

Guidance for Resuming Research Involving Human Subjects

Revised as of April 12, 2021

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Introduction

This guidance is intended to assist researchers engaged in human subjects research projects, and should be read in conjunction with the information provided at the [UChicago Forward](#) page and in applicable unit research implementation plans. This document will be updated from time to time in accordance with University, local, state, or federal policy and relevant changes to the current understanding of the COVID-19 pandemic. This guidance applies to all human subjects research conducted during the COVID-19 pandemic, including research conducted off campus.

All investigators are required to undertake the training and complete an attestation regarding COVID-19 on the [UChicago Forward website](#).

The [UChicago Forward page](#) describes the levels of on-campus and off-campus research operations. Your dean can tell you the current level of research resumption for your unit.

Categories of Human Subjects Research

For the purposes of this guidance, human subjects research is divided into three categories based upon research activity, with specific considerations listed for each category. See Section 4 for a summary of restrictions that apply to categories #2 and #3.

- Category #1: Distance/remote research. This type of research does not involve any physical contact or proximity between the study team and the subjects. Examples of distance research are study procedures done online or via telephone.
- Category #2: In-person research that does not necessitate sustained close interaction with research subjects or equipment. This type of research is conducted in person without the involvement of medical equipment, machines, devices, drugs, or other study procedures that necessitate close proximity to the participants, or of participants to other participants. Any current physical distancing or other mandated requirements can be fully met while carrying out this type of research. Examples of Category #2 research include in-person surveys, interviews, ethnographic research, observations, or other conversations.
- Category #3: In-person research that necessitates close interaction of research subjects with the research team or equipment. There are two sub-categories of this research: 3.a) research that involves close interactions with equipment, but not with investigators or others—this type of research can still be accomplished without violating PPE and physical distancing requirements and with proper cleaning of equipment between subjects (i.e., no close contact with the research team or others, able to wear masks for the entirety of the activities), and 3b) research that necessitates close proximity of the research team (where physical distancing and/or proper PPE use cannot be maintained throughout the activities) or interactions with equipment that do not allow proper PPE use (e.g., masks must be removed).

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- 3a) Examples of activities that fall under this category can include research where any equipment or objects involved can be managed by the participant themselves, with investigators providing instructions/guidance while maintaining physical distance, and proper equipment cleaning and PPE use can be maintained throughout the activities (such as the participant being able to put on a wearable arm device, the participant being able to interact with an object/machine by themselves, etc.).
- 3b) Examples of this type of research include those that involve medical equipment, machines, devices, drugs, or other study procedures that necessitate close proximity of the researcher to the subjects. This type of research may present challenges to current physical distancing and spatial requirements that need additional consideration to manage. Examples of these studies include, but are not limited to, use of an fMRI, EKG, EEG, and use of sensors/equipment that must be attached to a participant by a member of the research team or necessitate the removal of masks. Most, but not all, studies in which there is supervised acquisition of a biosample (saliva, blood, stool, hair) will fall in this category. Entirely self-monitored acquisition of a sample (i.e., home collection of saliva, stool or blood spots) may fall under Category 2 or 3a research.

Guidance for Each Research Category

Category #1: Distance/remote research

This category of research does not present risks to subjects due to COVID-19 as there are no in-person activities. Therefore, this category of research may resume or continue and should be carried out remotely.

This type of research does not require a Research Resumption Plan.

Category #2: In-person research that does not necessitate sustained close interaction with research subjects or equipment

Note: any research that can be done under category #1 should continue in that manner—researchers should not propose to move back to in-person activities if the research can be conducted remotely.

This category of research requires approval of a Research Resumption Plan (see [Process for Research Resumption](#)), must adhere to the following restrictions, and any special measures required to follow the restrictions must be included in the Research Resumption Plan submitted via AURA for approval by the dean or their designee:

1. Research participants should follow visitor procedures as described on the [UChicago Forward](#) website.
2. Researchers must follow [University](#) and [CDC guidelines](#) with respect to physical distancing, proper personal protective equipment, personal hygiene, sanitation and disinfection procedures, self-monitoring, and reporting if you are sick.

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3. Participants should be provided with a COVID-19 Research Participant Information Sheet (included at the end of this document).
4. In-person interactions should be as brief as possible consistent with the study procedures.
5. The specific location(s) (including whether on- or off-campus) must be approved as part of the Research Resumption Plan or an approved amendment to a Research Resumption Plan.
6. The number of research personnel present during the interaction with the subject(s) should be limited to the minimum required to safely perform or assist with the interaction.
7. Prior to commencing in-person interactions, researchers should ask potential research subjects about potential COVID-19 infection or exposure. Currently, the following screening questions are recommended:
 - Do you currently have any symptoms known to be associated with COVID-19 as determined by the U.S. Centers for Disease Control and Prevention (CDC), and have you not had such symptoms within the past 10 days?
 - Do you currently have a positive COVID-19 test?
 - Have you been informed by a medical or public health entity that you have had close contact with a COVID-19 positive person?
 - Have you recently traveled to an area with widespread, ongoing transmission of COVID-19?
 - Are you currently required to self-quarantine to comply with any emergency travel order?

If the participant answers yes to any of the above screening questions the researcher must postpone the interaction.

Research subjects must also commit to following the University's other required COVID-19 mitigation measures, including:

- Maintaining a physical distance of at least six feet whenever possible when with others (and at least eight feet while eating or drinking indoors), and
- Washing hands with soap and water frequently, or using hand sanitizer when soap and water are not available.

Category #3: In-person research that necessitates close interaction of research subjects with the research team or equipment.

All of the guidance listed above for Category #2 must be met for research in Category #3. The following additional restrictions apply:

1. The protocols and practices associated with use of study equipment and study lab space must adhere not only to the policies specified by the institution at which the research is to be conducted (UChicago or any other) but also to any specified by the location (e.g., national, state, or local governmental requirements), facility, department, or institute at which the research is to be conducted.
2. When some or all of the research activities or procedures cannot be performed while following the University's guidance on mitigation measures (e.g., face coverings, physical distance, hand washing), before resuming research activities or procedures, the investigator must obtain explicit approval through their Research Resumption Plans that such activities or procedures are permitted despite the inability to comply with such guidance.
3. Additional information, such as a brochure or fact sheet, should be made available to prospective research subjects informing them about the current status of COVID-19, the potential risks for exposure, and the additional precautions that have been implemented by the research team to minimize the potential for exposure.
4. Research Resumption Plans subject to this guidance must include the following components:
 - What special attention or unique management plans are necessary for conducting the human subject research with regard to implementing hygiene, health, and safety practices? Consider physical distancing, potential for equipment failures, or adverse medical events unrelated to COVID-19.
 - How will any equipment used for the study be disinfected between research subjects (list product, contact time, frequency)? If a shared facility is involved, please reference the general facility SOPs and standards that are being followed.

Summary of Current Conditions and Restrictions Relevant to Category #2 and #3 Research

1. The University is currently prohibiting on-campus healthy human subjects research activities that fall under Category #3b that occur outside of the Medical Center.
2. On-campus research involving any in-person activities with healthy participants that fall under Category #2 or #3a may resume, if appropriate, with approved Research Resumption Plans. For those planning on-campus activities outside of the medical center, please see “Tips and Considerations for Resuming In-Person Interactions on Campus” at the end of this document.
3. Off-campus, in-person human subjects research is allowed as long as it adheres to international, domestic, and local travel and COVID-19 restrictions. It must be conducted following local regulations, other applicable governmental regulations, this guidance, and University procedures to mitigate health risks. A Research Resumption Plan detailing steps taken to follow these procedures must be submitted and approved.
4. Research that deviates from the University’s guidance on mitigating health risks may have to be discontinued.
5. If research participants refuse to comply with guidance on mitigating health risks, in-person activities should be discontinued.
6. Research that requires the collection of biospecimens using procedures different than in the approved protocol may need to be reviewed by the IBC and IRB. Any questions about required amendments should be directed to the IRB or IBC offices.
7. Research that requires behavioral data collection using procedures different than in the approved protocol may need to be reviewed by the IRB (e.g., switching from in-person to online; new use of recording devices; no longer being able to use a specified secure location for interviews because they now need to occur in a different location, etc.). Note that the use of COVID-19 screening and basic mitigation techniques (distance, PPE, etc.) do not need to be reviewed by the IRBs as a change in protocol unless the changes materially affect the approved conduct of the study. Any questions about required amendments should be directed to the relevant IRB office.
8. Researchers already at the intended site of research and not requiring travel may perform in-person human subjects research, as long as it follows local regulations, other applicable governmental regulations, this guidance, and University procedures to mitigate health risks. A Research Resumption Plan detailing steps taken to follow these procedures must be submitted and approved.
9. Who may be involved in research permitted under this guidance?
 - Faculty, researchers, postdocs, graduate students, and undergraduates may participate as a subject in an approved research activity if participation is consistent with the IRB-

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approved research protocol. All research participants are considered visitors for the purposes of resumption and should be treated accordingly and follow the procedures for visitors on the [UChicago Forward website](#).

- Off-campus visitors from the general public can also participate as long as specifically approved as part of the Research Resumption Plan.

COVID-19 Research Participant Information Sheet and Screening

Requirements for Face-to-Face Research Procedures

1. Researchers, research participants, and others involved in the in-person activities must answer no to all the following questions prior to in-person interactions:
 - Are you currently experiencing any of these symptoms?
 - Cough
 - Runny or stuffy nose
 - Shortness of breath
 - Headache
 - Fever
 - Difficulty breathing
 - Chills
 - Body aches
 - Sore throat
 - New loss of taste or smell
 - Nausea, vomiting or diarrhea
 - Have you recently been in contact with someone who recently acquired COVID-19?
 - Are you 65 year of age or older, immunocompromised, or have chronic health conditions.

If your response to any of the above question is yes, do not participate or continue your participation in the face-to-face procedures. Please contact the researcher to cancel your appointment.

2. A distance of six feet must be maintained between researchers and participants throughout in-person interactions, unless participation requires closer contact.
3. Surgical or cloth face coverings must be properly worn (over the nose and mouth) by researchers and participants throughout in-person interactions. Masks and other protective gear that may be needed will be provided to you by the researcher.
4. Research spaces and equipment, if any, are thoroughly cleaned and disinfected before and after in-person interactions according to the universal and University procedures.

5. If you participate in an in-person research study and within 14 days discover that you are COVID-19 positive, please contact the researcher with this information. This will help us identify others who may have been exposed to COVID-19 and provide recommendations to limit further spread of the virus.
6. If you have any safety concerns while participating in the research, you are highly encouraged to contact the IRB contact as listed on the consent form.

How to Protect Yourself and Others

Please follow the Center for Disease Control and Prevention (CDC) guidelines for protecting yourself and others.

- Wash your hands often
- Avoid close contact
- Cover your mouth and nose with a cloth face covering when around others
- Cover coughs and sneezes
- Clean and disinfect frequently touched surfaces daily.

For CDC Guidance regarding additional prevention measures, please see

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>. For extra precautions for high-risk people, see <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>. For additional information about COVID-19, see <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.