

(Gradual) RETURN TO IN-PERSON HUMAN SUBJECTS RESEARCH

TEACHERS COLLEGE INSTITUTIONAL REVIEW BOARD

FALL 2021 GUIDE

Hello, research lab or center lead investigator. This document contains information for researchers who wish to resume in-person activities with human subjects on- or off-campus in the Fall 2021 semester.

You can disregard this document if you:

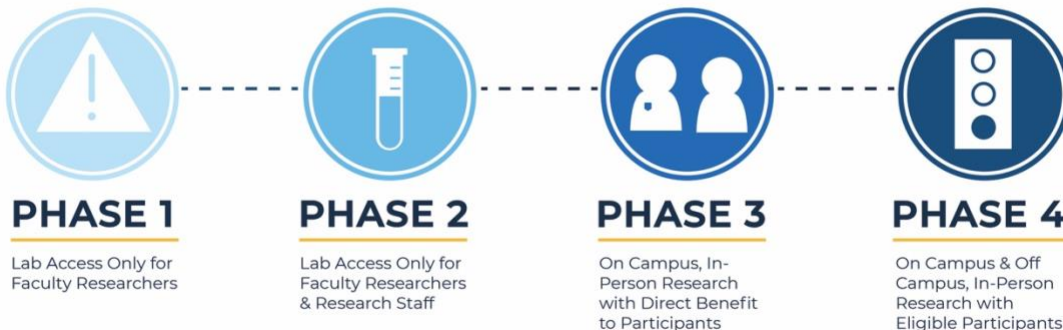
1. Are not a research lab or center lead, or
2. Do not plan to engage research participants in-person

The [TC Institutional Review Board \(TC IRB\)](#) office, in consultation with the [Research Compliance & Safety Committee \(RCSC\)](#), has moved [to Phase 3 for in-person data collection](#). Visit [this link](#) for a list of who is on the RCSC.

For COVID-19 research-related questions, please review Ethics Amid Uncertainty [FAQs](#), [TC's Ethics Amid Uncertainty: Moving to Phase 3 of the Research Ramp-Up](#), or "[Adapting Research in an Emergency](#)" before contacting the IRB office (IRB@tc.edu).

PHASED APPROACH TO RESEARCH RAMP UP

TEACHERS COLLEGE, COLUMBIA UNIVERSITY
RESEARCH RAMP-UP TASK FORCE



Please note, due to ongoing COVID-19 precautions, any study that *can* be conducted online or remotely should move forward with online procedures, and forgo in-person engagement.

Following guidance from New York State and Teachers College, the IRB is now reviewing proposals for in-person data collection on a case-by-case basis. The IRB is currently reviewing protocols that meet one or more of these parameters:

1. The study has direct benefit to research participants;
2. The in-person engagement is part of typical practice (e.g., a class already meeting in-person); and/or
3. The study cannot be carried out unless it is in-person (e.g., a physiological measurement study).

As a research lab or center lead, please review and follow these steps towards a safe return to in-person research with human participants.

- COMPLETE THE [JOB SAFETY ASSESSMENT \(JSA\)](#): The JSA identifies distinct tasks associated with each research group's work, analyzes the potential safety risks or hazards, and determines what Personal Protective Equipment (PPE) and other safety precautions are needed. Research lab or center leads who have not yet started their JSA should contact Patrick Mathelier, Director of Environmental Health and Safety, at ehs@tc.columbia.edu to schedule a JSA. Specify in your email to Mr. Mathelier that you are a researcher planning to engage in-person.
 - **Please complete a JSA prior to August 31, 2021 for a smooth Fall semester transition into in-person research.**
 - Acquiring PPE for your research activities will take time. Researchers should plan accordingly to comply with PPE requirements and fittings.
 - In some cases, the College may provide PPE. These inquiries are handled on a case-by-case basis. Please consult your department chair for guidance or contact ehs@tc.columbia.edu
 - [Contact the Office of Sponsored Programs \(OSP\)](#) for guidance about your research grant and acquiring PPE (sponsoredprograms@tc.columbia.edu).
- REQUIRED TRAINING: Have all research team members complete the "[Ethics & Safety Amid Uncertainty](#)" training modules via [TC's Preparedness website](#), and the [Return to Campus Training](#). Each team member should upload completion certificates to the TC Mentor IRB system under "Primary Investigator (PI) Documentation" (MyTC/Faculty Resources/Research Resources (*right hand side*)/Mentor IRB).
- RESEARCH SAFETY MONITOR: The research lab or center lead (and, if applicable, [other research personnel – excluding students](#)) should review and sign the [Research Safety Monitor Agreement](#). Upload the signed document to the Mentor IRB system under "PI Documentation."

- **SUBMIT AN IRB PROTOCOL FOR REVIEW:** Communicate with the [TC Institutional Review Board](#) about in-person research intentions by submitting either a [modification to an existing IRB protocol](#) or a [new IRB protocol for review](#). Please be sure to update consent (parent permission or assent) forms to include COVID-19 language (*templates are available in Mentor IRB, under "Documentation"*).
 - **Conducting Research On-Campus:** TC IRB will contact TC's Campus Re-Opening Group *after* your IRB protocol has been reviewed and approved. At that point, any final determinations will be made about site requirements for restarting in-person data collection on-campus. This may include conversations with [Environmental Health & Safety \(EHS\)](#); [Human Resources](#); [Office of Access and Services for Individuals with Disabilities](#); [Office of Public Safety](#); [Office of Facilities Management](#); or the [Office of Risk Management](#).
 - **Conducting Research Off-Campus:** If the study is off-campus and site dependent, please complete the "Off-Campus_Access Requirements_2021_TC IRB" document to compare off-campus site hygiene and safety requirements against TC's policies. Additionally, upload a site permission form with COVID-19 language, pending IRB approval (*required documents and templates are available in Mentor IRB, under "Documentation"*). A signed site permission form can be uploaded as a modification *after* the IRB protocol is approved.
- **CONTACT LIST & SAFETY PLAN:** For a guide on creating a safety plan, review the "Researcher Safety Assessment Guide_2020_TC IRB" document available in Mentor IRB, under "Documentation," and [for a sample contact list see this link](#). A safety plan should be specific to your research lab or center.
- **RESEARCH RAMP-DOWN:** Prepare a [Research Ramp-Down Plan](#) to support your research staff in the event that in-person engagement must be suspended due to updates about viral spread or other circumstances.

Resuming in-person study activities with human subjects



Please note, following these procedures *does not* automatically mean that you can engage human research participants in-person. **Remember, recruitment or research cannot begin until you receive a final IRB approval letter. IRB protocols will be reviewed on a case-by-case basis.** At this time, all proposed in-person research with human subjects will be [reviewed by the IRB Full Board](#), regardless of its review category.

For questions about human subjects research, contact IRB@tc.edu or visit the [TC Institutional Review Board's website](#). If you have questions about whether proposed safety/hygiene standards are Americans with Disabilities Act (ADA) compliant, contact [OASID](#) via email oasid@tc.edu.

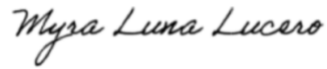
If possible, we encourage researchers to conduct research activities online (remotely) into the foreseeable future. Minimizing the density of in-person engagement is crucial for everyone's safety. **Please do not engage in a return to in-person research activities unless it is necessary for your work.**

We are aware that researchers may have concerns about COVID-19 vaccination status and how to handle situations when there is uncertainty about whether a research participant is COVID-19 vaccinated. We are discussing these important issues with experts and considering responses on a case-by-case basis. If you have questions, email IRB@tc.edu or [review this link for challenges concerning vaccinations](#).

We may need to adapt or change these procedures in response to new information or campus-wide changes. We will do our best to communicate openly, and researchers should reach out to the IRB office at any time with questions (IRB@tc.edu).

Thank you for your continued efforts to remain safe!

Best wishes,



Dr. Myra Luna-Lucero
Research Compliance Director
Research Compliance & Safety Committee Co-Chair



Dr. Karen Froud
IRB Chair
Research Compliance & Safety Committee Co-Chair