus) must complete a daily check for exposure to or symptoms of COVID-19. Anyone with a fever, other symptoms, or reporting a potential exposure is not allowed on campus.
2. All individuals on Cornell’s campus are required to have a face covering on their person when outdoors on campus and to put on their face covering when it is not feasible to maintain physical distancing measures (i.e., at least 6 feet of separation from others).
3. A face covering must be worn prior to entering any Cornell building, and while in any common space inside the building (e.g., elevators, lobbies, bathrooms, hallways).
4. All Cornell University researchers must also wear other appropriate PPE (personal protective equipment) specific to their research activities.
5. We will maximize physical distancing when possible. We are reducing the number of people within any building to facilitate maximizing physical distancing.
6. We are performing careful disinfection procedures multiple times each day.
Appendix B: Sample Study Participant COVID-19 Self-Screening Attestation

I acknowledge that:

- I must comply with all set procedures to reduce the spread while participating in the study, including wearing a face covering when I come to Cornell’s campus.

I attest that:

- I do not have a temperature of 100.4 degrees or higher, or 2 degrees higher than my normal temperature.
- I am not experiencing any symptom of illness 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 have not traveled internationally within the last 14 days.
- I have not traveled to a highly impacted area within the United States of America in the last 14 days.
- I do not believe I have had close contact* with someone with a suspected and/or confirmed case of COVID-19.
- I have not been diagnosed with COVID-19 and not yet cleared as non-contagious by state or local public health authorities.

______________________________
Print name

______________________________
Signature

______________________________
Date

*Close contact is defined as contact closer than 6 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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