Guidelines for Reactivating Human Subjects Research

During New York State Phase 2 and Greater

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1. Introduction and Principles

The Committee on Human Subjects Research Reactivation was created to recommend guidelines for human subjects research reactivation on Cornell's Ithaca, Geneva, and Cornell Tech campuses when those campuses enter NY State Business Reopening Phases 2 or greater. The members of the committee are Alexis Brubaker, Associate Compliance Officer; Pat Cassano, Professor and Director, Division of Nutritional Sciences; Myles Gideon, Senior IRB and COI Administrator; Mark Hurwitz, (Chair) Interim Chief Research Compliance Officer; Sumit Niogi, WCM Radiology and Director of the Cornell University Magnetic Resonance Imaging Facility; Karl Pillemer, CHE Senior Associate Dean for Research and Outreach, Professor of Human Development; and Andrew Willford, IRB Chair, Professor of Anthropology.

The following principles underlie our recommendations:

A. All guidelines and requirements that apply to reactivating on-campus activity also apply to human subjects research.

B. Study participants and researchers are entitled to equal care and protection with respect to the risk of COVID-19.

C. Approval to reactivate human subjects research does not replace or circumvent any regulatory and legal requirements. Protocol changes may require IRB approval and researchers should consult the Institutional Review Board (IRB) for guidance.

D. In addition to the requirement in this report, research conducted in off-campus locations must comply with the laws and regulations applicable to those locations and is not addressed in these recommendations.

For the purpose of reactivation, human subjects research plans are partitioned into three broad categories according to the degree of risk of viral transmission for researchers and study participants. The categories and requirements for each are described in section 3. In section 2, requirements for all human subjects research are described. Appendix A provides a flow chart to help determine the category of a research plan.

These guidelines provide a means for each college, or other Unit, to decide if a research reactivation plan can be approved. Once approved, following the normal regulations for human subjects research, the researchers must submit to IRB protocols including the coronavirus protections, or amendments to existing protocols that account for the changes required to protect against the corona virus. It is the IRB

review that finally determines whether the human subjects are sufficiently protected. These guidelines do not, and cannot, impinge on the regulatory authority and responsibility of the IRB.

2. Requirements for All Human Subjects Research

Certain requirements must be met to reactivate human subjects research in any category. These are:

1. All activities that can be conducted remotely, that is not in presence of a study participant, should be conducted remotely. For example, whenever possible, completion of screening procedures and forms should be conducted remotely before study participants arrive on campus.
2. All requirements listed in the Reactivating Research and Supporting Operations Report must be met, including approval of a research reactivation plan, and any additional requirements imposed by the PI's college or equivalent academic unit.
3. The reactivation plan adheres to the approved maximum density and other facility requirements for the location in which the research is conducted, taking into account the presence of study participants as well as researchers. Researchers may need to consider staggered appointments and working in shifts to meet these requirements.
4. Study participants must adhere to EHS Mask and Face Covering guidelines.
5. To protect researchers from possible coronavirus infection, all study participants must, at a minimum, agree to the same health screening required for researchers. The screening questions to be self administered by study participants are provided in flowchart form in Appendix B.
6. Study participants are subject to the same travel restrictions as researchers. Those that do not reside in the local area may be subject to a 14 day quarantine on arrival at a Cornell Campus. As New York regions progress through the phases of reopening, travel requirements may change.
7. All regulatory and legal requirements must be met. Examples include required training, submission of IRB protocols and amendments, and submission of IBC MUAs and amendments. Researchers should check with IRB administration for guidance on language related to the coronavirus in consent forms, attestations, and other information for study participants.

3. Definitions of Risk Categories and additional requirements

A. **Lower Risk Research:** Research in this category has the most limited degree of interaction with study participants and has the lowest risk of viral transmission. The research can be conducted with researchers and study participants complying with the social distancing rules required for reactivating any business doing Office-Based Work[1] in Phase 2, including wearing masks and maintaining separation of at least six feet between persons occupying the same room. The research activity may require that study participants be in direct contact with an instrument of some kind, but the procedure cannot increase risk of viral transmission, and the instrument must be disposable. There are no additional requirements for research meeting these Lower Risk criteria.

[1] See the Summary Guidelines for Office-Based Work in NY state Phase 2 reopening.

B. **Moderate Risk Research:** In this category, there is some risk of viral transmission that is clearly mitigated by the research procedures and protocols and there is minimal to no risk of aerosolization of virus containing droplets. For example:

- The research activity requires that study participants or researchers must be within six feet of another, but proper PPE[2] is worn at all times during these interactions;
- The research activity requires that study participants be in direct contact with an instrument of some kind, but the procedure does not increase risk of viral transmission and the instrument is sanitized according to appropriate protocols;
- Study participants or researchers cannot wear proper PPE but can be positioned greater than six feet apart to minimize risk of viral transmission. For example, study participants must observe the investigator's facial expressions in a behavioral study, or must remove mask to consume food under investigator's observation;

Research can be reactivated in the Moderate Risk category if, in addition to meeting the requirements listed in section 2 for all human subjects research, the research plan includes no risk for virus aerosolization and procedures are in place to minimize the risk due to inability to follow social distancing rules or PPE usage.

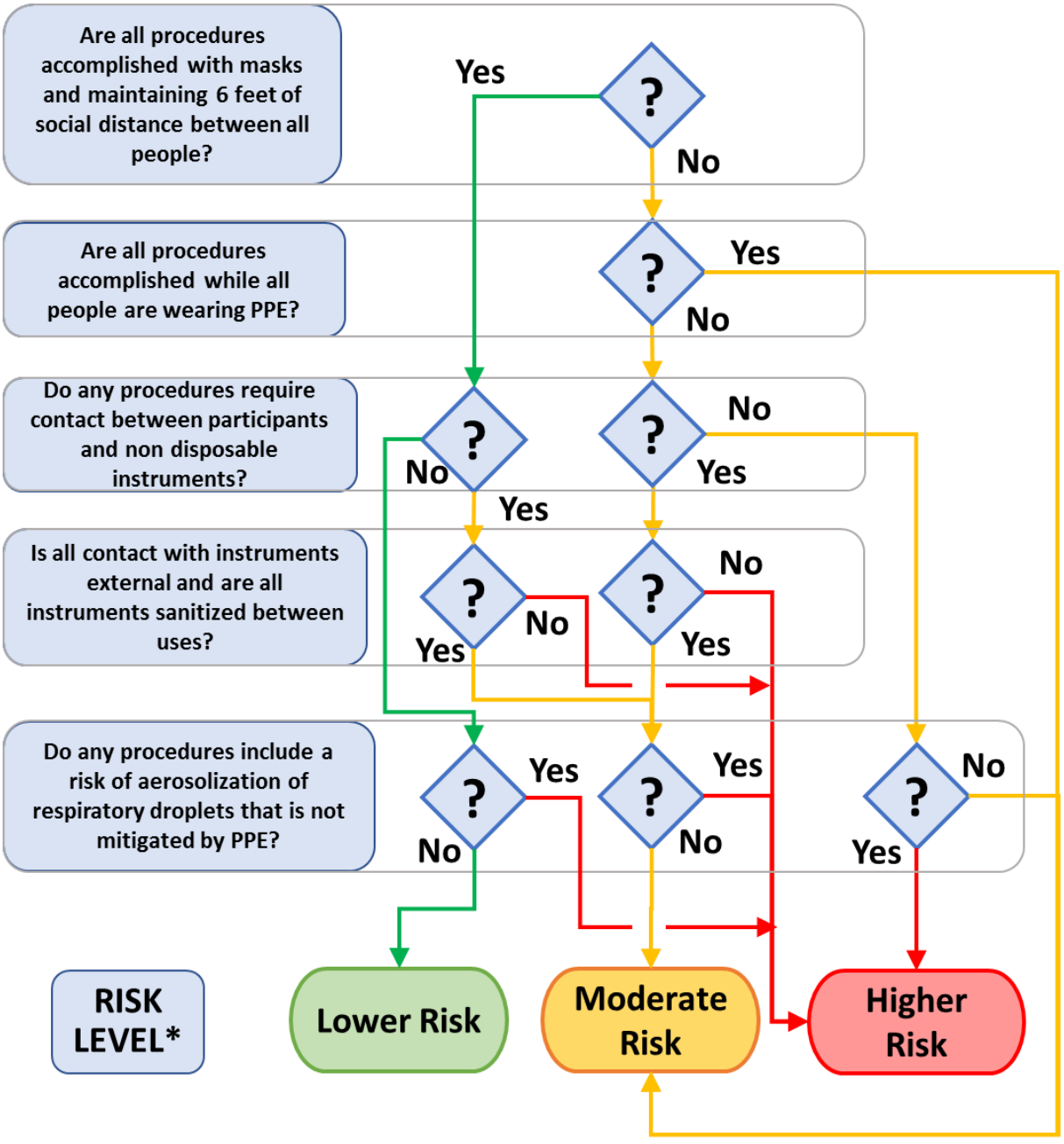
C. **Higher Risk Research:** In this category, there is a higher risk of viral transmission or the study participants are members of a vulnerable population. For example, respiratory function testing may cause aerosolization of virus laden droplets that cannot be captured by PPE or the study participant may have diminished lung capacity. In other cases, prolonged contact between study participants and researchers without effective PPE may be necessary for the research.

It is not possible to delineate all the circumstances that would cause a research plan to be Higher Risk. Nor is it possible to delineate all the requirements for conducting Higher Risk research in this report. However, the IRB protocol must include appropriate mitigation of the risk of coronavirus infection specific to the research planned. A College or Academic Unit may approve a reactivation plan contingent on IRB approval of protocols or amendments. The IRB Committee, on examining any particular protocol, may determine that it falls into the Higher Risk category and require mitigations appropriate to that specific case.

[2] Proper personal protective equipment, PPE, as defined by Cornell University Environmental Health Services (EHS)

Appendix A. Flowchart to Determine COVID-19 Risk Category of a Human Subjects Research Plan

This flowchart will help researchers decide what level of COVID-19 risk their procedures entail. It should be noted that this is only a general guide. Final determination will depend on IRB review. IRB will review planned PPE with EHS as needed.



*Note: IRB review of protocol details may alter risk category.

Appendix B. Study Participant Self-Monitoring Health Check Procedure

When study participants arrives on campus, they are representing to the researchers conducting the study, and to any other participants in the same study, that they are not ill, are fever-free, have not had known close contact with a person diagnosed with COVID-19, and they have not been asked to self-isolate or quarantine by a public health authority or by their personal healthcare provider. This flow chart is provided to assist study participants in checking themselves for symptoms before arriving at a Cornell campus.