

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, etc.

In-person non-essential human subjects research must at least adhere to the following Emory IRB guidelines in order 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 must take precedence. If a partner facility (e.g. CHOA, Grady, etc.) have less restrictive policies, the below will take precedence.

Be aware that 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).
- 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"
- **All** in-person research requires **COVID-19 pre-screening** of both researchers and participants. Sample screening questions and information script/email are in Appendix 2.
 - Researchers must complete *and document* a symptom screen and temperature check on each day that in-person contact is planned with one or more research participants. The symptom screen and temperature check must be completed prior to in-person contact with a research participant.

- The participant screening questionnaire must include information about risk factors for severe illness to allow participants to evaluate their individual risk.

MODIFICATIONS TO IRB PROTOCOLS:

- SOP’s for personal protective equipment (PPE) or COVID-19 screening questions and temperature checks 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.

RESEARCH ACTIVITIES AND REQUIRED SAFETY MEASURES

Research Activity	Location	Guidelines	Notes
Verbal interaction with no physical contact <ul style="list-style-type: none"> • Interviews • Focus groups • Behavioral tasks and observation • Education 	<ul style="list-style-type: none"> • Emory site 	<ul style="list-style-type: none"> • 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 not all parties can 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 	

		<ul style="list-style-type: none"> If offering snacks, they need to be individually wrapped servings. 	
	<ul style="list-style-type: none"> Community/field site 	<ul style="list-style-type: none"> Emory-research-driven gatherings shall not take place indoors 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. 	Emory researchers do not control the space, so risk is higher for noncompliance with guidelines
Physical contact or other procedures that require close proximity	<ul style="list-style-type: none"> Emory or affiliated clinical space 	In addition to following the guidelines above, Emory Healthcare clinical guidelines must be followed (e.g. gloves, lab coats, surgical masks)	
All	<ul style="list-style-type: none"> International 	In addition to following the Emory IRB guidelines for the above categories of research, researchers must also comply with any more restrictive guidelines in country and any additional safety requirements of the setting.	

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.

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. Please refer to your facility's screening requirements if applicable, as well.

Note: Using these screening questions, with or without a temperature check, do 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, even if they were mild?

- Fever
- Cough
- Shortness of breath or difficulty breathing
- Loss of the sense of smell or taste
- Sore throat

2. In the last 14 days, have you lived with, visited, cared for, or been in a room for a prolonged period of time with someone who is under investigation or has been confirmed for COVID-19/coronavirus infection?

- Yes
- No

If any of the above are checked, in-person visits should be postponed. Otherwise, proceed to the next item.

3. Decisions about in-person visits should be especially conservative for people at higher risk per public health recommendations. If any of the below describe you, you may wish to postpone in-person visits.

- Over 60 years of age
- Underlying health conditions including heart disease, high blood pressure, lung disease, obesity, or diabetes
- Weakened immune systems
- Pregnant