

Restarting Research – Phase C –RU-N

In Person Human Subject Research

In Phase C, our goal is to gradually ramp up human subjects research at RU-N. The general RU-wide guidelines still apply. Notably, social distancing must be maintained, face coverings must be worn, and only approved personnel (with a negative COVID-19 test) are allowed in the buildings. Furthermore:

- The participation of staff, graduate student and postdoctoral associates is voluntary.
- Density in the research spaces must be kept below **75%**.
- Undergraduate students are allowed to participate only if they satisfy the stringent conditions outlined in separate guidelines.

Steps to resume the project:

- 1. Informal conversation with the Chair/Director.** Given the complex logistics associated with many human subject studies we strongly recommend that the PIs discuss their intent before they submit the online form and initiate the approval process.
- 2. Submission of the online form at:** <https://tinyurl.com/y47x3zjl>
- 3. IRB Approval.** IRB approval is **not** required **unless**:
 - The consent procedure is being moved fully online. PIs can avoid this by having at least some component of the consent procedure remain face to face.
 - Mask wearing is not feasible due to the nature of the study. In this case, the PI should explain the reason, and their proposed additional precautions in the PI/Project Approval form *before* submitting an amendment to the IRB. The sole exception to this rule is taking masks off inside the MRI scanner bore - this has been already approved by the IRB as part of the RUBIC common policies.
- 4. COVID-19 testing.** If you envision the need for regular COVID-19 testing of the personnel associated with the project, submit the request form to the RU TPAG at https://rutgers.account.box.com/login?redirect_url=https%3A%2F%2Frutgers.app.box.com%2Fs%2Ftjiftmzpjls14d9jphob4fq4ifxa690x
Note that the request is not likely to be approved if the conditions of the study can readily comply with the RU social distancing and face covering rules. TPAG will not provide testing for the subjects.

Human Subjects Procedures

In addition to the general RU guidelines, Laboratories must adhere to and enforce the following procedures for all Participants:

- Participants who are at increased risk of severe illness from COVID-19 (Appendix 1) are not allowed to enter the building.
- Participants aged 65 or over are not allowed to enter the building.

- **Screening on the Day Before Arrival:**
The Laboratory directs a participant to the online self-screening form at <https://tinyurl.com/y5bsfakf>
The form asks routine symptom questions, and screens for the risk of severe illness from COVID-19. The participant enters their Subject ID provided by the laboratory in this form.
Upon completion, the laboratory contact person receives an email copy of the form.
For participants without reliable access to the internet, this process can be replaced with a phone interview, using the same form, by a designated lab member.
- **Screening on Arrival:**
Participants contact the designated lab member who meets them at the building entrance. The lab member takes their forehead temperature and asks the same questions as on the online questionnaire. The participant signs the form.
- **Distancing:**
If the participant does not have a mask, lab personnel provide a surgical mask, which the participants must wear whenever they are within 6 ft. of people not belonging to their household and whenever in the public spaces of the building (hallways, restrooms, etc).
- **Hygiene:**
Lab personnel provide the participant with hand-disinfectant to be used on entering and leaving the building.
- **Cleaning Requirements:**
All commonly touched objects or surfaces must be cleaned following the procedures detailed in Appendix 2, before and after each visit. The cleaner must wear gloves, a mask, and preferably a face-shield or other eye protection.
- **Personnel Screening:**
Lab Personnel must self-screen (using the questionnaire and a thermometer) each day, before coming to the campus.

PIs whose projects need to deviate from these guidelines must provide justification during the approval process. While exceptions are unlikely to be granted for the current Phase C, we encourage PIs to submit their requests early to be ready for Phase D.

Participant concerns and feedback:

The participants, staff members, graduate students and postdocs must be informed that any concerns regarding the adherence to the RU COVID-19 safety protocols and social distancing rules should be submitted to Ms. Lisa Condobery at lisaj@newark.rutgers.edu The feedback will be kept confidential, however, verified violations will lead to the suspension of the project.

Appendix 1. Subjects at risk of severe illness from COVID-19

According to the CDC, medical conditions listed below are at increased risk. Subjects suffering from any of these conditions are not allowed to participate in human subjects research in Phase C. This list is current as of July 28th, 2020 and will be updated as CDC information changes.

Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
Cancer
Chronic kidney disease
COPD
Obesity (BMI _≥ 30)
Sickle cell disease
Solid organ transplantation
Type 2 diabetes mellitus

Source: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/evidence-table.html>

Appendix 2. Cleaning and Disinfection Protocols

This protocol provides guidelines for routine cleaning and disinfecting of common surfaces when there are NO presumed or confirmed case of COVID-19. Under these conditions, anyone can clean and disinfect using these protocols. In the event of a suspected or confirmed case of COVID-19, REHS should be consulted.

The CDC writes: “Cleaning is the necessary first step of any disinfection process. Cleaning removes organic matter, salts, and visible soils, all of which interfere with microbial inactivation. The physical action of scrubbing with detergents and surfactants and rinsing with water removes substantial numbers of microorganisms. If a surface is not cleaned first, the success of the disinfection process can be compromised”.

- **Cleaning solutions:**
 - Multi Surface Cleaning Products (Purell, Clorox Multi Surface Spray, etc.)
 - Soap and water
- **Disinfecting solutions**
 - Alcohol solutions with at least 70% ethanol or isopropanol content
 - EPA-registered household disinfectants
 - Products with EPA-approved emerging viral pathogens claims are listed at: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19>
 - Sodium hypochlorite (bleach) solution diluted with water
 - 5 tablespoons (1/3rd cup) of bleach per gallon of water
 - 4 teaspoons bleach per quart of water

Routine Cleaning/Disinfection Procedure

- Prior to disinfecting, soiled surfaces are cleaned with multi surface sprays or soap and water. Allow surfaces to air dry prior to disinfecting.
- Spray or wipe the surface with disinfectant solutions or sprays.
 - Follow manufacturer instructions on disinfection. Many solutions require that surfaces remain wet for a specified period of time, after which point they should be allowed to air dry.
 - Soft or porous surfaces should be cleaned with an EPA-approved disinfectant that is suitable for porous surfaces.
 - For electronics, such as tablets, touch screens, keyboards, remote controls, etc:
 - Consider putting a **wipeable cover** on electronics.
 - Follow manufacturer’s instruction for cleaning and disinfecting.
 - If no guidance, **use alcohol-based wipes or sprays containing at least 70% alcohol**. Dry the surfaces thoroughly.