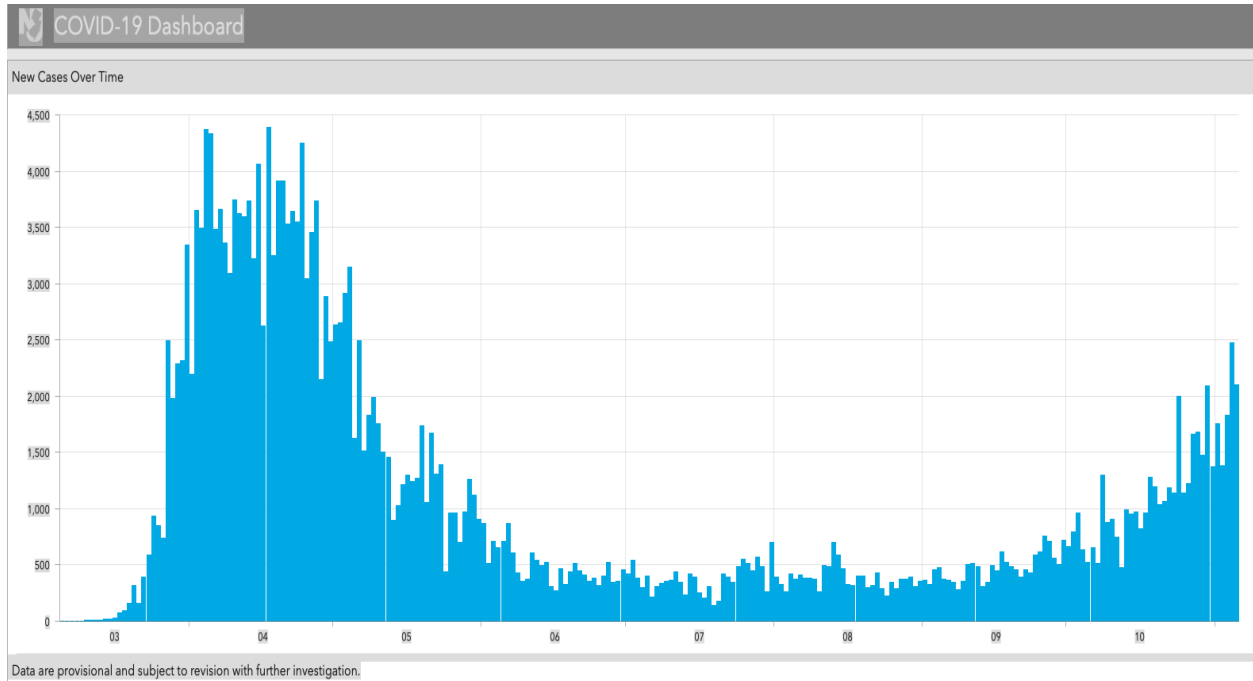


# Returning to Research at Rutgers University



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Emergency Operations Committee Research Team  
November 6, 2020

## Overview

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### **Introduction**

On March 25, Rutgers University restricted research to programs deemed “critical” as the COVID-19 pandemic rapidly spread through the tristate area. The ramp-down of research was necessarily rapid and was highly disruptive of important ongoing research. Herein is the plan to restore and repopulate research at Rutgers University as rapidly as feasible in a safe, sustainable and adaptable process. The guidelines below are specific for research; more general guidance has been provided in the *Returning to Rutgers* document (<https://ipo.rutgers.edu/sites/default/files/2020%200618%20Returning%20to%20Rutgers.pdf>), published June 18, 2020.

Research is foundational to Rutgers University’s mission, reputation and future. A commonality of shared values, effort and willingness to sacrifice for the greater good is likewise a cornerstone of our vigorous academic research culture. It has been inspiring to see these shared values and goals in practice during the urgent and discontinuous process of ramping down the research engine at the university. As eager as we all are to be back at full capacity, it will be critical that everyone exercise patience and flexibility because we cannot simply return to the way things were before COVID-19. We will almost certainly have to make changes to our plans as the process evolves, and will have to abide by the decisions made at the dean and chancellor levels that will allow us to gear up research as rapidly as possible.

Repopulating research must start from a grassroots level, taking into account the detail and context of individual research settings, laboratories, and facilities. The process has involved an online Return to Research survey to collect requests from individual investigators to ramp up their research activities, in an effort to provide sufficient information to enable the chair and research dean to review and assign priority. The prioritization from each campus is shared with the Office for Research and Economic Development for purposes of coordination.

The Research Team of the Emergency Operations Committee, convened by President Barchi, organized faculty advisory groups to identify and flesh out issues specific to research settings in social and behavioral sciences, humanities, agriculture, biomedical sciences, physical sciences, animal research and clinical research. Return to Research plans collected from the Principal Investigators have provided detailed insight into specific conditions in their research setting that will inform how research administrators within schools manage the safe return to research by disciplines from the humanities to clinical trials at affiliated hospitals.

The phased approach to returning to research, and overall considerations for returning to laboratories and other research environments at the university are below.

## Guiding Principles

The resumption of full-scale research at Rutgers University will be guided by:

- Compliance with relevant federal, state and local laws and Executive Orders
- Attention to the specific health conditions and risk factors of all individuals
- Desire to return all researchers to full capacity as soon as possible in a safe and sustainable manner
- Strategic use of scarce resources in staffing and operations to maximize impact for research and attract external funding
- Ability to respond effectively to new developments in the COVID-19 pandemic
- Action in a coordinated way across the university chancellor units

## Safety

- Safety is a shared responsibility across the entire university community. Meticulous community adherence to public health practices including hand hygiene, physical distancing, proper cough/sneeze etiquette, disinfection of common and high traffic areas, symptom assessment and face covering in public will be the new normal at Rutgers University.
- COVID-19 safety training, equipment use and procedure training will be completed by all personnel.
- Protective equipment commensurate with COVID-19 exposure risk is mandatory regardless of pre-pandemic safety protocols in each lab. Protective equipment includes the following:
  - Researchers will wear a face covering at all times while on campus
  - Lab coats will be required while in the laboratory
  - Gloves and other appropriate protective equipment that is fit to purpose for the specific research will be provided by the individual laboratories
  - Gloves, masks and lab coats are required to enter the vivaria
  - Wipes and disinfectant will be available in university research buildings.
  - Disinfection of common equipment and benches must follow each use.
- Social distancing will be strictly enforced:
  - During the Phase B and C of repopulation, guidance is set at one researcher per 150 square feet in order to maintain a minimum 6 foot spacing between individuals
  - Scheduling may be required to avoid high density in laboratories
  - Scheduling will be enforced for high density areas such as common rooms and core facilities
  - Appropriate protective equipment and distancing between researchers and human subjects must be strictly enforced





## Personnel

- During Phase B (“50%”) and Phase C (“75%”), return to campus is voluntary.
- Personnel should stay home as much as their responsibilities allow; when on-site, strict interpersonal distancing is required. All research activities that can be done remotely, must be done remotely (lab meetings, data analyses, etc.).
- Personal factors should be considered in initial return-to-work scheduling: need for public transportation, family responsibilities (dependent care, etc.), personal health, etc. The following factors have been identified by the CDC to place individuals at higher risk for severe illness from COVID-19: 65 years and older, chronic lung disease or moderate to severe asthma, serious heart conditions, immunocompromised, body mass index  $\geq$  40, diabetes, chronic kidney disease with dialysis, and liver disease. Colleagues at risk are strongly advised to avoid on-campus research if possible during phases B and C of repopulation (“50%” and “75%”).
- Special consideration should be given to the career needs of Early Stage Investigators and late stage pre- and postdoctoral trainees.
- Return of research personnel will be staggered to assure no more than a 25% at each stage, with 2-4 weeks separating stages.

## Managing potential CoV-2 infection

- Testing and Tracking  
Researchers will be evaluated for active SARS CoV-2 infection using RUCDR’s saliva test; researchers with a negative test result who have fulfilled other requirements (**safety training video; attestation for trainees**) will be permitted to return to campus. The test kits are sent to researchers’ home addresses following completion of the Return to Research survey form (which also has a link to the safety video).  
Researchers should practice daily symptom self-monitoring. Symptoms of potential COVID-19 infection include: fever, cough, shortness of breath, sore throat, loss of taste or smell, congestion, chills, muscle pain, runny nose.
- Once active on campus, all researchers will be required to undergo periodic follow-up testing, which can be conducted at Rutgers testing sites on several campuses.
- Active illness management should follow CDC guidelines and advice of an employee’s physician. See the “Employee Screening” paragraphs in the **Administrative Functions** portion of *Returning to Rutgers*.

## Returning to Research in a safe and phased manner

	Phase A "25%" capacity/density	Phase B "50%" capacity/density	Phase C "75%" capacity/density	Phase D "post-COVID" 100%
Phase change triggered by course of pandemic				
Aspirational Timeline	May	June	July/August	?

### Phase A (lockdown mode)

Essential personnel have been on site since Phase A, and designated critical on-site research studies including COVID-19 research, clinical trials and maintenance have continued during this phase. All other non-critical research activity has been conducted remotely. During this period the State of New Jersey and University "Stay-At-Home" advisories were in place.

### Phases B-C (thoughtful repopulation of research settings)

Existing basic science, social science, humanities and new clinical research will be permitted to restart as associated non-essential personnel are scheduled to return on-site during this phase of workforce re-entry. Covid-19 testing will be available for all personnel returning during these phases

### Phase D (return to a "new" normal)

All research may recommence without restriction and all personnel may return to campus when we reach this final phase of workforce re-entry. Research performed remotely may now continue on-site; including all research involving direct interaction with human subjects and community outreach; out-of-state and international research may resume as dictated by university and individual state/country regulations.

## Implementation Process and Timelines

In evaluating specific requests to return to research, prioritization by the chairs and deans should consider a number of factors: early stage investigators, research required for 2020 grant submissions and/or near complete manuscripts, graduate student and postdoctoral fellow needs, availability and need for animal care, access to core facilities, etc.

### Timelines for critical activities:

Return to Research form sent to faculty  
 Complete prioritization by chairs and deans  
 Phase B: Repopulate research to *ca.* 50% capacity begins  
 Phase C: Repopulate research to *ca.* 75% capacity begins  
 Phase D: Repopulate research to 100% capacity begins

May 29<sup>th</sup>  
 June 12<sup>th</sup>  
 week of June 22<sup>nd</sup>  
 July-August  
 TBD - requires sustained safety at Phase C; without risk of viral resurgence

- Principal Investigators begin to develop their plans for resuming research and submit to their chairs through the Return to Research survey distributed the week of May 25<sup>th</sup>.
- Principal Investigators develop a plan for ordering and receiving supplies and reagents necessary for sustaining research before ramping up.
- Designated academic leadership (i.e. Chairs, Institute Directors, Research Deans) evaluate ramp-up plans for laboratories, common areas and cores; ongoing operations and compliance for assigned labs and for common use must be managed locally.
- Schools develop plans to control population density, pedestrian flow and social distancing as per Rutgers guidelines. In parallel, facility administrators contact IP&O and REHS to coordinate staffing, cleaning and disinfecting and any modifications necessitated by the new university guidelines.
- Ramp-up plans must take relevant dependencies into account (security, core facilities, support infrastructure, shared spaces, etc.).

### **Conditions for Return of Research to Campus**

Our actions affect not only ourselves, but our colleagues and the communities in which we live. These guidelines have been designed to protect each researcher individually, and also the health and safety of the entire university and of the state. Failure to comply with these guidelines could result in local surges of infection, which may in turn necessitate the ramping down of research within that local department or building.

- **Wear face coverings whenever inside a university building or other research facility, except when alone in a private office.** See the “Face Coverings” paragraphs in the **Administrative Functions** portion of this document.
- **Maintain 6-foot physical separation between all individuals.** In the rare cases in which this is not possible, those situations should be kept to the shortest time possible
- **Work together to de-densify research facilities to no more than one person per every 150 square feet in the initial phase of repopulation.** Steps to achieve this include limiting the number of people permitted in a facility at any one time, working in shifts, and scheduling shared facilities and equipment. Sometimes a density of no more than one person per every 150 square feet cannot be maintained. Incidental encounters with other people (e.g., passing in a hallway) are unavoidable, but should be reduced whenever possible, for example, by not sharing passenger elevators and limiting the number of people in restrooms and other common areas.
- **Use appropriate protective equipment as required by the specific nature of the research activity.**
- **Clean research equipment and “high-touch” surfaces in shared spaces.** Shared equipment should be cleaned by each user, using appropriate disinfectants provided by the university, both before use begins and after it is completed. Similarly, researchers

should frequently clean “high-touch” surfaces (e.g., door handles, drawer handles, faucets, etc.) in shared spaces. The university will increase regular cleaning of common areas, but not scientific or other specialized equipment.

- **Maintain good personal hygiene.** This includes washing hands for at least 20 seconds with antibacterial soap upon entering and before exiting all buildings regularly throughout the day and, using hand sanitizer when hand-washing facilities are unavailable, and covering coughs and sneezes.
- **Ensure symptomatic colleagues stay or return home as soon as symptoms (e.g., fever, cough, difficulty breathing) develop.**
- **Comply with the [daily symptom check protocol](#)** as described in *Returning to Rutgers*.
- **Comply with the university’s policy and applicable law on testing for COVID-19, tracing people who may have been exposed to it, and quarantining people who test positive for COVID-19 or who are likely to have been exposed to it.**
- **Participate in a “buddy” safety system** so that any researcher working alone in a research facility in which dangerous chemicals, equipment, or other material are used has an identified “buddy” working elsewhere in the building or who is in contact electronically and is aware of the researcher’s presence in the facility.
- **For field work and other research conducted in facilities under the control of an entity other than RU, researchers must comply with the policies of that third party and with applicable law in that jurisdiction, in addition to these guidelines.**
- **Changing COVID-19 conditions may require re-activation of ramp-down measures.**

## **Trainees**

Students are critical to research at Rutgers, and research plays an important role in their education, especially for graduate students. However, students also pose special concerns.

### **Guidelines for undergraduate research in Fall 2020 are:**

- Undergraduate Junior or Senior students may work in a research laboratory if they meet all of the following criteria and are approved by the Research Advisor:
  - Laboratory research credits are necessary to avoid a delay in time to degree or thesis completion,
  - The student’s academic advisor or undergraduate program director endorses participation on the research activity, and

- The research can be conducted safely as endorsed by the Research Advisor and department chair.
- No student should be required or pressured to participate in on-campus research during the COVID-19 pandemic.
- Graduate students may participate in on-campus research consistent with these guidelines. Graduate students should consult as appropriate with their faculty supervisors and/or graduate program advisors. Permission to participate in on-campus research is requested and granted as part of the Principal Investigator's Return to Research request.
- Graduate students returning in Phase B must complete the attestation provided in the Return to Research email.
- During the summer of 2020, undergraduates will not be permitted to participate in on-campus research.

### **Visiting Researchers/Scholars**

Visiting researchers are permitted in university research and other facilities provided they:

- Abide by all RU safety protocols & testing cadence
- Are approved by the appropriate chair and research
- Have at least a Bachelor's degree + one year or greater experience if in a research setting

"Visiting Researchers/Scholars" could include e.g., Fulbright Scholars, humanities and social sciences researchers.

### **Visitors**

- With the exception of visiting scholars, all other visitors must be registered daily in the Rutgers Visitors Log by their faculty invitee.
- Visitors from other academic institutions who are coming to campus for a short-term project (defined as one week or less) do not have to go through the Rutgers Return to Research process, must should adhere to the process outlined at their own institution as well as other Rutgers health safety guidelines. These visitors will also have to provide evidence of a negative COVID test that has been taken within a week of their arrival on campus.
- Visitors who are performing specialized services such as repairing equipment or providing training are permitted in university research facilities provided they comply with these guidelines.



- Visitors who are making deliveries should remain outside of labs or other research spaces to the greatest extent possible; buildings housing research facilities should designate spaces to receive deliveries and from which researchers may collect those deliveries.
- Casual visitors and researcher friends and family members are not permitted in university research facilities.

### **Research Involving Human or Animal Subjects**

Research involving animal or human research subjects must also comply with the requirements of Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), and Institutional Biosafety Committee (IBC) protocols, and any special guidelines that those committees issue.

### **Travel**

Travel related to research is controlled by the Rutgers University travel policy, which currently does not permit either out-of-state domestic or international travel. This policy is reviewed periodically.

Local (in-state) travel to field sites or other research facilities is permitted, provided that these guidelines are followed to the extent possible.

### **Research Pause or Wind-down Plans**

Researchers should be aware that there may be a need to pause or wind down on-campus research in the future in response to new information about COVID-19, new outbreaks, or changes in the capacity of our communities to respond. Principal Investigators resuming research under the current guidelines should have in place a plan for the orderly reduction or cessation of on-campus research on a temporary or long-term basis.

### **Awareness and Training**

All researchers conducting research on campus should be familiar with the requirements of these guidelines. PIs bear responsibility for compliance with these guidelines throughout their research teams and facilities, and academic units (e.g., schools, departments, centers, institutes) also have additional responsibility for oversight and support.

Training materials and sessions for the safe post-COVID return to research will be provided by REHS.

Up-to-date information will be available at the REHS website (<https://ipo.rutgers.edu/rehs>).

## **Enforcement**

Rutgers University expects all researchers to comply fully with these guidelines to protect the health of each other and our broader communities. Principal Investigators bear additional responsibility for compliance with these guidelines throughout their research teams and facilities, and must lead by example.

Persons observing noncompliance with these guidelines should address it as appropriate and possible, either with the individual(s) involved, the department chair, Dean, Vice Chancellor for Research or Senior Vice President for Research. Complaints may be made anonymously through the University Ethics and Compliance reporting system at <https://uec.rutgers.edu/compliance-hotline/>

# **Guidelines for Clinical and Field-Based Research During COVID-19**

*(from the Subcommittee on Field Research, Social & Behavioral Sciences & Humanities)*

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## **Primary Goal**

The primary goal of this document is to provide general guidance for the resumption of clinical and field-based research at Rutgers University while protecting the health and well-being of all Rutgers faculty, students, staff, research participants, collaborators, and community.

## **Guiding Principles**

**Safety First:** The responsibility for the safety, health and wellbeing of all research faculty and staff at Rutgers University, and the communities we serve, is shared among all University personnel across all schools and research facilities. During COVID-19 the health and safety of researchers, staff, and research participants is served by adherence to a minimum of five guidelines:

- **Wear a Facial Mask** – Use facial covering when coming into contact with any other person in an office, building, lab, and/or the field.
- **Practice Personal Hygiene** – Do not touch your face, wash hands regularly, wear gloves and/or regularly use a hand sanitizer that contains at least 60% alcohol. Wash one’s hands when coming into contact with another person.
- **Maintain Protective (Social) Distance** – Maintain six feet distance from all other people.
- **Perform Health Monitoring** – Do not come to work when sick (including when suffering from an elevated temperature); Send people home if they exhibit symptoms.
- **Disinfect Work Areas** – Using appropriate cleaners and regularly disinfecting one’s workstation, lab, office, supplies, books, and equipment.

**Remote Operations:** During the initial ramp-up, all research activities that can be done remotely, will be done remotely. For example:

- Trials where in-person visits can be eliminated or conducted remotely via telemedicine and investigational meds can be delivered to the participant’s home.
- Non-interventional research where research participants do not need to come on campus and research staff can effectively execute the research activities remotely without direct contact with participants.
- Non-laboratory studies that can be performed remotely

**On-Going Changes:** Please expect these guidelines to evolve in response to changes in science and circumstances.

**Training:** All involved personnel, including external monitors, must take COVID-19 safety training ([https://myrehs.rutgers.edu/online\\_training/covid19/](https://myrehs.rutgers.edu/online_training/covid19/)) prior to resuming on-site activities.

**Research Ramp-Up Phases A-D:** Ramp-up is based on the nature of the research protocol and current public health conditions; reviews and approvals will be made by Department Chairs/ Institute Directors, then Research Deans (or equivalent) and the research regulatory office for final determination/validation.

**Local Governance and Decision Making:** Ongoing operations and compliance activities for all offices, labs, clinics, hospitals, and other on-site space used for research (including clinical labs and common areas) will be managed locally (i.e. by PIs, Clinical Department Chairs/ Institute Directors) under appropriate safety guidelines.

**Voluntary Nature of Resumption of Research:** Faculty, students, and staff must not be compelled to engage in research activities that they are not comfortable with until restrictions on research are removed (Phase D). Rutgers faculty researchers will inform their staff that they have the right to refuse to engage in activities that could expose them to the public and obtain positive consent of their willingness to assume the risks involved.

**Questions or Concerns:** Researchers with questions or concerns associated with the resumption of research should consult with the principal investigator. In the event this is not satisfactory, s/he may also contact the Chair of the Department, Dean of the School, Director of the Research Center, University Human Relations, REHS, University Ethics & Compliance and/or the Office of the Senior Vice President for Research and Economic Development.

**Potential Disruption:** All research faculty and staff should keep in mind that an increase in COVID-19 infections may require rapid ramp-down of certain research activities with relatively short notice.

## Tools

The primary defense against COVID-19 infection and spread include education, personal hygiene (especially proper hand-washing), disinfection, the use of appropriate personal protective equipment (PPE) and/or facial covering, and social distancing.

## Scope

This document provides only general guidelines for the resumption of clinical, social, behavioral, and humanities research at Rutgers University during the COVID-19 pandemic. ***This guidance does not and cannot address all of the activity-specific and location-specific challenges, circumstances and scenarios that Rutgers' research teams will encounter. These guidelines are provided as general guidance intended to help research faculty and administration develop project-specific strategies to undertake research in a manner that protects the health and safety of all involved during the COVID-19 pandemic.*** Such strategies should seek the highest level of compliance with the guidance provided in this document. Faculty must work with their department chairs and deans to ensure that for each research project they develop strategies that ensure the highest possible compliance with the requirements of these general guidelines. These guidelines cover all persons involved in Rutgers research including but not limited to

faculty, post-doctoral students, undergraduates, graduate students, research participants, Community-Based Participatory Research (CBPR) members, vendors and collaborators. Research personnel across each of the four campuses are expected to follow the requirements and guidelines in this document.

These requirements and guidelines are to complement and read consistent with the University's Policy for Human Subjects Protection and the Institutional Review Board (<https://policies.rutgers.edu/90211-currentpdf>).

## Venue

These general guidelines will govern all clinical, social, behavioral, and humanities research that is conducted in-person at Rutgers University researchers including field research (research that takes place wholly or in part in public spaces, community agencies, schools other than Rutgers, archives, libraries, museums, hospitals and clinics, and private homes), Rutgers' labs and offices, as well as research that is out-of-state and international. University researchers include faculty, staff, and graduate and undergraduate students.

## Implementation

*In collaboration with their department chairs and deans, faculty must develop strategies specific to their research that ensure the highest possible compliance with the requirements of these guidelines.* When changes occur to the research/circumstances that impact compliance with these guidelines, these strategies should be changed accordingly and in a timely manner. Such strategies should be formally discussed with department chairs and/or deans. Issues that cannot be resolved (or questions that cannot be answered) at the department or school level should be escalated to the campus Vice Chancellor for Research and/or the Office of the Senior Vice President for Research and Economic Development.

## Governance

Everyone engaged in the conduct of research is responsible for adhering to these requirements and guidelines. This includes but is not limited to all individuals who are defined as principal investigators and key personnel on a research protocol (<https://orra.rutgers.edu/researchroles>). It additionally includes department chairs and deans, who also bear responsibility for ensuring that these guidelines are adhered to.

## Questions:

- Questions related to these guidelines or their implementation (such as the application of facial covering, the use of PPE, appropriate social distancing, monitoring of health, and disinfection of workspace, supplies and/or equipment) should be forwarded to the *Rutgers Environmental, Health and Safety Office*.
- Questions related to the ethical impact that adherence to these guidelines may have on research participants or changes to the research protocol should be forwarded to the *Rutgers Institutional Review Board*. See also the memo issued by the IRB (below)

entitled *Guidance to Human Subjects Researchers on Ramping-Up Research: When to Submit Protocol Modification to the IRB and When Not To*.

All other questions or issues can be forwarded to the Office of the Senior Vice President for Research and Economic Development, who has the final authority to interpret these guidelines and judge the effectiveness of their implementation.

## **Human Subject Research - Ramp-Up Phases**

### **Phase A**

Critical on-site research and remote research activity performed with essential personnel. Please note that during this period the State's and the University's "Stay-At-Home" general advisories remain in place.

1. Essential Clinical Trials and Research
  - a. New and existing clinical trials and research that have the clear prospect of benefit for patients or research participants with life threatening or serious conditions.
  - b. In-person study visits required to assess safety of patients who were enrolled in clinical trials or research prior to the pandemic.
  - c. New and existing clinical trials where enrollment into the trial is the only available treatment option for the patient.
2. COVID Clinical Research  
Includes treatment trials, observational trials, and data collection protocols.
3. Ramped-Up Clinical Care Generated Trials – New and existing clinical trials and non-interventional clinical research can occur during inpatient stays and during patients' regularly scheduled outpatient visit if only essential personnel are performing the research activities. Non-essential personnel may not return to campus to perform this research at this time, but this might change in the future. The PI and the Department Chair/Institute Director must also confirm that all other research-specific services are available to execute the trial.

### **Phases B-C**

Existing and new clinical research will be permitted to restart as associated non-essential personnel are permitted to return on-site during this phase of workforce re-entry. The enhanced safety requirements in phases B and C may require additional consultation and approval from REHS or the IRB.

1. Existing observational and interventional clinical trials and other clinical studies from all sponsors that do not meet the criteria defined in Phase A.
2. Existing research in the social and behavioral sciences and humanities from all sponsors that do not meet the criteria defined in Phase A.

### **Phase D**

All clinical research and all personnel without restriction will recommence during this phase of workforce re-entry. Research performed remotely may now continue on-site. Finally, all out-of-state and international research may resume.

## General Policy as Applied to Human Subjects Research

Plans to resume research at Rutgers University should include a combination of work at home and essential research that can only be performed on-site or in the field. All faculty are encouraged to consider changes to their research that will minimize (or if possible, eliminate) face-to-face interactions and maximize on-line, remote activity. Strategies to resume on campus and field research should include:

- **Instructions** that are communicated to all persons involved in the research prior to entering the field. Such instructions will include information on PPE (or facial covering) acquisition and use, the use of disinfectants, social distancing, and the reporting of adverse incidents.
- **Schedules** to help stagger work assignments and work locations to allow for appropriate physical distancing.
- **Specified work spaces**, when possible, to minimize direct contact between staff or contact with materials or surfaces touched by others.
- **Contingency plans** for carrying on research if one or more personnel become sick or is no longer willing to work on site.

## Health of Personnel

- Any person who has experienced potential COVID-19 symptoms<sup>1</sup> during the past 14 days should contact their physician and Occupational Health to determine their fitness to return to research.
- All health-related information shared by a Rutgers employee with his/her supervisor or colleagues should be treated as confidential protected health information (PHI) and shared only with the appropriate Rutgers staff on a need-to-know basis.

## Personal Protective Equipment (PPE)

- All research staff will use facial covering while they are working in the office, lab, field, or have the possibility of contact with any other human person. (Contact is defined as standing less than 6 feet away from another human being for longer than fifteen minutes; facial covering includes surgical, cloth or dust masks.
- Facial covering will be provided to all Rutgers research staff.
- Researcher may also use their own cloth-based facial covering.
- Disposable masks must be discarded when soiled or damaged. Reusable cloth face covering must be regularly cleaned by the wearer.
- Individuals must ensure that they do not contaminate their face covering by incidental contact with contaminated hands or gloves.
- Individuals must ensure proper hygiene when donning and doffing their face covering.

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<sup>1</sup> Symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

- Individuals should use gloves as required for clinical work or for working with chemicals or other reagents. Gloves must not be used outside of the laboratory or clinical setting, and they must be properly discarded after use.
- A mask, shield, or other form of barrier is required when dealing with research subjects. For example, during interviews - whether on the street or in an office/lab.

### Safe Distancing

- Protective (social) distancing is defined as standing 6 to 10 feet away from other people.
  - If interactions need to take place in person, they will be conducted with a minimum separation distance of 6 feet.
  - Within buildings, individuals must work at least 6 feet apart in all directions.
  - In order to minimize direct contact between/among staff or contact with materials or surfaces by more than one person, field staff should be "permanently" assigned to specific work spaces whenever possible.
  - Use appropriate disinfectant to clean your assigned space before, during, and after use.

### Hand Washing

- Wash hands upon arrival, at each break, and at the end of the work day.
- Wash your hands with soap and water for at least 20 seconds especially after you have been in a public place, dealing with a research participant, or after blowing your nose, coughing, or sneezing. (Cough or sneeze into your elbow as recommended by the CDC.)
- If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol.
- When using sanitizer cover all surfaces of your hands and rub them together until they feel dry.
- Avoid touching your eyes, nose, and mouth with unwashed hands.

### Disinfection

- A daily checklist of what needs to be disinfected is highly recommended.
- Everyone is expected to have hand sanitizer and disinfectant. Hand sanitizer may be used when hand washing is not possible.
- Daily disinfecting is recommended for commonly touched surfaces, for example, desk tops, telephones, computer and technical equipment keyboards, door handles, toilet handles, tools, steering wheels and hand controls of vehicles/tractors, including farm equipment.
- Disinfect surfaces following best practices (60% alcohol or other EPA approved disinfectants). Wipe surface with disinfecting wipe or spray disinfectant on paper towel and then wipe on surfaces. Allow surface to air dry for 10 minutes. Discard paper towel in trash.



- Wash hands immediately after disinfecting surfaces and after any potential exposure.
- All research teams should supplement typical janitorial cleaning with additional sanitation of workspaces and equipment.

### Field Equipment and Supplies

- Whenever possible, all necessary field research equipment and supplies will be assigned to specific individuals and labeled with that user's name for the duration of the field season.
- No sharing of equipment or supplies will be permitted once they are distributed and assigned to individuals.
- When not being used, equipment and supplies will be stored in a user's personal vehicle or personal storage space.
- If possible, all newly acquired supplies will be disinfected (thoroughly cleaned).
- Some field/farm experiments require the use of machinery.
- When possible, a single person should operate the equipment.
- If two individuals are needed, practice physical distancing.
- If physical distancing is not possible, plexiglass shielding will be installed between individuals to provide a physical barrier; personnel will also wear facial covering.

### Library Research

- All library research must be conducted in compliance with all safety guidelines including the use of facial covering, personal hygiene, and social distancing.
- While in the library all research staff must maintain at least 6 feet distance from all other library users.
- If physical distancing is not possible, plexiglass shielding should be installed between individuals to provide a physical barrier; personnel will also wear facial covering.
- Any additional COVID-19 related health and safety protocols established by the Rutgers Library must be followed.
- When working in a library/ archive other than Rutgers, researchers and their staff are expected to comply with these guidelines.

### Facility Maintenance and Usage

- The use of all Rutgers facilities must be coordinated by the principal investigator.
- A daily log must be kept of visitors in the [Rutgers Visitor Log](#).
- In facilities where multiple groups, faculty, and students have ongoing operations, the principal investigator is responsible for coordinating with other groups to ensure appropriate social distancing and other health and safety measures.
- No visitors are allowed without the expressed consent of the principal investigator.

### Research Participants

(These guidelines govern research not related to COVID-19; for COVID-19 related research, the research participants guidelines will be governed by the IRB approved protocol.)

- Principal investigators and research staff will take all possible precautions to protect the health and safety of all research participants.
- Research participants will be instructed to bring/use facial covering. Research participants will be provided facial covering if they cannot supply it. Research cannot be conducted with participants who do not have facial covering, unless facial covering is not feasible due to the nature of the study and lack of facial covering is specifically approved by the IRB.
- When working with research participants research staff will use facial covering and, if in a clinical setting, gloves.
- If physical contact is required, whenever possible such contact must be minimized. Gloves must be discarded after each use.
- Any equipment used during such contact must be immediately disinfected. If a research subject was in an office or lab, surfaces that were touched should be cleaned and disinfected before such areas are used again.
- Whenever possible, research participants will be pre-screened 24 hours before participating in research activities. (There is a pre-screening protocol for this purpose; please see appendix to this document.)
  - If it is not possible to pre-screen the research participant 24 hours before the research activity, research participants will be pre-screened on the day of the research activity.
- If the research participant is exhibiting COVID-19 related symptoms the participant will be instructed to contact his/her preferred medical professional or the nearest hospital.

## Travel

- Local (in-state) travel to field sites or other research facilities is permitted, provided that these guidelines are followed to the extent possible. Under current Rutgers policy, out-of-state and international travel is not permitted.
- It is recognized that research travel is critical for many research faculty. For faculty or research staff who must travel to perform their work function, social distancing guidelines will be followed.
- Two people may drive together in a standard vehicle. They should wear facial covering and sit in opposite corners from each other. The driver can improve the ventilation by opening windows or setting the air ventilation/air conditioning to non-recirculation mode.
- People who live together may travel together in a shared vehicle.
- While traveling with colleagues do not share food or drink.
- If overnight travel is necessary, there must not be more than one person per room, unless two people routinely share a room off-campus.
- While traveling, purchasing of food and supplies and contact with people outside the research team should be limited to minimize interpersonal interactions.
- Travel related to research is controlled by the Rutgers University travel policy, which currently does not permit either out-of-state domestic or international travel. This policy is reviewed periodically.

- If a member of the research team presents flu-like symptoms during travel, the following steps are required:
  - The individual must cease field work and self-quarantine. Contingency funds for a separate hotel room or other measures must be considered by the principal investigator before research begins.
  - The individual must be tested for COVID-19 as soon as possible.
  - The remainder of the research team may continue their work but must take extra precautions to isolate the crew from potential sources of infection.
  - The individual can return to work if tested negative or is symptom free for at least 14 days.

### Guidelines for Preparation of Materials for Field Studies

- Preparation of materials is to be conducted indoors in an on-campus laboratory or at home.
- It is acceptable to prepare materials at home only with prior approval of the principal investigator and provided it is safe to do so, i.e. non-hazardous.

### Field Data Collection

- A minimum of 6 feet will be maintained between individuals while collecting data in the field.
- Some data collection projects involve the deployment and use of equipment such as computers, sensors, lasers, cameras, etc. In all cases the installation and operation of these devices will be conducted in such a way as to maintain 6 feet of separation between individuals.
- Such research processes must be designed to minimize the possibility of cross-contamination (see cleaning guidelines above).

### Lab-Based Research

- Some research may require laboratory access, e.g., for the stabilization of collected samples prior to long-term storage or the genotyping of individuals to determine appropriate genetic crossing strategies. In such cases appropriate safety measures must be implemented (see guidelines above).
- See also Rutgers established safety guidelines governing lab-based research.

## Off-site Research Activities and Collaborating Organizations

- As stated earlier in this document, this guidance does not and cannot address all of the activity-specific and location-specific challenges, circumstances and scenarios that Rutgers' research teams will encounter. This is provided as general guidance intended to help research faculty develop project-specific COVID-19 response strategies. Such strategies should seek the highest level of compliance with the guidance provided in this document, especially as it relates to facial covering, social distancing, personal hygiene, workstation sanitation/disinfection, and health monitoring.
- Any research activities conducted at collaborating community-based organizations, schools, hospitals/clinics, etc., must be undertaken in compliance with these guidelines.

## Rutgers University Protocol for Pre-Screening Research Participants

Rutgers University recommends that researchers develop a Covid-19 screening procedure and ask research participants to complete this screening before reporting for any study-related visits or engaging in any in-person interactions with Rutgers research staff. (*This type of screening procedure does not require IRB approval.*)

### Preparing for Screening

1. Become familiar with study protocol.
2. Establish a formal plan to manage research projects when staff are sick or unavailable.
3. Make sure that you understand the visit flexibility of your protocol(s) and also any safety considerations regarding delaying an investigational treatment visit.
4. Rutgers' IRB will need to review any protocol modifications (other than this pre-screening); nonetheless, such submissions to the IRB's will be given priority if you use COVID-19 in the submission title.
5. Research participants with possible exposure or symptoms of illness should be (1) urged to get medical care and (2) scheduled/re-scheduled for a date in the future.

### Screening protocol

A designated study staff member should call the participant 24 hours before the appointment and ask the following screening questions:

- 1) In the past 14 days, have you traveled outside of the United States?
- 2) In the past 14 days, have you had any of the following symptoms?
  - a) Fever or chills
  - b) Cough
  - c) Shortness of breath or difficulty breathing
  - d) Fatigue
  - e) Muscle or body aches

- f) Headache
  - g) New loss of taste or smell
  - h) Sore throat
  - i) Congestion or runny nose
  - j) Nausea or vomiting
  - k) Diarrhea
- 3) In the past 14 days, have you lived with, visited, cared for, or been in a room for a prolonged period of time with someone who is under investigation for or has been confirmed for COVID-19?
  - 4) If the answer to **any** question is “yes”, the coordinator should reschedule the visit and direct the participant to seek medical care.
  - 5) If the answer to **all** questions is “no”, inform the participant that we are restricting entrance of unnecessary visitors, and they can only be accompanied by those individuals essential to the visit. This would include legal guardians or a person who must be present with the participant for health care/research related decisions.
  - 6) Research participants should be provided with face coverings.

# **Guidance to Human Subjects Researchers on Ramping up Research: When to Submit Protocol Modification to the IRB and When Not To**

(This guidance is limited to IRB-related protection of human subjects)

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## **Purpose**

*This IRB guidance is intended to help researchers working with human subjects determine whether or not they need to submit a protocol modification to the University's Institutional Review Board (IRB) as part of the ramp-up of research during the COVID-19 pandemic.*

Rutgers University has provided formal guidance to research faculty and their teams regarding the safety of researchers, patients, and human subjects during the COVID-19 pandemic. Up-to-date information can be found on the University's COVID-19 website ([coronavirus.rutgers.edu](https://coronavirus.rutgers.edu)):

- Research specific information can be found at <https://coronavirus.rutgers.edu/faqs/#research> or at the Office for Research COVID-19 website (<https://research.rutgers.edu/coronavirus> )
- Matters related to personal and personnel safety can be found on the Rutgers Environmental Health and Safety website: <https://rehs.rutgers.edu>.

## **Questions Regarding COVID-19 Guidelines**

**Rutgers Environmental Health and Safety (REHS):** REHS provides comprehensive and professional health, safety, and environmental services to the entire university community. Human subject-related questions regarding guidelines to protect against COVID-19 or their implementation (for example, issues associated with the application of facial covering, the use of PPE, social distancing, monitoring of health, and disinfection of workspace, supplies and/or equipment) should be forwarded to REHS.

**The Institutional Review Board (IRB):** The IRB's work, expertise, and mission are limited to the regulatory and ethical protection of human subjects as it relates to: (1) research methods, (2) undue influence, and (3) completeness and candidness of the informed consent process. When such issues arise, the IRB must be consulted.

## **Scope**

*What types of human subject research are covered under this guidance?*

This guidance applies to all types of human subjects research: field work, humanities, social-behavioral, and/or biomedical research. Not all research with human subjects, however, meets

the legal and University threshold for requiring IRB review. We have developed a quick and easy-to-use tool to aid you in determining whether your study requires IRB review. The tool is available online at Human Subjects Determination Tool.

([https://rutgers.ca1.qualtrics.com/jfe/form/SV\\_0B7ICECsq6uceqx](https://rutgers.ca1.qualtrics.com/jfe/form/SV_0B7ICECsq6uceqx))

Additionally, if you require more information than offered by the quick tool, you can find guidance on when research requires IRB review online at Am I Doing Human Subjects Research? (<https://orra.rutgers.edu/irb-review#:~:text=Once%20an%20activity%20is%20determined,be%20reviewed%20by%20Rutgers%20IRB.>) You may also call and consult the IRB office.

*What about protocols directly involving research on the COVID19 pandemic (biomedical, social-behavioral, or humanities research exploring the impact of COVID19 or finding treatments)?*

Protocols or modifications to protocols that specifically address the COVID19 pandemic are prioritized above other submissions and receive rapid attention and review. Please see the end of this document for instructions on submitting such protocols for a pre-review by the COVID19 IRB Rapid Response Team.

*Is this the final guidance on IRB protocol modifications?*

Please expect these guidelines to evolve in response to changes in science and circumstances. Therefore, continue to regularly check this site for updates. Notices regarding updates to the document will be emailed to all human subjects researchers with accounts in [eIRB.rutgers.edu](http://eIRB.rutgers.edu) and will be posted on the IRB's website: <https://orra.rutgers.edu/hspg>. Make sure that your email address in eIRB is up-to-date; you should have on record an email that you check regularly.

What if I have questions about this guidance or about protocols?

The IRB staff stand ready to answer your questions. You may contact them directly via email or phone: IRB HSPP Staff Directory (<https://orra.rutgers.edu/hspgstaff>). Additionally, we have created two centralized email addresses:

- For general inquiries: [irb@ored.rutgers.edu](mailto:irb@ored.rutgers.edu)
- For COVID19-related IRB questions only: [covidirb@ored.rutgers.edu](mailto:covidirb@ored.rutgers.edu)

### **When a modification is NOT needed**

**If I am changing the research to include wearing masks, protective (social) distancing, and other health protection measures, do I need to submit a modification?**

No. Because health and safety requirements and guidance are university-level requirements, they do not need to be included in a protocol, nor do they need to be submitted as modifications to existing protocols.

In other words, no modification is needed for changes to study procedures that will include wearing masks when interacting with subjects, protective distancing, plastic or other barriers, meeting outdoors instead of indoors, etc. **However, researchers should consult with their department chairs and research deans to determine whether the safety measures put in place are sufficient to guarantee that the benefit of the study outweighs the risk to the participant.** Researchers will still need to ensure that appropriate confidentiality or privacy measures continue to be in place to protect research subjects.

Health and safety units within Rutgers University are responsible for guidance related to the health and welfare of University personnel surrounding the COVID19 pandemic. Up-to-date information can be found on the [University's COVID19 website](#).

- Research-specific information can be found on: <https://coronavirus.rutgers.edu/faqs/#research> and at [the Office for Research COVID-19 website](#).
- Matters related to personal and personnel safety can be found on the Rutgers Environmental Health and Safety website: <https://rehs.rutgers.edu>.

### **Which types of human subject studies do NOT need to submit modifications to the IRB?**

*You do NOT need to submit a modification if your study has been deemed “Exempt” AND is not supported by external funding. Exempt studies with federal funding must follow the guidelines for submitting changes as outlined further below.*

- **What is meant by a study with no external funding (i.e. an unfunded study)?**  
An unfunded study is one that is not funded by any of the following entities: federal, state, or local governments; non-profit organizations; for-profit or industry sponsors. An unfunded study is financed (paid for) with Rutgers resources (e.g. internal award, departmental grant, etc.) or the personal funds of the researcher.  
Please note, if in the future your study becomes externally funded, you will then need to submit a modification within 30 days of funding award and describe the changes to the consent process.
- **What is meant by approved as an “exempt” protocol?**  
“Exempt” research is a regulatory term that means that the research is in fact human subjects research, but is exempt from many, but not all, of the regulatory requirements. Your approval notice will indicate if your research is exempt.

You can find more information on exempt protocols online:  
<https://orra.rutgers.edu/reviewtype#Exempt>.

**What if I am changing from a written consent form to an online or oral consent form for an exempt study with no external funding (e.g. consenting remotely, such as online through Qualtrics, over video through WebEx, or over the phone)?**



If your study does not receive external funding and was approved by the IRB as “exempt,” then you do not need to submit changes to the IRB if the changes are only to alter the consent process **and** are solely in response to COVID19 health measures.

Please note that although limited changes can be made to the consent process, the substantive content of the consent must remain largely as approved.

Changes to the consent form are permitted to the limited degree they explain or address converting from in-person to online video or phone interactions. For example, no modification approval is needed when:

- Transitioning from an in-person written consent to an online consent document, and changes largely are limited to the removal of the signature blocks and replacing it with a check box or text box where the subject indicates their consent to take part in the research.
- The consent document is read to a subject through a WebEx video session or over the phone.
- For research that is not anonymous, the consent document is emailed to the subject prior to the research-based interaction, and confirmation is received during the remote interaction that the subject has read the consent, understands the consent document, and has no questions.
- Moving from in-person focus groups to remote focus groups.

Please see the section below which outlines the circumstances under which changes to the consent form and process will require IRB review.

**If in-person research is later permitted under University policies, must I stop remote consenting for my exempt study and return to in-person consent?**

No. Your protocol can be flexible to include both types of consent processes (i.e. remote and in-person procedures). Remote consenting will remain the preferable consent method for the foreseeable future. If you were approved to do only written consent pre-COVID19, and converted to remote consent, you can continue either consent process. However, you must adhere to the University’s requirements surrounding the health and safety of all persons.

**What if I am doing in-person research but changing from a written consent form to an oral consent script?**

You do **NOT** need to submit a modification if your study has **no external funding AND your study is “exempt.”**

If your study does not receive external funding and was approved by the IRB as “exempt,” then you do not need to submit changes to the IRB if the changes are only to alter the consent process **and** are solely in response to COVID19 health measures.

As with the guidance above on moving from in-person to online, changes to the consent form are permitted to the limited degree they explain or address converting from in-person written consent to consenting a subject verbally. This is referred to as an oral consent process. No modification is needed to the protocol. Guidance on oral consent can be found online under [orra.rutgers.edu](http://orra.rutgers.edu).

### **Are there recommended templates for online or phone consent scripts or oral consent scripts?**

Yes, the IRB office has published several templates that are available online at: <https://orra.rutgers.edu/formsandtemplatesirb>. These templates were created with the input of several faculty and IRB members engaged in a variety of human subjects research and can help you with your specific type of research. Templates are also available in non-English languages.

### **What do I need to document for these changes?**

Although you do not need to submit a modification to your protocol, you will need to document all changes in converting from pre-COVID19 consent methods to post-COVID19 methods. You must keep documentation on hand for changes to the consent process. In the event of an audit, such documentation will be used to assess whether subjects were appropriately consented. Please contact the IRB office if you have questions regarding such documentation.

### **When a modification IS needed**

#### **Which types of studies require submission of changes related to restarting research to the IRB for review?**

**Any studies that meet these two criteria:**

##### **Type 1:**

- Full Board studies (e.g. studies involving greater than minimal risk to research participants)
- Studies involving vulnerable populations (e.g. children, oncology patients, elderly subjects, prisoners or those on probation or parole, individuals who are otherwise in legally vulnerable status such as undocumented immigrants)
- Expedited studies
- Exempt studies with federal funding
- Ongoing studies for which federal funding has recently been obtained.

##### **Type 2:**

Modifications other than the basic COVID-19 protections such as wearing masks when interacting with subjects, protective distancing, plastic or other barriers, meeting outdoors instead of indoors, etc.

## **What type of modifications must be submitted to the IRB for review?**

In general, modifications to protocols are likely necessary when they:

- Impact the aims of the research or research methods, or significant aspects of interactions with human subjects (e.g. moving from focus groups to individual interviews, modifying the recruitment methods);
- Add or modify inclusion of deception or concealment procedures where a debriefing process is needed or needs to be changed;
- Change the location of the research (e.g. moving from one site to another, but no modification is needed if a room is changed within the same site such as a room change within a school); or
- Directly increase the risk to human subjects related to the research design.

## **What if I am changing from a written consent form to a remote consent form for an expedited or full-board study?**

You will need to submit a modification, regardless of whether your study receives external funding or has no funding. There are two time periods during which you must submit a modification:

### **A. Have you changed from a written consent process to a remote consent process and recruited new subjects anytime from March 16<sup>th</sup> up to June 29, 2020?**

If you made temporary changes to the consent process in your protocol to avoid immediate COVID19-related health hazards to subjects, and your protocol is a minimal risk study with no vulnerable populations, then you must submit a modification to your study at **either the time of your continuing review or by September 30<sup>th</sup>, whichever date is earlier.**

If your study is greater-than minimal risk or has vulnerable populations and you have recruited new subjects through an online or phone consent, you must submit a modification to your non-exempt protocol by **July 13, 2020.**

### **B. What if I have not yet recruited subjects under an online or phone consent?**

If by June 29<sup>th</sup> you have not recruited any new subjects since March 16<sup>th</sup>, and you want to move from a written and in-person consent process to a remote consent process, then such a modification will be treated as any modification prior to the COVID19 pandemic. You need to submit a modification prior to starting the work described in the modification by submitting such modification to the IRB through the eIRB platform.

You can determine whether your study is “expedited” or full-board on your approval notice, or in eIRB. Further information can be found online at:

<https://orra.rutgers.edu/reviewtype#Expedited>.

**Are there recommended templates for online or phone consent scripts or short documents?**

Yes, the IRB office has published several templates that are available online at: <https://orra.rutgers.edu/formsandtemplatesirb>. These templates were created with the input of several faculty and IRB members engaged in a variety of human subjects research and can help you with your specific type of research. Templates are also available in non-English languages.

**What if I am changing both the consent process as well as other aspects of the study?**

You need to submit a modification prior to starting the work described in the modification. Changes sought to the study other than to the consent process need to be submitted to IRB. More information is available at: <https://orra.rutgers.edu/modifications>.

For example, modifying a survey instrument or focus group guide, adding additional research sites, adding additional types of subjects, adding other avenues of subjects recruitment, adding key personnel to help with the research, etc., each require that the researcher submit a modification for IRB review prior to commencement of the work.

**(Please note: if you need to submit a modification through eIRB related to changes such as those described in the above paragraph, you should also describe the changes you have made regarding the consent form or process. In this way, the protocol in eIRB will be brought up to reflect the actual state of the research.)**

**What if I am seeking to do in-person research but it is not yet permitted by the University?**

If you are seeking an exception from the University's safety requirement, then that exception will have to be routed through the appropriate academic and administrative leadership channels prior to seeking the approval of the IRB.

This process is described in more detail online at: [https://ored.rutgers.edu/sites/ored.rutgers.edu/files/03.17.2020-Communication\\_to\\_Rutgers\\_Researchers.pdf](https://ored.rutgers.edu/sites/ored.rutgers.edu/files/03.17.2020-Communication_to_Rutgers_Researchers.pdf) (see page 2).

Only after those academic and administrative safety approvals are secured may you submit the modification to the IRB. The IRB will consider the request within the narrow confines of its mission: the regulatory and ethical protection of human subjects as it relates to (1) research methods, (2) undue influence, and (3) completeness and candidness of the informed consent processes.

**What about FDA regulated work, such as HUD, INDs, and IDEs?**

In the majority of instances, you will need to submit a modification to the protocol. Please additionally note that for research conducted under INDs or IDEs, sponsor reporting requirements and FDA reporting requirements are different from IRB reporting requirements. Please consult with the [FDA's guidance on COVID-19 and clinical trials](https://www.fda.gov/media/136238/download) (<https://www.fda.gov/media/136238/download>). Check with your study sponsors to be sure you have met all reporting requirements.

## What if I am working with a Single IRB, Multisite IRB, or External IRBs like WIRB?

- A. For WIRB:** Submissions must be created and submitted through [eirb.rutgers.edu](http://eirb.rutgers.edu). Please refer to the “How to Submit” section for further guidance on WIRB submissions: <https://orra.rutgers.edu/westernirb>.
- B. I am relying on an external IRB. What are the instructions to complete such a review?**
- 1) Log into <https://eirb.rutgers.edu/>.
  - 2) Create new study with the Rutgers lead investigator listed as “Principal Investigator” and list any Rutgers personnel only.
  - 3) Select “Administrative Review” under the application type.
  - 4) Upload the External Institution’s IRB approval.
  - 5) Upload all the External Institution’s IRB-approved study documents (i.e. protocol, consent, etc.) in the appropriate sections of the Administrative Review application.
  - 6) The Rutgers lead investigator will need to complete the Local Context Supplement form (available at <https://orra.rutgers.edu/hsp>).
  - 7) Upload the Reliance/Authorization Agreement from the Reviewing IRB. \*If the Reviewing IRB does not have an Authorization Agreement document, Rutgers University template can be used.\* Please send an email to [irbrelianceadmin@ored.rutgers.edu](mailto:irbrelianceadmin@ored.rutgers.edu).
  - 8) All ancillary reviews (biosafety, conflict of interest, radiation safety, etc.) must be completed by all sites consistent with their own institution’s requirements.
- C. What if the Single IRB, External IRB, or Relying IRB requested changes to my protocol at Rutgers?**
- 1) **If Rutgers University is the Reviewing IRB:** All documents will be approved and stamped on the Rutgers template. If the external site has stated in their Local Site information sheet that they have specific language that is required to be added to the consent form, this can be done after the review process is complete. The external site may change the letterhead to match their own site, if applicable. All these changes are part of their own Administrative Review process at the external site.
  - 2) **If Rutgers University is the Relying Site:** You should submit an administrative review application with all the External IRB’s approved documents (IRB approval, protocol, consent form, etc.) and follow the instructions as stated under the Reviewing IRB bullet above. Please note that the Rutgers IRB does not need to stamp these revised consent forms.
- D. Rutgers University is the single IRB (sIRB) for my multisite study. Do relying sites have to follow Rutgers University restrictions?**
- Rutgers University restrictions on human subjects research apply to Rutgers University research only. For multisite research where Rutgers University serves as the single IRB for other Non-Rutgers sites, the Rutgers University/lead site PI should take inventory of

each relying sites' local policies/procedures and assess whether activities can continue at those sites.

If a relying site decides that research activities at that site must stop or be limited, the Rutgers IRB cannot override that decision. The site only needs to report their local restrictions if their local IRB requires submission to Rutgers IRB.

In addition, we understand that some relying sites do not have local IRBs. In those instances, the relying sites' leadership is responsible for setting the guidelines governing participant safety.

Although local circumstances may vary, PIs involved in multisite research are encouraged to consider implementing restrictions that accommodate circumstances at all sites whenever possible. As local circumstances may change on a daily basis, developing a study-wide plan that accommodates all site restrictions may be easier to manage.

### **Research on COVID-19**

*Protocols or modifications to protocols that specifically address the COVID19 pandemic are prioritized above other submissions and receive rapid attention.*

**Since March 16<sup>th</sup>, the IRB has established a COVID-19 IRB Rapid Response Team comprised of expert IRB reviewers and regulatory staff who are knowledgeable in a range of human subjects research. The Team often provides a preliminary review and comment on COVID19 research within a 48-hour period. After that preliminary review, the researcher makes modifications and submits the study to the IRB.**

#### **How do I let the IRB know that I have a COVID19 study or modification?**

Please email our dedicated COVID19 IRB Rapid Response Team at [covidirb@ored.rutgers.edu](mailto:covidirb@ored.rutgers.edu). This email is checked every day, including weekends, so that we can be as responsive as possible. The team will respond to you with instructions on how to provide study documents for a pre-review (e.g. through OneDrive or Box). Again, the pre-review is conducted outside of eIRB, so please do not submit through the eIRB system until you have received initial feedback from the COVID19 IRB Fast Response Team.

#### **How do I stay up-to-date on these changes?**

Please check the University's COVID19 website. Research-specific information can be found on that website at <https://coronavirus.rutgers.edu/faqs/#research> and also on ORED's COVID19 webpage. If you have any questions, please contact the IRB at: [irb@ored.rutgers.edu](mailto:irb@ored.rutgers.edu).

## Returning to Research Process Explanation

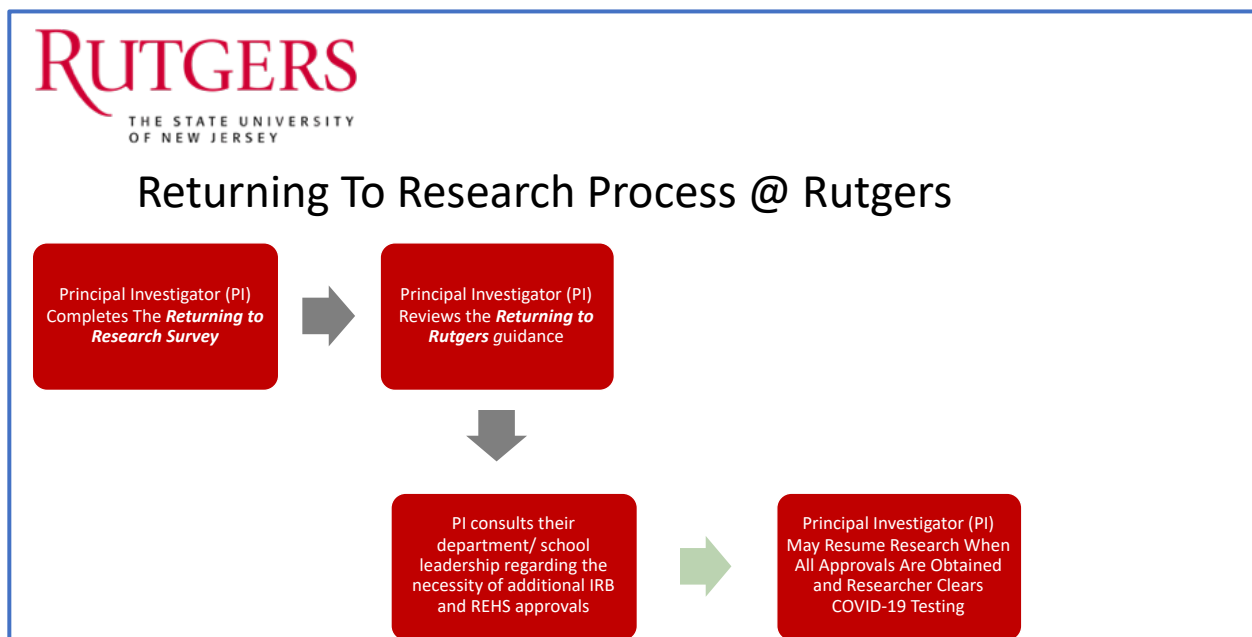
1. Returning to research begins with every Principal Investigator (PI) completing the Return to Research Survey. This survey was designed to provide health-risk based data that will help inform a process of consultation between PIs and their Department Chairs, Deans, and Center Directors.
  - a. At this initial stage issues associated with operational capacity, or the distinctiveness of risks associated with the project (such as health-related vulnerability of a research participant population, the venue of research, etc.) should have been addressed by the PI with their department/school research leadership.
2. In the rare instances where the risk of the project are deemed significant by the department/school research leadership, such leadership can consult with the IRB and REHS before making a final decision.
3. To assist research faculty and their teams we have also published The Resumption of Research Guidance which provides answers to four fundamental questions:
  - a. **What principles should guide PI's in designing strategies to secure the health, safety and wellbeing of all persons involved in their research project.** There are essentially five guiding principles:
    - Facial Mask – Use facial covering when coming into contact with any other person in an office, building, lab, and/or the field.
    - Personal Hygiene – Not touching one's face, washing hands regularly, wearing gloves and/or regularly using a hand sanitizer that contains at least 60% alcohol. Washing one's hands when coming into contact with another person.
    - Protective (Social) Distance – Maintaining six feet distance from all other people.
    - Health Monitoring – Not coming to work when sick (including when suffering from an elevated temperature); sending people home when they get sick.
    - Disinfecting Work Areas – Using appropriate cleaners and regularly disinfecting one's workstation, lab, office, supplies, books, and equipment.
  - b. **Where to go to with questions related to these principles or their implementation:** Questions such as the application of facial covering, the use of PPE, appropriate social distancing, monitoring of health, and disinfection of workspace, supplies and/or equipment should be forwarded to the ***Rutgers Environmental, Health and Safety Office (REHS)***.
  - c. **Where to go with questions related to the research ethics or research methods impact that adherence to these guidelines may have on research participants**

or research protocols: Such questions should be forwarded to the **Rutgers Institutional Review Board (IRB)**.

d. **What protocol changes will require IRB approval and what changes do not?**

- Rutgers University will govern COVID-19 related guidelines in the same manner it manages all other health and safety guidelines associated with research (i.e., by complying with REHS and other requirements by related offices). All protocols requiring IRB approval will undergo the appropriate IRB review (e.g., those where the research methods have changed or the research ethics have been altered). The IRB will consult with REHS on all technical questions (questions related to the health, safety, and environmental welfare) arising from the implementation of the COVID-19 guiding principles.
- Once approved by REHS and the IRB, and their department chairs/deans, PIs will be able to resume their research.
- Any questions related to this process can be forwarded to the **Rutgers Institutional Review Board (IRB)**.

4. The Vice Chancellors for Research or their designees reserve the final right to withhold approval for the resumption of any specific research project.





## Frequently Asked Questions for the Return to Research Process

### **1. How does the “return to research” process work?**

The Research Deans will approve any plans for a safe return to the research environment relying on discussion with chairs, PIs and deans. Following approval by the research dean, the researcher will receive information on testing for SARS-COV2 prior to returning to the research setting.

### **2. Who is covered by the Return to Research process?**

Researchers have been identified as a group at increased risk of viral transmission, due to the nature and physical spaces they occupy in the course of their work. The objective of the Return to Research process is to manage the safe and phased ramp up of research efforts on campus, while avoiding any flare up of COVID-19. This pilot initiative is specific to the research environment and researchers, and does not involve on-campus teaching, students or staff not directly involved in the research efforts.

### **3. What happens if my Chair rejects my proposal?**

The survey is needed to start the dialogue between the Chair and the faculty member. We understand that this will be an iterative process and there should be a back and forth communication between the concerned parties.

### **4. I don't need to be onsite to continue my work**

Anyone that can work from home and continue their work unimpeded must do so in Phases B and C.

### **5. Information on the COVID-19 test:**

#### **a. What type of testing is being done?**

The type of test used is the saliva test from RUCDR, which has been approved by the FDA under an Emergency Use Authorization.

#### **b. Who will be tested- faculty, students and staff?**

At this point in time the test is being administered to all faculty researchers and research staff (post-docs, graduate students, research associates) who are on campus or conducting field research.

#### **c. Is having a negative test pre-requisite to work in the lab? If not, how soon after we return to work will someone be tested?**

Yes, it is our shared responsibility to ensure a safe working environment for our staff that are returning and ensure that there are no asymptomatic spreaders within the community. No one should return to campus without being tested; researchers already on campus may continue their research and will also receive testing.

#### **d. How will tests be scheduled and where will they be administered?**

Once research plans (list on SharePoint XL) are submitted, ORED will approve the test codes that will link the researcher to the telemedicine provider and the diagnostic lab. Test kits with instructions will be sent to the staff members home by priority

mail. Staff will collect the sample at home as per the instructions and ship samples back using a pre-paid UPS envelope that can be dropped off at any UPS location.

***e. How will the test results be shared or communicated?***

The test results are Protected Health Information and will be **shared with the individual and Occupational Health only**. If you test positive for the virus, Occupational Health will follow up with you to inform you when you may retake the test, and when you may return to work. In this instance, your supervisor will be notified in confidence, so your work responsibilities may be managed. Separately, the health department will work with you to identify others in your social network who may have been exposed as part of the standard contact tracking program. An individual can always share their results voluntarily, but there is no requirement to do so beyond sharing with Occupational Health. The COVID status of an individual who is not cleared to return should not be shared. Failure to return to research labs in a timely fashion could be due to a failed test, positive COVID result, or other issues.

***f. What happens if someone tests positive?***

Anyone that is positive for the test will need to be in contact with Occupational Health **immediately** as per University policy. Occupational health will provide the necessary guidance to individuals about returning to work. Anyone who tests positive will be retested at the appropriate interval as determined by Occupational Health.

***g. Should a PI communicate to other lab members about a positive test from a lab member?***

**NO!!** Due to privacy concerns and HIPAA regulations **no public disclosure should be made** about a positive test except by the individual themselves. If anyone has been exposed to an affected individual Occupational Health or the health department will contact team members as part of contact tracing to identify potential exposure and provide instructions on how or whether to self-quarantine.

***6. Will the planned return to research dates be affected in case of future spike in cases?***

The phases of research return are meant to be **reversible**. While we expect that the measures we are taking will contain and isolate any flare up of viral infection, it may become necessary to ramp down if new infections spike within the community

***7. When can research with human subjects begin?***

Please refer to the Guidelines for Clinical and Field based research for details (above). Clinical and Field research plans must be reviewed and approved at the local level by the Chairs and Deans. Additionally, attention must be paid to any **changes that might require REHS involvement or IRB approval**.

***8. Is the engagement of undergraduate students envisioned in the plan?***

Guidelines for undergraduate research in Fall 2020 are:

- Undergraduate Junior or Senior students may work in a research laboratory if they meet all of the following criteria and are approved by the Research Advisor:

- Laboratory research credits are necessary to avoid a delay in time to degree or thesis completion,
- The student’s academic advisor or undergraduate program director endorses participation on the research activity, and
- The research can be conducted safely as endorsed by the Research Advisor and department chair.

We have not yet defined the process and guidelines for undergraduate laboratory research contemplated for spring, 2021.

## Revision of Guidelines

These guidelines will be reviewed regularly to respond to changing conditions and new information. Researchers will be advised of any significant changes. These guidelines may be revised, suspended, or terminated as soon as the COVID-19 pandemic permits. Suggestions for revisions and questions may be sent to [EOC@Rutgers.edu](mailto:EOC@Rutgers.edu), with Research Feedback in the Subject line

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*Updated 9/15/20 for inclusion in Return to Rutgers  
Undergraduate requirements added*