



COVID -19 Safety-Focused Procedures for Clinic Visits

Safety procedures should be in place for all clinic visits. Subject in-clinic visits at our site comply with Federal, State, Local, and Institutional guidelines, as well as clinical judgment to protect subject and staff safety during the conduct of the in-clinic assessments. As we resume in-clinic study visits, we would like to provide the following recommendations for study conduct to reduce risk of COVID-19. Procedures are extrapolated from the Centers for Disease Control (CDC), Health and Human Services (HHS), and Centers for Medicare & Medicaid Services (CMS) guidance for healthcare professionals (HCPs) in a clinical setting

PRIOR TO ARRIVAL

- Subjects will be contacted and scheduled to return to site for COVID-19 testing by local lab (to be conducted no more than 72 hours prior to expected admission). Results must be received onsite and **NEGATIVE** for subject to proceed with admission to CRU.
- The subject is contacted the day prior to the scheduled appointment to assess for possible symptoms of COVID-19.
- Subject is advised to wear their own face covering (i.e., cloth or mask), regardless of symptoms before entering the building.
- Subjects and HCPs who have recovered from COVID-19 can come to the clinic if:
 - ❖ At least 3 days (72 hours) have passed since recovery defined as resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (e.g., cough, shortness of breath); and,
 - ❖ At least 7 days have passed since symptoms first appeared.

The following screening questions are asked via telephone prior to all clinic visits

In the past 14 days, have you:

1. Traveled outside the U.S. or been exposed to (physical contact with) someone traveling outside of the U.S.?
2. Have you been in close contact with anyone who has tested positive for COVID-19 such as someone you live with or visit frequently?
3. Have you been exposed to any high-risk environments such as nursing facilities or adult group homes with potential widespread infection rates?
4. Experienced a fever of 100.4 F or above?
5. Experienced persistent cough, difficulty breathing or shortness of breath, or other flu-like symptoms such as sore throat, chills, muscle pain, new loss of taste or smell, and/or vomiting or diarrhea?
6. Have you been previously diagnosed with COVID-19 and since recovered from it? If yes, when?

If a subject has endorsed possible symptoms or confirmed COVID-19, do not schedule an in-clinic visit and refer subject for appropriate medical care. For enrolled subjects, the study the staff can conduct a remote visit as approved by specific sponsor and COVID-19 will be documented as an Adverse Event (AE).



ONSITE VISIT PROCEDURES

- On day of admission, site staff will perform rapid COVID-19 fingerstick testing prior to any study related procedures and admission to CRU.
 - A. Results must be **NEGATIVE** or **ONLY IgG POSITIVE** to proceed.
 - B. Rapid testing must be done at each admission if admitting multiple times within the study.
- Points of entry to the facility are monitored.
- Caregivers or others accompanying the subject are also be queried and screened for COVID-19 symptoms, with appropriate protection in place during the visit.
- Subjects are also questioned if they have been in contact with persons with suspected or confirmed COVID-19 and the level of their symptoms.
- Upon Arrival and During the Visit subjects are questioned again about possible exposure and their temperature is taken.
- Visitors are limited to only those essential for the subject's physical or emotional well-being and care.
- Advise subjects and visitors, regardless of symptoms, to maintain a cloth face covering or facemask during their visit.
- Staff ensure everyone adheres to respiratory hygiene and cough etiquette, hand hygiene, and all persons follow procedures throughout the duration of the visit.
- Supplies for hygiene including, facemasks or cloth face coverings, alcohol-based hand rub with 60-95% alcohol, tissues, and no-touch receptacles for disposal are provided.
- Close contact between personnel and potentially infectious subjects is limited.
- Personnel taking vitals and assessing subjects wear appropriate personal protection equipment (PPE: e.g., facemask, eye protection, and gloves).
- Subjects and other persons with symptoms of COVID-19 will be isolated and referred for treatment.
- Social distancing in waiting areas, is maintained with signs, some subjects might opt to wait in a personal vehicle or outside the healthcare facility where they can be contacted by mobile phone.

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