

## ELON UNIVERSITY IRB

### Best Practices for Minimizing the Risk of Transmission of Infectious Disease during COVID-19 Pandemic





All researchers are expected to apply these best practices for the foreseeable future. All investigators who have currently approved protocols will be expected to submit and have approved an amendment describing how they will apply these best practices by August 1, 2020. After this time, data collection must be suspended until an appropriate amendment is submitted and approved. All protocols approved after June 1, 2020 will be required to incorporate these best practices in their research protocol.

1. **In-person data collection should be avoided whenever possible.** Researchers are encouraged to develop research designs and environments that do not require in-person data collection by using on-line resources. These procedures could encompass all or part of the experimental procedures used in an investigation.
2. **Exclude subjects who are at elevated risk of being impacted by COVID-19 when possible.** People above 65 years of age or older, that are immunocompromised, are severely obese (BMI>35), have diabetes, have moderate to severe asthma, or suffer from chronic disease (e.g. heart, lung, liver, kidney) are consider to be at elevated risk of being significantly impacted by COVID-19. Inclusion of these subjects in in-person data collection should be avoided and will need to be justified as essential to receive approval. Potential subjects with multiple risk factors will be considered to have exponentially elevated risk. Inclusion of these subjects in data collection procedures where droplet precautions are necessary will receive heightened scrutiny during the review process.
3. **Rigorous screening procedures for research participants and investigators must be implemented.** All individuals participating in research activities should be screened for symptoms of COVID-19 24 hours before, immediately before, and 24-48 hours after an in-person interaction. Researchers are required to follow the screening procedures provided in the Elon University IRB COVID-19 Screening Guide.
4. **Develop and apply data collection procedures that minimize the risk of infectious disease transmission.** Whenever possible, investigators should use procedures that allow for physical distancing (> 6 feet), are low-touch, and are high hygiene. During the IRB application process, these procedures must be documented in writing and with visual evidence (pictures, videos, or diagrams). Included in these procedures should include cleaning methods that are consistent with University policy. If necessary, the IRB may request an on-site inspection of the spaces proposed for use in the protocol.
5. **Special care and precautions should be taken when the virus could be aerolized.** Experimental conditions that precipitate high levels of ventilation for prolonged periods of time (>5 minutes) and increase the possibility that the virus can be aerolized should be avoided. Exercise is an experimental condition that can precipitate high levels of ventilation. The Physiologic Society has provided guidelines for resuming exercise testing in the COVID-19 environment (<https://www.physoc.org/covid19/returning-to-the-lab/resuming-laboratory-testing-with-human-participants/>). When an experimental condition is used that facilitates high levels of ventilation, physical distancing between the participant and the researcher should be extended to >12 feet whenever possible. If a researcher needs to be within 12 feet then appropriate personal protective equipment should be used.
6. **Personal Protective Equipment (PPE).** Principal investigators should evaluate their protocol (using the attached Table 1) to assess the level of physical contact needed to complete the proposed protocol. During the IRB application procedure, principal investigators must affirm that they will have access to

the PPE needed to safely administer the protocol. Guidance for the appropriate procedures for use of PPE is provided by the CDC, including a cloth mask (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wear-cloth-face-coverings.html>) as well as more advanced PPE (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>)

7. **Cleaning.** Principle investigators are responsible for ensuring that spaces used for research purposes are cleaned prior to, between, and after each research subject using the procedures provided by the CDC (<https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>).

**Table 1. Physical Contact and Personal Protective Equipment needed to complete protocol.**

				
Level of Contact	None	Physically Distant	Minimal	Significant
Research Conditions	<ul style="list-style-type: none"> <li>Exempt</li> <li>Not in person</li> <li>Established Setting with own safety Guidelines</li> </ul>	<ul style="list-style-type: none"> <li>Exempt or Expedited</li> <li>In person</li> <li>Social Distance Possible</li> </ul>	<ul style="list-style-type: none"> <li>Expedited</li> <li>In-person with minimal physical contact</li> <li>Minimal droplet risk</li> </ul>	<ul style="list-style-type: none"> <li>Expedited or Full</li> <li>In-person with significant contact</li> <li>Droplet or Breath Risk</li> </ul>
Example Activities	<ul style="list-style-type: none"> <li>On-line</li> <li>Educational Settings</li> </ul>	<ul style="list-style-type: none"> <li>Interviews</li> <li>Focus Groups</li> <li>Cognitive Fxn Tests</li> </ul>	<ul style="list-style-type: none"> <li>Biomechanics</li> <li>Range of motion</li> <li>Anthropometrics</li> </ul>	<ul style="list-style-type: none"> <li>EEG</li> <li>Blood Draws</li> <li>VO2 measurement</li> </ul>
Recommended PPE	<ul style="list-style-type: none"> <li>None or determined by facility</li> </ul>	<ul style="list-style-type: none"> <li>Cloth Masks</li> </ul>	<ul style="list-style-type: none"> <li>Procedure Mask</li> <li>Gloves</li> </ul>	<ul style="list-style-type: none"> <li>Procedure mask</li> <li>Face Shield</li> <li>Gloves</li> <li>Gown</li> </ul>