

Guidelines for Clinical Research at Rush during the COVID-19 pandemic *(Revised 06/24/2021)*

The Rush campus is a healthcare setting, and the most recent guidance should be followed ([CDC Guidance](#)).

The Chicago Department of Public Health updated the emergency travel order (effective June 15, 2021; [CDPH Emergency Travel Order](#)).

The city of Chicago is currently in Phase 5 ([City of Chicago](#)). The CDPH guidelines previously included an Emergency Travel Order that reflected the changing nature of the pandemic and provided specific guidance to travelers entering or returning to Chicago. Under that system, states were placed in three categories – red, orange and yellow – based on the status of the outbreak in the states and how the data compares to the situation in Chicago. The guidance is:

- **Yellow:** States with a rolling 7-day average less than 15 cases/day/100k residents.
 - No quarantine or pre-arrival test required. Maintain strict masking, social distancing and avoidance of in-person gatherings
- **Orange:** States have a rolling 7-day average **between** 15 cases/day/100k residents and the Chicago rolling 7-day average (currently 60)
 - 14-day quarantine OR **pre-arrival negative test** no more than 72 hours before arrival in Chicago with strict masking, social distancing and avoidance of in-person gatherings
- **Red:** States have a higher 7-day rolling average of positive cases/day/100k Chicago residents.
 - 14-day quarantine

Based on data available on **June 15, 2021**:

- All US states and territories are in **yellow status (no requirements)**

Guidance on Clinical Research

1. Any research that does not require in-person visits, and can be done remotely, should continue without restriction.
2. Clinical research must adhere to the clinical protocols:
 - a. *Universal masks*
 - b. *Faceshield or goggles*
 - c. *Routine hand washing*

Clinical Research

1. All Clinical Research can be resumed. All research staff must adhere to clinic protocols for management of participants – this will likely include symptom assessment, universal masking, and other precautions.
2. If universal precautions or other current distancing protocols would impact research, the protocol should be reviewed by Infection Control, Occupational Health, and Research Compliance.

Recommendations from these groups should be forwarded to the Vice Provost for Research for adjudication and decisions about if and how to proceed with the protocol.

3. Research staff are directed to not participate in research activities involving participants if they exhibit any signs or symptoms of COVID-19 unless they are in a COVID-19 study.
4. In the event that a research staff member believes that they contracted COVID-19, and could have exposed participants to risk of infection (during a window or asymptomatic time period), this should be reported to the Rush IRB as an adverse event and appropriate documentation should be provided to explain the event and corrective actions.
5. Home visits / home & community-based research can continue with the caveat that attempts should be made to transition these research visits to video or telephone-based platforms.

Student & Trainee Research

1. Any student or trainee clinical research that can be done remotely or via video/telephone-based visits can continue.
2. Clinical trainees that are seeing patients in person may do so at the discretion of their Chair or Section Chief who should assess the risk/benefit ratio for the project.
3. Patients in clinical research studies who are on campus for clinical care may also have clinical research visits with trainees at the discretion of the Chair or Section Chief.

Criteria for faculty, staff, and trainee research

Clinical and laboratory research are cornerstones of Rush University's vital mission. The guidelines for the research environment during circumstances such as the COVID-19 pandemic are rooted in safety for the health and well-being of faculty, staff, trainees, and the public

Faculty, staff, or trainees who have needs (health or otherwise) that would preclude them from participating in research at this time should seek accommodations according to the university guidelines for accommodations due to COVID-19 related issues. Personnel who have tested positive for COVID-19 should follow the Rush System for Health or University guidelines for personnel who test positive for COVID-19.

Personnel who test positive for COVID-19 or are having symptoms associated with COVID-19 infection must follow Rush's policy - [Rush COVID19 testing](#)

Guidelines for faculty, staff, and trainees who have been infected with COVID-19

The following guidelines are in place to assure that faculty, staff, and trainees who perform research on campus, and who test positive for COVID-19, take the required precautions to assure they are taking care of themselves as well as protecting others around them. Faculty, staff, and trainees should adhere to the following guidelines if they have tested positive for COVID-19:

1. Faculty, staff, and trainees who test positive for COVID-19 must report this outcome to their supervisor and Rush Employee Corporate Health Services immediately.
2. Faculty, staff, and trainees who have tested positive for COVID-19 should comply with their treatment and inform their supervisor one day after they have been cleared to return to campus or research site. Faculty, staff, and trainees who are on campus should follow the guidelines for contact tracing according to Rush System for Health.