

Georgia Institute of Technology IRB Guidelines

Resuming Non-Essential In-Person Human Subjects Research

For other Institute guidance related to resuming research and other activities on campus, see <https://research.gatech.edu/research-ramp-up>.

The IRB's primary focus in these guidelines is to protect human subject participants in research. They supplement the guidelines and policies of the Georgia Institute of Technology which are aimed at protecting the campus community, faculty, lab workers, students, staff, and other groups.

Approved dates for restarting different categories of Human Subjects Research:

- Verbal interaction with no physical contact: July 15th, 2020.
- Interaction with physical contact: July 15th, 2020.
- Research studies that take place in participant homes: July 15th, 2020.
- Research with adults ages 65 and up: October 30, 2020.
- Minors at the CABI facility: October 30, 2020.
- All research involving minors: March 29, 2021.
- International research studies: When appropriate to restart international research, investigators should submit restart plans to the full committee for review.

In-person non-essential human subjects research must at least adhere to the following Georgia Institute of Technology IRB guideline in order to resume once the Institute and applicable Unit and School allow for it.

Georgia Institute of Technology, schools, and units may require additional protections, or may require some or all human subjects research activities to cease depending on public health circumstances as the pandemic evolves.

The most protective measures among the CDC, State, Local, facility, and Georgia Tech's Environmental Health and Safety Office (EHS) guidelines must take precedence. If the Georgia Tech IRB is the reviewing IRB and the research will be conducted in a partner facility (e.g. Children's Healthcare of Atlanta, Emory, Grady, etc.) that has less restrictive policies, the Georgia Tech IRB guidance below will take precedence.

For collaborative efforts where an Inter-Institutional Agreement (IAA) exists, the IRB with oversight must work in conjunction with the facility where the research is performed to set the rules for restart. The reviewing IRB will establish the policies and procedures for restarting the research.

Be aware that Covid-19 EH&S training videos must be completed before returning to campus and in order to resume research activities: <https://ehs.gatech.edu/covid-19/training>.

GENERAL CONSIDERATIONS

- The IRB expects researchers to use **remote technologies such as video conferencing** to conduct research whenever possible.
- All in-person research must incorporate the recommended precautions as defined by the CDC (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>) and outlined in the Faculty and Staff Initial Return to Campus Planning Resources (<http://health.gatech.edu/tech-moving-forward>) and all existing orders from the governor of Georgia; this may include but is not limited to guidelines on physical distancing, disinfection, PPE (face coverings, masks, face shields), symptom screening, washing hands often, use of hand sanitizer, avoid touching eyes, nose and mouth, cover coughs and sneezes with a tissue or inner elbow).
- Details regarding PPE, spacing, and disinfection are available at EHS https://ehs.gatech.edu/sites/default/files/lab_ramp_up_guidance_checklist.pdf in the guidelines entitled “Laboratory Ramp Up Guidance” and the Georgia Tech Research Ramp-Up page <https://research.gatech.edu/research-ramp-up>. In particular, density measures appropriate to the current phase of research ramp-up must be observed. Density measures are defined per Institute guidance as the maximum density of people consistent with the current phase of the research ramp up plan and no greater than one person per 150sf (6 ft physical distancing).
- To minimize risk to research participants and researchers, 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. Both researchers and each research participant must complete the screening. The symptom screen and temperature check must be completed prior to in-person contact between a researcher and a participant.
 - The participant screening questionnaire must include information tailored to the reading/comprehension level of the potential participants, about risk factors for severe illness to allow participants to evaluate their individual risk.
 - The study team must encourage the participant to arrive alone for their appointment (except for minor research subjects). If the participant will need a caregiver or legal guardian/parent, the study team must also pre-screen and perform a temperature check of the caregiver or legal guardian/parent and inform the research staff in advance. It is important

to inform caregivers or legal guardian/parent that they will need to bring their own mask.

- Researchers, participants, caregivers (if applicable) and legal guardian/parent are required to participate in contact tracing. If any individual tests positive for COVID-19 within 14 days of being physically present in a Georgia Tech research facility, they must contact the contact person named in the consent form or Stamps Health Services to report the positive test result for COVID-19. If the contact person for the study is informed by a subject that they have tested positive for COVID-19, the information will be forwarded to Stamps Health Services. In accordance with Institute guidance, Stamps Health Services will notify the Georgia Department of Public Health for possible contact tracing.

MODIFICATIONS TO IRB PROTOCOLS

- Standard Operating Procedures (SOPs) 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 being used for research purposes. However, documentation that the screening took place should be maintained by the principal investigator. If it is not clear whether an activity is considered human subjects research, please contact the Office of Research Integrity Assurance.
- If revisions to existing IRB-approved procedures are needed (such as moving to the use of remote technologies), a modification amendment must be submitted to the IRB before proceeding with the modified protocol. Amendments are not required if the change only involves adding the use of PPEs by participants or a COVID 19 pre-screening questionnaire.
- Also, if a research study cannot adhere to the applicable safety guidelines for scientific reasons, the PI must request an exception to the safety guidelines by submitting a modification amendment to the IRB. The modification amendment 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	Georgia Institute of Technology	<ul style="list-style-type: none"> • On-campus in person human subjects research involving vulnerable populations is allowed at this time. Vulnerable populations relating to COVID-19 as defined by the CDC: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html • Schedule participants to avoid overlap and waiting time • Disinfect research area per EH&S guidelines between participants (https://www.ehs.gatech.edu/sites/default/files/lab_ramp_up_guidance_checklist.pdf) • Researchers and participants must wear surgical or cloth masks (or face shields depending on exposure to aerosols during research procedures or high intensity athletic procedures) 	<p>fMRI at the CABI must follow CABI facility procedures for human subjects research participants.</p> <p>Minors allowed</p> <p>Ages 65 and up allowed in-person on campus</p> <p>If participants must interact with or on equipment during the study, verbal instructions should be provided for correct operation, without direct physical contact. All</p>

		<ul style="list-style-type: none"> 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 Studies with participants must be held in separate dedicated spaces to avoid exposure to others PI's must adhere to the most protective guidelines regarding density, face covering, and physical distancing If offering snacks, they need to be individually wrapped servings. 	equipment must be sanitized after the study according to EH&S guidelines.
	Community/Field site	<ul style="list-style-type: none"> Georgia Tech-research-driven gatherings may take place outdoors if they follow State and Local recommendations: number of people, spacing, and face coverings. No contact is permitted between participants. During site visits or on-site observations, GT researchers must comply with host organization's Covid-19 guidelines in addition to GT IRB Guideline Requirements. 	<p>Georgia Tech researchers do not control the space, so risk is higher for noncompliance with guidelines.</p> <p>During on-site observations, GT researchers may observe daily behavior and activity as well as interacting with the host employee(s).</p>
Physical contact or other procedures that require close proximity	Georgia Tech or within research space in a collaborating Institution	In addition to the guidelines above, Georgia Tech laboratory guidelines issued by EH&S must be followed (e.g. gloves, lab coats, surgical masks, cleaning equipment, density measures/physical distancing)	Research must also adhere to the IRB guidelines of the collaborating institution.
Home-based study visits with individuals or households	Studies only requiring the installation of technologies in participant homes with minimal interaction in the home.	<ul style="list-style-type: none"> All home studies require IRB review before proceeding. Must follow the same Georgia Tech EHS guidelines for researchers. All materials brought into the home (e.g. technology, cameras, clipboards) must be sanitized directly before entering the home. Set up visit with participant, ask that only one person at most be present in space of installation. A mask and shoe covers must be worn at all times when in the home and hands should be washed/sanitized upon entering and leaving the home. All surfaces that have been touched within the home should be wiped down and disinfected after use. All researchers and home occupants must complete the COVID-19 pre-screening. Researchers should minimize face to face interaction with occupants; preferably limiting interaction to one adult occupant at a safe distance. Participants meet researchers outside and consent to the study. Researchers describe the installation procedures and ask participants for permission to enter homes to install the equipment. Participants either remain in a different room or outside during the estimated 45-minute install. If shipping research materials to participant homes, guidelines for cleaning and should be followed prior to shipping (see notes) 	If you intend to ship products and/or interventions related to human subjects research during this situation, Georgia Tech recommends the following process/order (approved by EH&S): Wipe/spray item with EPA-approved disinfectant and allow items to air dry, Wash hands, Pack items to ship, Ship items
	In-Home Studies	<ul style="list-style-type: none"> When meeting with participants in their homes for interviews and observations, researchers use medical-grade masks, gloves, shoe coverings, and protective suits. Participants will be required to use masks and gloves. In-home meetings will be limited to 45 minutes or less and will only include data that cannot be gathered by other means. 	
International Research	International	In addition to the Georgia Tech IRB guidelines for the above categories of research, researchers must also comply with any more restrictive guidelines in the country where the research is taking place and any additional safety requirements of the setting.	
Research involving children	Georgia Tech	In-person research with children is permitted	Minors participants are allowed on campus and in-person.
	Off-site	Researchers shall follow the guidelines and requirements of the facility where the research is taking place.	

Research involving older adults age 65 and up	Georgia Tech and off-site	Research involving participants age 65 and up is allowed. Researchers shall follow the guidelines and requirements of the facility where the research is taking place.	
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FREQUENTLY ASKED QUESTIONS

Q. What if a participant refuses to wear a mask or comply with 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, in the role of a researcher, cannot follow all the guidelines while conducting my in-person research activities?

- A. Submit a modification amendment to the IRB to determine if an exception can be made prior to resuming those activities.

Q. What if my international research is in a resource-poor settings and I cannot obtain the required PPE?

- A. At this time, the research may not resume.

Q. What if my research is conducted at museums, schools, hospitals, or other external partners?

- A. Researchers shall follow the guidelines and requirements of the facility where the research is taking place.

Q. What if a participant appears to be sick before or during a research interaction?

- A. Follow the GT guidelines (<http://health.gatech.edu/campus-guidelines>) as follows:

Step 1: Communicate

1. Notify the Principle Investigator and/or faculty member(s).
2. Email Stamps Health Services at covid19reporting@health.gatech.edu or call the Emergency Management Team within the Georgia Tech Police Department at 404.894.2500.
3. Inform the participant to contact their primary care doctor for guidance regarding medical evaluation.
4. Send the participant immediately home and if possible, have them avoid all public transportation, ridesharing, or taxis.

APPENDIX 1: MODIFICATION GUIDELINES FOR EXCEPTION REQUEST (MODIFICATION AMENDMENT)

1. Which specific safety precautions are impossible to perform while maintaining the integrity of the research activity?
2. Why is it not possible to comply with those precautions?
3. What proposed steps will be taken to mitigate risk in lieu of those precautions?
4. Does the research involve any populations that may be at heightened risk (e.g., immunocompromised individuals) if the safety precautions are not used?

APPENDIX 2: COVID-19 PRE-SCREENING QUESTIONNAIRE/SCRIPT

Appropriate screening questions should include the following, which could be modified to fit your specific participant population and the location of in-person interactions. Any YES answer should be considered a sufficient reason to postpone in-person visits for at least 14 days. If applicable, please also refer to your facility’s screening requirements.

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

Protocol #: _____ PI Last Name: _____

Subject ID: _____

Research Personnel’s Name: _____

Date, Time of Phone Screen: _____

Script for Research Staff:

“For health safety reasons, and to help prevent the spread of the Coronavirus, we are asking a few questions regarding how you are feeling and any cold or flu-like symptoms you may have, before you are scheduled for your research study”

Have you had any of the following within the past two weeks (14 days):

1. A fever (temperature over 100.4⁰ F or 38⁰ C)?
2. A loss of smell or taste?
3. A cough?
4. Muscle aches (those not associated with physical over-exertion)?
5. Sore throat?
6. Shortness of breath?
7. Chills?
8. A new or unusual headache?
9. Any gastrointestinal symptoms such as nausea/vomiting, diarrhea, loss of appetite?
10. Have you, or anyone you have been in close contact with, been diagnosed with Covid-19, or been placed on quarantine because of possible exposure to Covid-19?
11. Have you, or anyone you have been in close contact with, been in a workplace or other setting where someone has been diagnosed with Covid-19, or been placed on quarantine because of possible exposure to Covid-19?

12. Have you been asked to self-isolate or quarantine by a medical professional or a local public health official?
13. Have you traveled domestically to any other major cities within the US, or internationally within the last 14 days?

If any of the questions have been answered **YES**, the in-person visits should be postponed for 14 days.

“Out of an abundance of caution, we must reschedule your in-person appointment. You will be contacted by a member of the study team in 2-3 weeks.”

[If the subject has fever:] *“We recommend you self-quarantine (stay at home) and contact your healthcare provider. Thank you for your understanding.”*

If all answers have been answered **NO**, proceed to the next item.

14. Decisions about in person visits should be especially cautious for people at higher risk per public health recommendations. If any of the below describe you, you may wish to postpone your in person visit:
 - Older adults age 65 and over; and
 - People of all ages with underlying medical conditions, including but not limited to:
 - Heart disease/conditions, high blood pressure, chronic lung disease or moderate to severe asthma, severe obesity(body mass index of 40 or higher), diabetes, chronic kidney disease, or liver disease
 - Weakened immune system (immunocompromised)
 - Pregnant

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