July 3, 2020

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.

We previously issued a guidance letter on June 10, 2020. However, the Chicago Department of Public Health released a new order that will go into effect on Monday July 6, 2020 (https://www.chicago.gov/city/en/sites/covid-19/home/emergency-travel-order.html). We have therefore modified our guidance to study monitors for clinical research projects that requires them to follow the CDPH guidelines. This means that if study monitoring personnel have traveled to States covered by the order, they must quarantine for 14 days and be symptom negative prior to coming to Rush facilities for study visits.

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

- 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 1 of 3 designated entry points, at which they will be temperature screened, will be provided with a visitor badge, and a Rush approved face mask that must be worn at all times while on campus. If a monitor does not pass this screening satisfactorily, the monitoring visit must be rescheduled.
- 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.