

# Guidance for Resuming Human Subjects Research

Revised Sept. 9, 2021

## 1. INTRODUCTION

This guidance is to be interpreted in the context of the [Plan for Phased Resumption of On-Campus Research](#), as well as any policies or restrictions specified by the individual facilities, institutes or departments, within Princeton or other institutions at which the research is conducted. This document will be revised in accordance with any relevant changes to guidance issued by Princeton University, or any relevant changes to the current understanding of the COVID-19 pandemic. This guidance applies to all on- and off-campus human subjects research conducted during the COVID-19 pandemic.

The [Plan for Phased Resumption of On-Campus Research](#) describes four levels of on-campus operation, which include 1 (normal operations), 2 (phased resumption), 3 (essential operations), and 4 (operations suspended). Princeton is currently in level 2.

## 2. CATEGORIES OF HUMAN SUBJECTS RESEARCH

This document divides human subjects research into three categories based upon research activity followed by specific restrictions for each category of research. The last section provides a summary of the restrictions that apply to research categories #2 and #3.

- **Category #1: Distance 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 phone.

- **Category #2: In-person research that does not necessitate 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 subjects. Any mandated requirements can be fully met while carrying out this type of research. Examples of Category #2 research include in-person surveys, ethnographic research, observations, or other conversations. This type of research may occur on-campus or off-campus.
- **Category #3: In-person research that necessitates close interaction of research subjects with the research team or equipment.** This type of research is conducted in person and with the involvement of medical equipment, machines, devices, drugs or other study procedures that necessitate close proximity of the researcher to the subjects. Examples of these studies include, but are not limited to, use of an fMRI, EKG, EEG, eye tracking or computer labs to gather data. Most, but not all, studies in which there is supervised acquisition of a biosample (saliva, blood, feces, hair) will fall in this category. Entirely self-monitored acquisition of a sample (i.e., home collection of saliva or blood spots) may fall under Category 2 research.

### **3. GUIDANCE FOR EACH RESEARCH CATEGORY**

#### **Category #1: Distance research**

This category of research does not present risks to subjects due to COVID-19. Therefore, this category of research can continue and may be carried out whether one is on or off campus.

#### **Category #2: In-person research that does not necessitate close interaction of research subjects with the research team or equipment**

This category of research may occur at on-campus locations or off campus. Regardless of location, all category #2 research must adhere to the following restrictions:

1. Researchers and research subjects must follow Environmental Health and Safety's [Guidelines for Safe Research During COVID-19 Pandemic](#) and the [Princeton University Health Services guidelines](#) for what to do if you are experiencing symptoms.
2. Consent forms must be modified to include the following statement of risk. This language is pre-approved by the IRB and can be implemented without submission of an amendment to the IRB:
  - ***“The study team has taken CDC and local public health authorities-suggested safety measures to minimize exposure to SARS-CoV-2 (the cause of COVID-19).”***
  - Note that with the exception of the modification to the informed consent language described above, changes to an approved IRB protocol must receive approval from the IRB prior to implementation.
  - Research subjects that have already consented do not need to provide new consent incorporating this language. In this case, researchers should verbally indicate to the research subject:
  - ***“The study team has taken CDC- and Princeton University-suggested safety measures to minimize exposure to SARS-CoV-2 (the cause of COVID-19).”***
3. In-person visits should be as brief as possible consistent with the study procedures.
4. The number of required research personnel present during the interaction with the subject(s) should be limited to the minimum required to perform or assist with the interaction.

5. If research subjects do not have the required PPE recommended by Environmental Health and Safety's [Guidelines for Safe Research During COVID-19 Pandemic](#), such PPE must be provided by the researcher to the research subject(s).

- **For on-campus category #2 research**

1. All restrictions outlined in 1-5 above must be followed.
2. Enrolled undergraduate and graduate students, postdocs, faculty, and staff, with permission to access University buildings can participate in human-subjects research, either as a researcher or as a research subject.
3. Researchers and research subjects must be in compliance with the University's COVID policies and guidance, including but not limited to vaccination, COVID-19 testing, face coverings, and visitors:
  - a. [Faculty and Staff Vaccination Requirement](#)
  - b. [Student Vaccination Requirement](#)
  - c. [Asymptomatic Testing Protocols](#)
  - d. [Face Coverings Policy](#)
  - e. [Visitor Policy](#)
  - f. [International student health related requirements and frequently asked questions](#)
4. Research subjects who are not considered enrolled students or employees of Princeton University are considered *Sponsored Visitors* as defined in section IV of the [Visitor Policy](#). Researchers sponsoring such visitors must follow the procedures outlined in the Visitor Policy under section V: [Procedures for Requesting Visitor Approval](#). Sponsors must fill out a Sponsored Visitor Request Form.

5. There may be research needs that involve non-Princeton research subjects (sponsored visitors), who are eligible for the vaccine but who have received an accommodation that they will not be vaccinated. Consistent with current visitor policy, these individuals may not enter campus buildings. Special consideration may be given on a case-by-case basis by contacting EHS at 609-258-9294 or via email at [ehs@princeton.edu](mailto:ehs@princeton.edu). Investigators must submit an amendment to the IRB to reflect the accommodations.
  6. Children who are not yet eligible for the vaccine may not participate in HSR until the required modifications to the relevant protocols are reviewed and approved by the IRB.
  7. Students or employees expect that research projects will be designed and implemented to encompass all of the health and safety measures required by the University in response to the COVID-19 pandemic and may not be coerced to work on or participate in research projects.
- **For off-campus category #2 research**
    - Any travel necessary to reach the off-campus location must be performed in compliance with [current University permissible travel guidelines](#).
    - Prior to commencing in-person interactions off-campus, researchers interacting with research subjects who are not part of Princeton University's testing program or using the Daily Symptom Check app for potential SARS-CoV-2 infection or exposure should screen potential research subjects with the following questions:
      - Do you have any of the following symptoms?
        - Fever greater than 100°F

- Cough
- Shortness of breath
- Loss of taste or smell
- Body aches or chills
- In the past 14 days, have you lived with, visited, cared for, or been in a room for a prolonged period of time (within 6 feet for 15 cumulative minutes during a 24-hour period) with someone who is being monitored or has been confirmed to have COVID-19?
- Have you recently had a test for COVID-19 that is still pending?
- If the research subject answers “yes” to any of the above screening questions the study staff member must cancel the study visit. Research subjects who exhibit symptoms consistent with COVID-19 disease must email University Health Services at [communityhealth@princeton.edu](mailto:communityhealth@princeton.edu) (Princeton University faculty, staff, postdocs, and students) or should be encouraged to consult with their medical provider (non-University people).

**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 (Princeton or any other) but also to any specified by the facility, department or institute at which the research is to be conducted.

2. 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. SUMMARY OF RESTRICTIONS**

1. Research that deviates from this guidance may need to be reviewed by the full IRB, which may delay implementation of the changes.
2. 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.
3. Off-campus, in-person, human-subjects research, both domestic and international, is allowed as long as it is conducted following local regulations, CDC recommendations, and this document's guidance.
4. University [international and domestic travel restrictions](#) are still in effect. Researchers already at the intended site of research may perform in-person human subjects research, as long as it is conducted following local regulations, CDC recommendations, and this document's guidance.
5. Who may be involved in research?
  - Enrolled undergraduate and graduate students, postdocs, faculty, and staff with permission to access University buildings are allowed to act as research subjects in on-campus research labs provided they are approved to be back on campus by the University, and follow the recommendations in Environmental Health and Safety's [Guidelines for Safe Research During COVID-19 Pandemic](#) and this guidance.
  - Enrolled undergraduate and graduate students, postdocs, faculty, and staff with permission to access University buildings are allowed to perform in-

person research on campus provided that they are under an approved IRB protocol, approved to be back on campus by the University, and follow the recommendations in Environmental Health and Safety's [Guidelines for Safe Research During COVID-19 Pandemic](#) and this guidance.

- Non-University personnel may be permitted to participate as research subjects as Sponsored Visitors (see definition in section IV) as defined in the [Visitor Policy](#). Researchers sponsoring such visitors must follow the procedures outlined in Section V: Procedures for Requesting Visitor Approval and must fill out a Sponsored Visitor Request Form. Other questions regarding visitor approval should be directed to EHS (609-258-9294, [ehs@princeton.edu](mailto:ehs@princeton.edu)).