August 26, 2021

To Whom It May Concern,

Rush University has developed guidelines for study monitoring visits in the time of COVID-19. These guidelines are meant to inform research study monitors, CROs, and sponsors that they are able to come back to the Rush campus for onsite visits, if required by the research contract and the research itself, under conditions that provide for the safety of our faculty, staff, trainees, patients, and the public. Study monitors are not considered essential personnel. 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 August 24, 2021; CDPH Emergency Travel Order). We have therefore modified our guidance to study monitors for clinical research projects that requires them to follow the CDPH guidelines as well as those of Rush University Medical Center. This means that study monitors must abide by the Emergency Travel Order, be symptom negative, and be vaccinated against COVID19 by October 1, 2021 (Rush mandatory vaccination) prior to coming to Rush facilities for study visits.

The city of Chicago is currently in Phase 5 (City of Chicago) with a requirement for masking indoors. The CDPH guidelines also previously included an Emergency Travel Order that reflects the changing nature of the pandemic and provides more specific guidance to travelers entering or returning to Chicago. Under the system, states are 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 **August 24, 2021**:

Any unvaccinated people traveling from these states and territories are advised to obtain a negative COVID-19 test result no more than 72 hours prior to arrival in Chicago or quarantine for a 10-day period upon arrival. Vaccinated individuals do not need to quarantine or receive a negative test.

Onsite visits remain possible if study monitors abide by the above guidelines and under the following conditions:

- As of October 1, 2021 all study monitors must have proof of COVID-19 vaccination
- All monitors must participate in universal masking. Rush will provide the mask to be worn on campus.
- All monitors must participate in social distancing, particularly in all monitoring rooms.
- All monitors should self-screen prior to entering Rush campus for signs or symptoms of COVID. If any signs/symptoms are present the monitor may not come onto campus and the visit should be rescheduled.
- All monitors should coordinate visit dates/times with study staff. This will help to minimize the number of study staff members that would need to be onsite for the monitoring visit to protect the well-being of study staff.
- All monitors must enter campus through designated entry points where they will be provided with a visitor badge, and a Rush approved face mask that must always be worn while on campus.
- Monitors should not be working in clinical care areas. Appropriate conference rooms and offices located a distance away from patients is ideal.
- There may be restrictions or areas of the campus or clinics where the monitor may not visit. Please check with Rush personnel for area-specific instructions.
- For the safety of all staff, patients, monitors, and the public, please limit the time and duration of visits to only the time required. Any monitoring that can be done remotely or in an alternate manner should be explored.

Rush University reserves the right to modify the onsite visits depending on the COVID-19 environment.

Kind regards,

Andrew Bean, Ph.D.