

Re-Start of IRB Approved Studies conducted at Upstate Medical University in Ambulatory Settings

General

- 1) The Clinical Research Team will comply with all Upstate COVID-Related Policies and Procedures. This includes staff wearing masks etc.
- 2) Cleaning services: Need to comply with Upstate's recommendations for cleaning of ambulatory areas during COVID-19
- 3) PI's will continue to be responsible for oversight of all study activities, including maintaining up-to-date IRB approval(s) and order sets, and assuring that all staff are kept up-to-date on all protocol changes related to activities/orders.
- 4) No staff or study participants with known COVID-19, with signs or symptoms consistent with COVID-19, or at high risk of having COVID-19 (homeless, or residents of nursing homes, senior residencies, group homes, assisted living facilities) will be allowed to accompany subjects to visits
- 5) Participants will wait in their cars until research staff are available to check them at the door of the entry to the study location (staff will call or text them when ready).
- 6) Study participants will all be checked for symptoms, fever (temperature taken) and will be given masks at entry (outside door)
- 6) Participants are escorted by research staff DIRECTLY to a clean, empty exam room setting, not stopping in any hallway and not using any waiting area or bathroom.
- 7) In addition to wearing masks and frequent hand-washing, all will comply with social distancing (6 feet).
- 8) At the conclusion of each study visit, participants will be escorted directly out of the building by research staff
- 9) All exam rooms will be carefully cleaned after each patient visit per Upstate guidelines.

Phase 1 (Current Situation)

- 1) Only necessary and urgent visits. These include:
 - a) Participants and staff involved in COVID-19 clinical research.
 - b) For all other studies: Study visits are being conducted that are considered urgent or necessary for safety reasons. This is determined by specific study PIs, sponsors, protocols and IRBs. Please find attached Upstate's IRB Guidance.
- 2) Visitors not allowed unless absolutely necessary.

Phase 2

- 1) Add additional high priority visits (protocol-specific). This is determined by specific study PIs, sponsors, protocols and IRBs. Please review [Upstate's IRB Guidance](#).

- 2) Continue all procedures listed under "General"
- 3) Allow 1 visitor per patient
- 4) If Upstate and/or Onondaga County no longer meet the requirements for resuming elective procedures, will revert to Phase 1.

Phase 3

Fully open