Emory IRB Guidelines: Resuming Non-Essential In-Person Human Subjects Research

For the IRB’s other COVID-19-related guidance, see our Covid-19 page.

The IRB’s primary focus in these guidelines is to protect human participants in research. Emory University has other guidelines and policies aimed at protecting the general population (e.g., restriction of visitors to campus, lab workers, students).

In-person non-essential research with human participants must at least adhere to the following Emory IRB guidelines to resume once the University and applicable Unit and School allow.

Emory University, Schools, and units may require additional protections or may require all research to cease depending on public health circumstances as the pandemic evolves.

The most protective measures among the below, State, Local, facility, and Emory’s Environmental Health and Safety Office (EHSO) guidelines take precedence. If a partner facility (CHOA, Grady, etc.) has less restrictive policies, the below takes precedence.

Covid-19 training is required to come back to campus and to resume research activities. You may find this training by logging into ELMS and searching for “Mandatory Covid-19 Phased Return to Campus Training”

GENERAL CONSIDERATIONS

• The IRB expects researchers to continue to use remote technologies to conduct research whenever possible.
• All in-person research must incorporate appropriate risk reduction strategies (distancing, disinfection, PPE, symptom screening).
  o PPE and gloves should be changed frequently if taking the temperature of several participants at the same time. Follow CDC and EHSO guidance below.
• Details re: mask material, spacing, disinfection are available at www.ehso.emory.edu in the guidelines entitled “Personal Protective Equipment (PPE) And Disinfection Matrix For Emory University Employees”
  o Children younger than 2 years old are not required to wear a mask.

RESEARCHERS AND PARTICIPANTS SCREENING REQUIREMENTS BEFORE STUDY VISITS

All in-person research requires COVID-19 pre-screening of both researchers and participants:

Participants:
Use the sample screening questions and information script/email in Appendix 2 if your facility does not already provide them.
  o The participant screening questionnaire, and or other materials must include information about risk factors for severe illness to allow participants to evaluate their individual risk.
  o If your facility is asking every person entering the building to fill out questionnaires that contain questions similar to the ones in Appendix 2, save an unfilled copy of the questionnaire for your study records and document that participants completed the screen when entering the facility.

Check the participants’ temperature before they enter the building or area where the research will be conducted (if not done by the facility already) ¹
  o If your facility is taking the temperature of every person entering the building, document that subjects likely had a temperature lower than 38°C or 100.4 as they were permitted to enter the facility.

If you are obtaining them, the completed screening questions and temperature reading should be saved in the research record.

Researchers:

Researchers must complete and document a symptom screen, plus the temperature reading if available, on each day that in-person contact is planned with one or more research participants. The symptom screen must be completed prior to in-person contact with a research participant. Use the sample screening questions and information script/email in Appendix 2 if your facility does not already provide them.
  o If your facility is asking every person entering the building to fill out questionnaires that contain similar questions like the ones in Appendix 2, please save an unfilled copy for your study records and document that your study team member completed the questionnaire when entering the facility.

Researchers must take their temperature at home before coming to work and provide the information to the research staff keeping the screen log. If the facility is taking the temperature of employees, researchers may use that reading to their research record, as above ².

MODIFICATIONS TO IRB PROTOCOLS:

SOP’s for personal protective equipment (PPE) or COVID-19 screening questions do not require approval by the IRB, as long as the screening data are not used for research.

However, if existing IRB-approved procedures must be revised, e.g. to adjust the number of study visits, or to make some data collection remote, please submit a Modification.

Also, if a research study cannot adhere to the applicable safety guidelines for scientific reasons, the PI must request an exception by submitting a Modification to the IRB. The Modification must include the information outlined in Appendix 1. Not being able to procure PPE is not an acceptable reason to grant an exception.

For external IRB studies, you need to submit a modification (or update the study) to ask for an exception for your study. Please reach out to the IRB staff leadership if you have any questions.

# RESEARCH ACTIVITIES AND REQUIRED SAFETY MEASURES

<table>
<thead>
<tr>
<th>Research Activity</th>
<th>Location</th>
<th>Guidelines</th>
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| Verbal interaction with no physical contact            | Emory site| • Covid-19 pre-screening questionnaire and temperature recordings for the researcher and participant prior to the visit  
• Schedule participants to avoid overlap and waiting time  
• Disinfect research area per EHSO guidelines between participants  
• Researchers and participants wear masks per EHSO guidelines at all times  
• If all parties cannot wear masks due to the nature of the research, then clear dividers or face shields must be used within six feet of separation  
• Hold visits in separate dedicated space to avoid exposure to others  
• Adhere to the most protective guidelines re: density, face covering, and physical distancing  
• Minor subjects must be mature enough to follow safety guidelines. Minors present with adult subjects should be kept away from research interactions  
• If offering snacks, they need to be individually wrapped servings |
| Community/field site                                   |          | • Emory-research-driven gatherings shall not take place indoors  
• Home-based study visits with individuals or households must follow the same PPE guidelines as above. Disinfect touched surfaces before leaving  
• Emory-research-driven gatherings may take place outdoors if they follow State and Local recommendations re: number of people, spacing, and face coverings. No contact is permitted between participants.  
**Note:** Emory researchers do not control the space, so the risk is higher for noncompliance with guidelines |
<p>| Physical contact or other procedures that require close proximity | Emory or affiliated clinical space | In addition to following the guidelines above, Emory Healthcare (or affiliate) clinical guidelines |</p>
<table>
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<tr>
<th>All</th>
<th>International</th>
<th>In addition to following the Emory IRB guidelines for the above categories of research, researchers must also comply with any more restrictive guidelines in the country and any additional safety requirements of the setting.</th>
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<td>must be followed (e.g. gloves, lab coats, surgical masks)</td>
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Frequently Asked Questions
Q. What if a participant refuses to wear a mask or comply with other safety precautions?
A. The study visit should either be rescheduled for a time when the participant agrees to comply or terminated if the participant states that they will not comply (in which case the subject should also be withdrawn from the study).

Q. What if I cannot follow all of the guidelines while conducting my in-person research activities?
A. Submit a Modification to the IRB to determine if an exception can be made prior to resuming those activities.

Q. What if my international research is in resource-poor settings and I cannot obtain the required PPE?
A. At this time, the research may not resume.

Q. What if I’m not sure how to apply the above guidelines to my unique research activities?
A. Please email or call the IRB. A modification may be required to document the specific precautions needed for your study.
APPENDIX 1: MODIFICATION GUIDELINES FOR EXCEPTION REQUEST

1. Which specific safety precautions are impossible to perform while maintaining scientific integrity?

2. Why is it not possible to comply with those precautions?

3. What steps will be taken to mitigate risk in lieu of those precautions?
APPENDIX 2: COVID-19 SCREENING QUESTIONNAIRE/SCRIPT

Appropriate screening questions might include the following, which could be modified to fit your participant population and the location of in-person interactions. Any YES answer should be considered sufficient reason to postpone in-person visits if it cannot be explained by an underlying medical condition. Please refer to your facility’s screening requirements if applicable, as well.

**Note:** Using these screening questions, with or without a temperature check, does NOT require an IRB modification if the data will not be used for research.

1. Have you had any of the following symptoms in the past two weeks, which were not diagnosed as something other than Covid-19 (e.g. COPD, heart failure, etc.), even if they were mild?³
   - ☐ Fever (higher than 100.4°F [38.0°C])
   - ☐ Cough
   - ☐ Shortness of breath or difficulty breathing
   - ☐ New loss of the sense of smell or taste
   - ☐ Sore throat
   - ☐ Chills
   - ☐ Muscle pain or body aches not due to injury or strain
   - ☐ Nausea or vomiting
   - ☐ Diarrhea
   - ☐ Fatigue
   - ☐ Headache
   - ☐ Congestion or runny nose

2. In the last 14 days, have you lived with, visited, cared for, or been in a room for a prolonged period with someone who is under investigation or has been confirmed for COVID-19/coronavirus infection?
   - ☐ Yes
   - ☐ No