

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 research participants in research. Emory University has additional 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. Find more information about what constitutes essential research [in this guidance](#). Review [this document](#) with specific information about what in-person-visits would be considered likely “essential”.

- If your study is considered “Essential” or if you are providing treatment to study subjects and the treatment is also considered “essential”, then follow the hospital recommendations on COVID-19 PPE use and prevention.
- 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”. For researchers not at Emory, follow your location training requirements.
- Patients admitted in the hospital may be subject to other safety requirements you will need to follow when conducting research.
- This guideline applies regardless of whether the IRB of record is at Emory or elsewhere.

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).
 - PPE should be used according to CDC, EHSO, and local institutional/hospital guidelines. Follow CDC and EHSO guidance below.
- Details regarding mask material, distancing, disinfection are available at www.ehso.emory.edu in the guidelines entitled “[Personal Protective Equipment \(PPE\) And Disinfection Matrix For Emory](#)

[University Employees](#)”, and also in the EHSO guidance “[Personal Protective Equipment \(PPE\) And Disinfection Matrix For IRB In-Person Human Subjects Research.](#)”

- Children younger than 2 years old are not required to wear a mask.

RESEARCHERS AND PARTICIPANTS SCREENING REQUIREMENTS BEFORE STUDY VISITS

Participants:

- Already hospitalized/ER/ICU patients: Refer to the patient’s chart for COVID-19 symptom information, and record results in the research record. Risk factor information is not needed since the patient is already in the hospital/clinic for treatment.
 - If specifically, enrolling Covid-19 patients, or those suspected of having Covid-19, symptom screening (including temperature measurement) is not required
 - You are required to use appropriate PPE per the EHSO guidance for IRB approved studies
 - If you anticipate that the group of subjects you intend to enroll cannot wear protective face coverings/mask, then make sure you include that in your study protocol (or modify an existing protocol via a modification), and detail why.
- Patients invited to come in for research visits: Use the sample screening questions and information script/email in Appendix 2 if your facility does not already provide them.
 - 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.
 - If your facility is asking every person entering the building to fill out questionnaires that contain questions like 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):
 - If your facility is taking the temperature of every person entering the building, document that subjects likely had a temperature lower than 38c or 100.4 as they were permitted to enter the facility.
 - If you have not secured thermometers provided by Emory, then your study team may use thermometers purchased in local pharmacies. Just ensure the thermometer is a non-contact infrared thermometer. For more information about the proper use of these thermometers, please review [this FDA guidance](#).
 - If the subject temperature is higher than 38 C or 100.4 F, and this could be explained by an external factor (for example, walking a long-distance), wait five minutes and retake.
 - If you (study team) are conducting the screening survey and temperature readings, the results should be saved in the research record. This documentation should be documented per subject. [See this example of a log for more information.](#)
- Research outside Emory Campus or at Participant’s home: use the screening questionnaire and take subjects’ temperature before starting any research activity. Ensure you are wearing the required PPE, and that the subjects are wearing masks. Additional Considerations:

- 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.
 - If your study must be conducted indoors, please request an exemption via a modification submission and provide the cleaning and distancing practices of the location where the research will take place.
- Home-based study visits with individuals or households must follow the same PPE guidelines as above. Disinfect touched surfaces before leaving. Stay outside the home if possible.
 - If additional people are inside the home, they should use masks (except children younger than 2 years old).

Researchers:

- Researchers must complete *and document* a symptom screen, including temperature (see below), 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.
 - 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 may take their temperature at home before coming to work and provide the information to the research staff keeping the screen log or have their temperature taken upon arriving at the facility. If the facility is taking the temperature of employees as they enter, researchers may use that reading to their research log, as above¹.

If a Participant or Researcher is Positive for COVID-19

If you screen a participant who later is diagnosed with COVID-19, you may be expected to get tested and quarantine before receiving negative results from the test, especially if you did not use appropriate PPE or got exposed for any reason. If you did use appropriate PPE, quarantine measures may not be required but testing is encouraged. Please contact your primary care provider for evaluation and assistance with testing and treatment, if needed.

Emory has established a hotline for employees who are symptomatic with what may be COVID-19 (404-71COVID). Because of community spread, we can no longer distinguish between workplace exposure and community exposure. By calling the hotline, you will be given an appointment for testing. Please identify yourself as being involved with essential research.

¹ <https://www.cdc.gov/coronavirus/2019-ncov/downloads/critical-workers-implementing-safety-practices.pdf>

MODIFICATIONS TO IRB PROTOCOLS:

- SOP's for personal protective equipment (PPE), and COVID-19 screening questionnaires, 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.
- Exception Requests: If a research study cannot adhere to the applicable safety guidelines for scientific or other 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 must still submit a modification (or "update") **to the Emory IRB** 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

Research Activity	Location	Guidelines
Verbal interaction with no physical contact <ul style="list-style-type: none">• Interviews• Focus groups• Behavioral tasks and observation• Education	Emory site	<ul style="list-style-type: none">• 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 not all parties can wear masks due to the nature of the research, then the PPE listed in <u>this EHSO guidance</u> must be used.• For research taking care in hospitals, inpatients should also use masks.• 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	<ul style="list-style-type: none">• Emory-research-driven gatherings shall not take place indoors

		<ul style="list-style-type: none"> • If your study must be conducted indoors, please submit an exemption via a modification submission and provide the cleaning and distancing policies of the location where the research will take place. • 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.
Physical contact or other procedures that require proximity	Emory or affiliated clinical space	In addition to following the guidelines above, Emory Healthcare (or affiliate) clinical guidelines must be followed (e.g. gloves, lab coats, surgical masks)
All	International	In addition to following Emory IRB guidelines, researchers must also comply with any more restrictive guidelines in the 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 of record to request an exception. Do not initiate research activities before the request has been reviewed and approved.

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?²

- Fever (higher than 100.4o F [38.0o C]) unexplained by a known non-COVID condition
- Cough unexplained by a known non-COVID condition
- Shortness of breath or difficulty breathing unexplained by a known non-COVID condition
- New loss of the sense of smell or taste unexplained by a known non-COVID condition
- Sore throat unexplained by a known non-COVID condition
- Chills unexplained by a known non-COVID condition
- Muscle pain or body aches not due to injury or strain unexplained by a known non-COVID condition
- Nausea or vomiting unexplained by a known non-COVID condition
- Diarrhea unexplained by a known non-COVID condition
- Fatigue unexplained by a known non-COVID condition
- Headache unexplained by a known non-COVID condition
- Congestion or runny nose unexplained by a known non-COVID condition

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

² <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>