APPENDIX 2
Guidance for Resuming Human Subjects Research
(Issued June 15, 2020)

1. Introduction

This guidance is to be interpreted in the context of the Plan for the 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 human subjects research conducted during the COVID-19 pandemic, including research conducted off campus. Please refer to Section 4, entitled “Summary of Current Conditions and Restrictions Relevant to Category #2 and #3 Research.”

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

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 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 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 current social 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, ethnographic research, observations, or other conversations.

- **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. This may present challenges to current social 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, 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 may continue and should be carried out remotely, without involving returning to on-campus laboratories.

Category #2: In-person research that does not necessitate close interaction of research subjects with the research team or equipment
This category of research must adhere to the following restrictions and any special measures required to do so must be included in the Research Laboratory Operations Plan (RLOP) submitted via SHIELD to the Office of the Dean for Research, following approval by the Department Chair:

1. Researchers must follow Environmental Health and Safety’s Guidelines for Safe Research During COVID-19 Pandemic and CDC guidelines on how to protect yourself and what to do if you are sick with respect to social distancing, proper personal protective equipment, personal hygiene, sanitation and disinfection procedures, self-monitoring and reporting.

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 all CDC-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 participant:

“The study team has taken all 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. Undergraduate students are not allowed to participate as researchers in on-campus laboratories, nor as research subjects on campus.

5. Off-campus visitors are not allowed to participate as subjects on campus.

6. 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.

7. Prior to commencing in-person interactions, researchers should screen potential research subjects for potential SARS-CoV-2 infection or exposure. Currently, the following screening questions are recommended:
   - In the past 14 days, have you traveled internationally?
• In the past 14 days, have you had any of the following symptoms?
  o Fever greater than 100°F
  o Cough
  o Shortness of breath
  o Loss of taste or smell

• 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 more than 10 minutes) with someone who is being monitored or has been confirmed to have COVID-19?

• If the participant answers “yes” to any of the above screening questions or currently has a skin temperature greater than 100°F the study staff member must cancel the study visit. Participants who exhibit symptoms consistent with COVID-19 disease must email University Health Services at communityhealth@princeton.edu (on-campus research) or should be encouraged to consult with their medical provider (off-campus research).

8. 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 participant. Subjects should wash their hands before and after a research interaction and wear an appropriate face covering.

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:

9. 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.

10. When research procedures cannot be performed while maintaining social distancing, the investigator must, before resuming research, obtain assurance from Environmental Health and Safety (ehs@princeton.edu) and the appropriate compliance committee (e.g., Institutional Biosafety Committee), that the added safety precautions are sound.

11. 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.

12. RLOPs subject to this guidance must include the following components:
  • 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.
● 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 social distancing, potential for equipment failures or adverse medical events unrelated to COVID-19.

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

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. Researcher must abide by University international and domestic travel restrictions.

5. Who may be involved in research?
   ● Undergraduates are not allowed to act as researchers or research subjects in on-campus labs.
   ● Once the University has moved to Level 2 for on-campus operations, faculty, researchers, post-docs and graduate students who are otherwise covered by an approved Research Lab Operations Plan may be eligible to participate as a subject in an approved research activity.
   ● Off-campus visitors cannot participate as human subjects.