



## Guidance on the Conduct of Clinical Research at Rutgers Biomedical and Health Sciences during the COVID-19 Pandemic

**Mission:** Our primary goal is to protect our patients, study participants, providers and researchers from COVID-19 exposure, and to fill the gap for our research community in the absence of guidance from the National Institutes of Health or the Centers for Disease Control pertaining to clinical research activities. RWJBarnabas Health has instituted mandatory COVID-19 travel- and health-screening for all patients. We are providing clinical research guidance for the RBHS community. Any non-human subject research can proceed unencumbered.

### Guidance:

1. **Studies being conducted in outpatient areas involving direct contact with study participants:**
  - a. Staff should review upcoming study visits and pre-screen all participants by phone one day prior to the scheduled visit, using the attached telephone script.
  - b. If a participant answers “yes” to any question, the study visit will be **cancelled**.
  - c. If a participant is unable/uncomfortable attending a face-to-face study visit:
    - i. **Network and Collaborative Studies:** Follow the general instructions below and any guidance from the Network or the Lead Site. Research teams should work with their funding and regulatory sponsors (IRBs) to develop plans for research participants and research procedures, in light of circumstances at the time.
    - ii. **Industry-sponsored Studies:** Follow guidelines from sponsor.
    - iii. **Investigator-initiated Studies:** Follow general guidelines below. Research teams should work with their funding and regulatory sponsors to develop plans for research participants and research procedures.
  - d. General instructions:
    - i. If feasible, a research visit can be conducted by phone as indicated by protocol and participant symptoms.
    - ii. If the study involves home visits, reschedule or conduct by phone.
    - iii. Safety labs can be done via local lab if feasible. If there is cause for a participant to remain at home and there will be a delay, the PI will determine if study drug can be safely continued. Discussion for continuation of study drug will be conducted with the PI and subject will be appropriately advised.
    - iv. Pharmacy will be notified to ship study drug if approved by PI, determined on a case-by-case basis.
    - v. IRB of record will be notified of the change in study visit procedure within 5 days per IRB policy. According to IRB policy, any changes in IRB-approved research procedures must be reported to the IRB and may not be implemented prior to review and approval by the IRB, **except when necessary to eliminate apparent immediate hazards to the subject**. This is permitted by both the Common Rule (38 CFR §16.108(a)(3)(iii)) and by FDA regulations (21 CFR §56.108(a)(4)). Beyond the regulation, Rutgers also has a responsibility to ensure the safety of its employees. As such, interim measures to reduce immediate hazards to research participants and staff – which may involve deviating from IRB-approved study procedures prior to securing IRB approval – may be warranted

to relieve an immediate hazard and to ensure consistency with Rutgers policies during this time.

- Examples include considering approaches that would reduce the need for “at risk” research participants to visit our facilities such as:
  - Conducting phone visits in lieu of in-person visits;
  - Research procedures that might be completed without requiring participants to travel to our facilities (surveys, imaging procedures/lab testing be done at other sites);
  - Permitting “out of window” visits and/or canceling nonessential research participant visits.

*\*Please note that the IDS will ship investigational medication to participants’ homes if requested.*

- Examples include considering approaches that would reduce the number of external vendors visiting our facilities, such as:
  - Conducting remote monitoring visits;
  - Conducting remote site initiation visits or other sponsor visits/meetings;
  - PI and/or sponsor temporarily stopping recruitment or placing the study on a temporary hold.

**2. Studies involving direct participant contact and sample acquisition**

- a. Follow the guidance under #1 above.
- b. Follow basic safety guidelines for handling biospecimens.

**3. Studies that do not involve direct participant contact**

- a. Studies that involve surveys or questionnaires or analysis of large datasets should be able to continue without change.
- b. If, however, a change is necessary due to the unavailability of the study participants (illness, quarantine, etc.), it may be necessary to amend the IRB protocol.

**4. Strategies for accommodating potential staffing shortages:**

- a. Everyone should self-monitor per same procedure of pre-screening guidelines and NOT report to work if any answers are YES.
- b. Keep all study participant binders updated to contain the study specific flow sheet for study visit procedures and to ensure the next scheduled study visit is clearly indicated.
- c. A central Master List binder containing all current Master Lists including patients’ full names and contact information (cell and/or email) will be maintained by the nurse manager and regulatory coordinator. This information will be needed to contact study participants in case of study visit cancellation, safety follow-up or pre-screening.

**5. Research Staff Preparing to Work Remotely:** Privacy and confidentiality provisions remain of paramount importance at all times. Consistent with University communications, clinical research staff should prepare for the possibility of working remotely.

- a. Research teams should maintain secure contact information for research participants should they need to reach them.

- b. Ensure that access to PHI and other protected clinical research information is enabled with all required security in place.
- c. Do not use personal email to conduct clinical research activities or communicate with patients.

If apparent immediate hazards will be sustained for a duration that would practicably allow for an amendment to cover such changes to be developed by an investigator and reviewed and approved, as appropriate, by the IRB, then approval of a protocol amendment must be sought.

**If you have questions about this guidance, please send inquiries to:**

- IRB-related inquiries: [cm816@ored.rutgers.edu](mailto:cm816@ored.rutgers.edu)
- Other research-related inquiries: [rodrigmg@rwjms.rutgers.edu](mailto:rodrigmg@rwjms.rutgers.edu)



## Telephone Script for Pre-screening Study Participants

Hello! I am calling about your study visit that is scheduled for [time/date]. We have a new screening process to ensure your health and safety and are asking all patients and visitors a few questions. Have you done any of the following in **THE LAST 14 DAYS?**

1. Have you returned from outside the US (check against countries listed)?
  - a. **China, Japan, Italy, South Korea, Hong Kong, Singapore, Taiwan, Vietnam, Thailand, or Iran or Other [which?]**
2. Have you had direct contact with an individual with confirmed Coronavirus?
3. Have you had a fever and cough in the **last 24 hours?**

### **If YES to any of the questions:**

1. Instruct them to contact their health care provider immediately if they have a fever or cough and have either traveled recently or been in direct contact with an individual with confirmed Coronavirus. Their health care provider will provide further instructions.
2. Indicate that the study visit will be rescheduled but only after they have received testing for Coronavirus.
3. Instruct them that if they have or develop acute respiratory symptoms, they should contact the nearest Emergency Department or call 911.
4. Remind them that they should be performing frequent hand hygiene with soap or waterless soap.
5. Explain that for their own health and those around them, they should remain at home as much as possible, and when away from home, keep a social distance of 6 feet from people around them.

### **If NO to all questions, provide the following instructions to the participant:**

1. If, between now and your study visit, you have contact with an individual with Coronavirus or have a cough or fever, please call us and we will reschedule your study visit. Call your health care provider for further instructions. Tell the participant that for their own health and those around them, they should go home, keeping a social distance of 6 feet from people around them, and remain home until they contact their healthcare provider who will provide further instructions.
2. Ask if the participant needs to travel to the study visit. If travel is involved, especially in public transportation, reschedule the visit.
3. If it does not, we can proceed with the visit. Before entering the hospital or clinic, **please perform HAND HYGIENE with waterless soap.**