Guidelines for In-Person Research During the COVID-19 Pandemic[1]

In response to the 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)—the Edgewood College IRB paused on-campus, in-person human participant research activities in mid-March 2020. As we begin to resume research on campus the Edgewood College Institutional Review Board (IRB) has developed guidelines relevant to researchers planning to initiate on-campus human participant research operations.

Requirements for On-Campus Human Participants Research

- As always, IRB approval is required for any in-person, on-campus human participant research project, whether it is a new study or an existing study being "reactivated." Research submissions should recognize that in-person research poses an additional potential level of risk/harm to the participant (See Appendix A for a flow chart to help determine COVID-19 risk for a given study), and should carefully consider the ability to effectively mitigate risks such that participant safety and research integrity are assured. Protocols and procedures to mitigate this additional level of risk needs to be outlined in the proposal.
- The research plan must adhere to the approved maximum density and other facility requirements at Edgewood College, 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.
- Potential participants should be advised of the potential risk for contracting COVID-19, as well as the protocols and procedures in place to mitigate that risk. This must be included in the consent form, as well as provided in advance and in writing to potential participants as part of a pre-visit information sheet (see Appendix B for an example).
- Prior to participating in research, study participants must complete a self-screening process for exposure to COVID-19 or symptoms of illness (see Appendix C for health check procedure) before participating in research. 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 D 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.*
- All individuals on campus must adhere to mask and face covering guidelines. The research team must have extra face masks on hand in case a study participant arrives without one.
- The research team must keep a daily log of study participants 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 E for a sample contact tracing log).
- The research team must keep abreast of Dane County COVID-19 Guidelines that might impact movement of researchers or study participants.

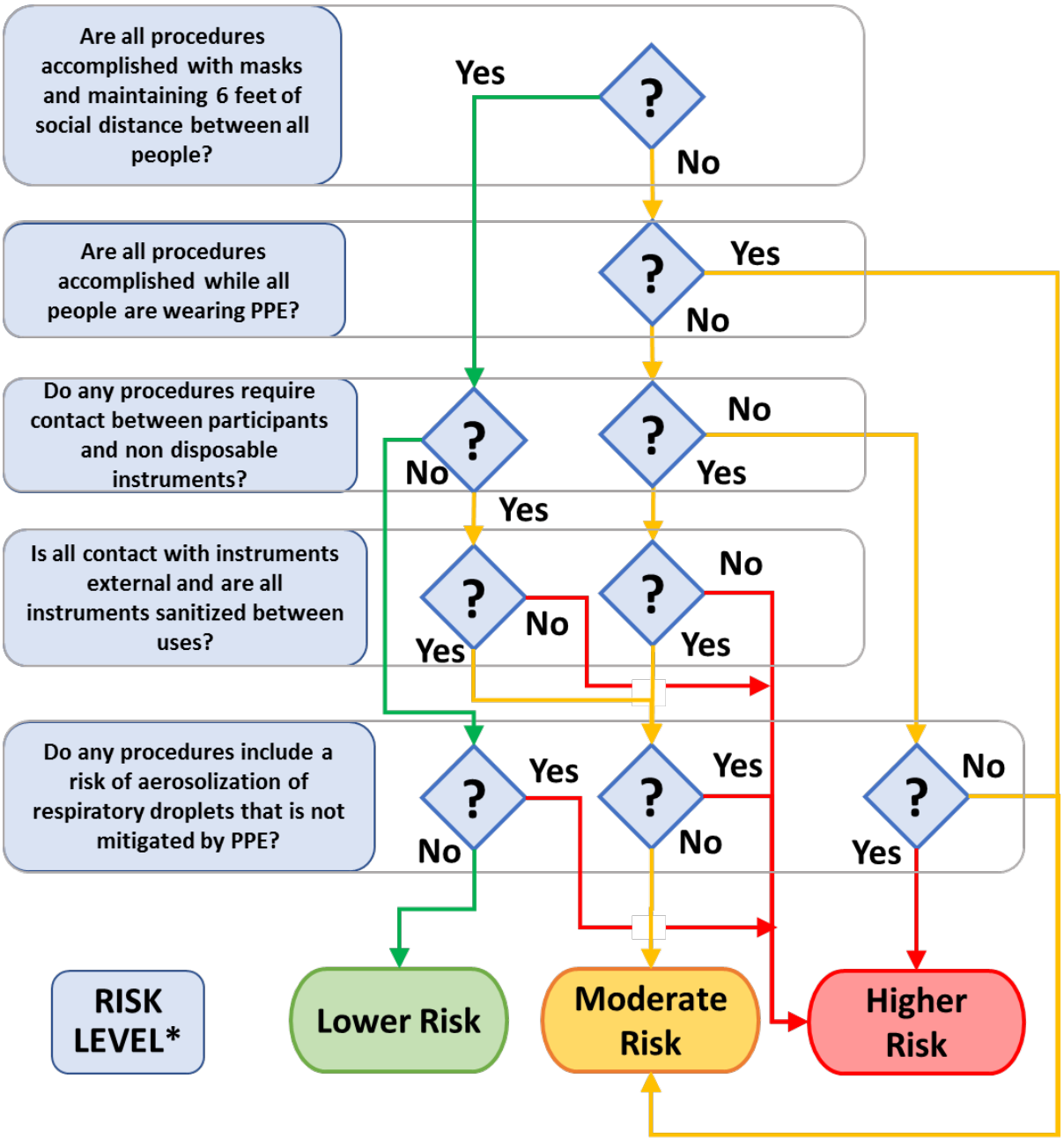
[1]Adapted with permission from Cornell University IRB, April 2021

Additional IRB Considerations

- Decisions about recruiting 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 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 Appendix F for guidance on cleaning).
- If your study involves a moderate to higher risk of viral transmission, 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 Change to Approved Research Form to be submitted to the IRB.
- The Edgewood IRB recommends that researchers consider whether any in-person activities can be modified to use remote interaction (e.g., online surveys, interviews using Zoom or Webex) thereby reducing risk of exposure to both researchers and participants. Such a change to study procedures would also require a Change to Approved Research Form.
- Regularly visit the Edgewood College COVID-19 webpage to stay abreast of new and revised guidance.

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.



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

Appendix B: Sample Study Participant COVID-19 Information Sheet

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.

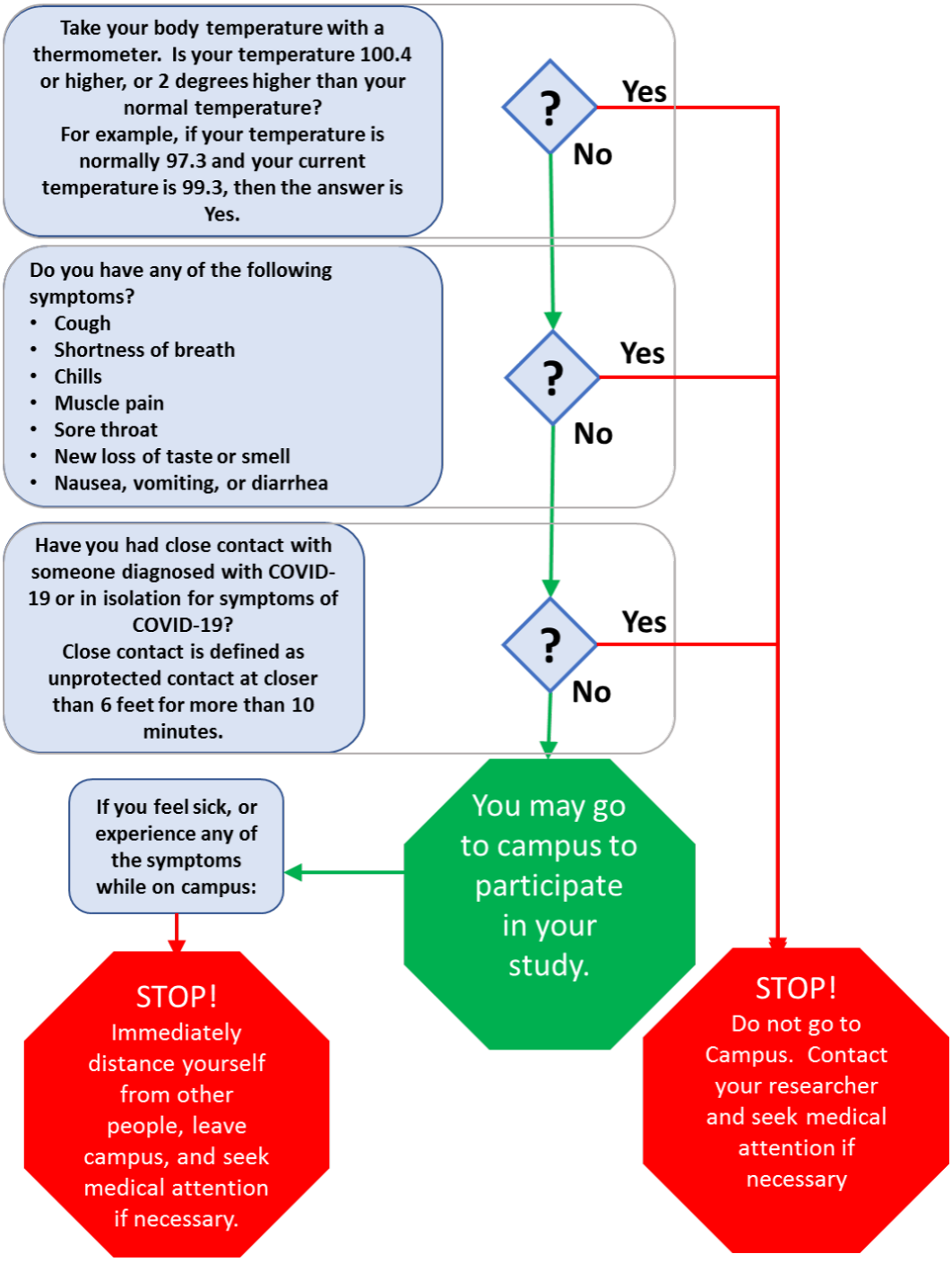
Presently in our community, there is an existing risk: The novel coronavirus 2019 (called SARS-CoV-2), which causes the disease COVID-19. Unless otherwise noted in the specific consent form for the study you are participating in, we believe that the risk to you for contracting COVID-19 by participating 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. Inaddition to adhering to local, state, and federal guidelines, Edgewood College IRB is taking additional steps to ensure the safety of all visitors, students, faculty, and staff:

1. Prior to coming to campus, all Edgewood College 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 the Edgewood College 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 Edgewood building, and while in any common space inside the building (e.g., elevators, lobbies, bathrooms, hallways).
4. As appropriate, all Edgewood College 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 withinany building to facilitate maximizing physical distancing.
6. We are performing careful disinfection procedures multiple times each day.

Appendix C. Study Participant Self-Monitoring Health Check Procedure

When individuals participate in research 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 participating in face-to-face research on-campus.



Appendix D: 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 am on the Edgewood College campus.

I attest that:

- I do not have a temperature of 100.4 degrees or higher, or 2 degrees higher than my normaltemperature.
- 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 (defined as contact closer than 6 feet for 10 or more minutes 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 localpublic health authorities.

_____
Print name

_____
Signature

_____
Date

Appendix E: 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 notidentify an individual as being an Edgewood College 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

Appendix F: Cleaning Devices/Objects that Contact Intact Skin

Some research procedures require participants to share the use of objects or devices that do not penetrate the skin, such as computers, computer mice, phones, tablets, writing instruments, pedometers, or eye trackers. In general, best practice is to disinfect or sanitize these materials betweenparticipant use per device manufacturer guidance and disinfectant manufacturer instructions. The IRB recommends the following common hygiene practices, below, when sharing these objects between participants. Use all disinfectants in accordance with manufacturer guidelines:

- Encourage participants to wash their hands with soap and water for 20 seconds and dry them before and after using the objects. Though soap and water are usually preferred, commerciallyprepared hand sanitizer that contains at least 60% alcohol may be substituted.
- If participants have minor cuts or wounds in the area that will be in contact with the object,have them wear a band-aid or another similar protective cover.
- If reasonable, have the participants wear disposable gloves or other personal protective equipment.
- When possible, sheath the object in a plastic sleeve, especially if the object is made of a porous material that cannot be cleaned and sanitized properly or there is prolonged contact with skin.
- Wipe off any obvious fluids, such as perspiration, between uses. Generally, sweat is not considered to contain materials that may be infectious. Other bodily fluids must be considered as potentially infectious.
- If the object is constructed of absorbent material, such as fabric or sponge, wash/launder between uses with the highest temperature water allowed.
- If using blood pressure cuffs, wrap the cuffs over a shirt sleeve or another appropriate material.If that is not possible, wipe the inside of the cuffs clean with sanitizing wipes and dry them before use, and wash periodically using the manufacturer's instructions.
- If using an object that uses a liquid gel (such as an ultrasound), sheath the object in a plastic sleeve and use fresh gel for each participant. If not possible to sheath the object, wipe it with asanitizing wipe or following device manufacturer's instructions.
- If an object needs to be disinfected due to frequent touching or potential contamination,consult with EHS prior to use of an appropriate chemical disinfectant to sanitize objects:
  - 70-90% ethanol
  - 1:100 household bleach (or Clorox Bleach Wipes) OR a ammonium compound such as Cavicide.