

Clinical Research Unit Collins Wing Guidance for Resuming Operations

Clinical research can proceed on the Clinical Research Units only to the extent that it can be performed safely for research subjects and staff.

UVA faculty, research team members and staff must continue to comply with executive orders and health authority guidance from national, state, local, and University authorities to protect the safety of research subjects, caregivers, staff, visitors (monitors, vendors, etc.), and faculty.

Consistent with the Governor's Reopening Plan, the approach outlined in these guidelines is based on established physical distancing requirements for our various research spaces, requiring the use of personal protective equipment (PPE) which remains a limited resource, and sound hygienic practices, such as recommended hand washing/use of hand gel, and routine sanitizing of work areas. Under no circumstances should safety be sacrificed due to the lack of adequate supplies, such as the type and quantity of PPE. Plan in advance for PPE supply chain issues when resuming your clinical research on the Clinical Research Unit (CRU).

The guidance below was developed in collaboration with the VPR with input from Environmental Health Services, the Medical Center and the SOM Dean's Office.

Scheduling

- Research subject visits must be scheduled in advance per the standard CRU scheduling process. Walk-ins or unscheduled visits cannot be accommodated.
- Subject visits will be scheduled with a 30 minute buffer in order to accommodate subject visits that go longer than expected, to allow the study team to wipe down the room after each subject leaves, and so that the next scheduled subject can be "roomed" immediately upon arrival. This applies even if the study team is scheduling multiple subjects in one day.

Prior to subject visit

- Research personnel must contact study subjects within 24 hours prior to the scheduled visit. Clinical research personnel should verbally confirm and document that the participant is well, and explain the procedures on site for screening. The subject should be informed to wear a mask to the visit and that they will be required to wear a mask throughout the visit.
- Research subjects must not bring guests to the research visit. Children and adults who require assistance may have one caregiver. If a caregiver is required, the caregiver must also be screened prior to the visit as outlined above. The caregiver must also wear a mask to the visit and will be required to wear it throughout the visit.

Entrance to the facility

- Per UVA Health, research subjects should be instructed to access the Collins CRU via the Hospital Drive entrance (Collins Wing entrance). Note: this only applies to subjects coming directly to the Clinical Research Unit. It does not apply to those subjects coming to the CRU from another clinic. Those subjects can be escorted to the unit directly from the clinic.

- Research subjects should park in the parking lot at the end of Hospital Drive. They must be instructed to inform the parking attendant that they have an appointment at the Clinical Research Unit.
- Study teams must instruct the study subject to call the study team upon arrival to the parking lot (or at some point before arrival at the unit) so that there is ample time for a study team member to meet the subject at the Collins Wing entrance. Please note, upon arrival at the entrance the signage on the door outside the Collins wing reads: “Team Member Access Only – patients and visitors please use West Complex entrance and parking – 1300 Jefferson Park Avenue – Charlottesville VA 22903”. This restriction has been waived only for visits to the Clinical Research Unit only. But, in order to gain access, a study team member must be present to grant them access. If the subject rings the buzzer, the door will NOT be opened remotely for the study subject.
- Prior to allowing the subject access, the study member must screen the subject (and caregiver, if applicable). The following must be done prior to proceeding to the CRU.
 - Ensure the subject (and caregiver, if applicable) is wearing a mask.
 - Ask the following: “Do you have a fever, cough, trouble breathing or other respiratory symptoms (like sneezing or congestion)?” Answer must be ‘no’ unless medical reason for chronic respiratory symptoms (i.e., COPD).
 - Take the subject’s (and caregiver’s, if applicable) temperature. The temperature must be <38°C (<100.4°F) in order to proceed. A touchless thermometer is available in the CRU for this purpose. (Please note, it is the study team’s responsibility to clean the thermometer after each use.)

Upon arrival to the CRU and during the visit

- Upon arrival to the CRU, research subjects must be taken immediately to their assigned room.
- Upon arrival in the room, research must be asked about symptoms consistent with COVID-19. The study team must document and log the screening results in the following system: <https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=H9AEYA3DCC>. This system is monitored.
- Research subjects and caregivers must wear either a surgical/procedural mask or a cloth mask/face covering throughout the visit, except when removal of the mask/covering is necessary (e.g., during a physical exam or other research procedure, or when eating/drinking/taking medication). If the subject’s face mask gets soiled during the visit, contact the CRU staff for a replacement.
- Clinical research related activities should be conducted by a minimum number of necessary people, with time limitations and minimal personnel density.

Completion of study visit

- When the study visit is completed and the study subject has exited, it is the responsibility of the study team to:
 - Wipe down all surfaces/equipment in the exam room. Approved disinfecting supplies will be available in each room.
 - Remove all linens and place in the appropriate receptacle.
 - Ensure that all trash and medical waste have been placed in the correct receptacles.

Staff requirements

- Before coming to work, all faculty and staff are required to self-screen each day for signs of COVID-19 symptoms and to complete the UVA Health Employee Wellness Attestation. Employees scheduled to work on-site but who are not feeling well and/or are experiencing any symptoms of illness must stay at home, and immediately contact their supervisor.
- All clinical research personnel must wear masks at all times while on the unit, including when in contact with research subjects.
- All clinical research personnel must also wear eye protection when in contact with the study subject. Note: glasses without side protection are not sufficient.
- Clinical research personnel must follow the recommendations on physical distancing and hygiene practices.
- Only those study team members or ancillary staff who actually need to be involved with the study visit will be allowed.
- Staff must wash hands frequently. At minimum, staff must wash hands at the beginning of the subject visit and then again at the conclusion of the study visit.
- Hand sanitizer is available outside each exam room, but should not replace hand washing.

CRU nurse's station space

- We must adhere to social distancing and safety guidelines established by the institution. Therefore, the following changes to the CRU space will be implemented:
 - The computers in the nurse's station will be limited for use by study personnel requiring access to Epic for study documentation. In order to ensure social distancing requirements, only one computer in the nurse's area will be available for this purpose.
 - After using the computer, the study team must disinfect the area.
 - We encourage study teams to bring/use their own laptops in the exam rooms.
 - The water cooler will not be available for use.
 - Coffee will only be available to study subjects. The coffee pot cannot be used by study teams.
 - The refrigerator on the CRU can only be used for food designated for research subjects.
 - Study team members cannot eat in the nurse's station area, or anywhere on the CRU.
 - When moving around, a minimum distance of 6 feet is recommended for social distancing.

CRU lab space

- The number of occupants permitted in the lab space is restricted to 2.
- In an attempt to keep the lab available during those times when the YSIs are needed, the YSIs will be moved out of the lab. The YSIs will be placed in Exam Room 7 during those visits.
- All other current lab use requirements apply.

Research Monitor space

- Once research monitors are allowed on site again, study teams can once again reserve space in the CRU for monitoring visits. The two rooms on the CRU utilized for that type of activity have a

maximum occupancy of 1 person. (Study team member can join the monitor in the room for short periods to review findings as long as each person is wearing a mask.)

The success of resuming clinical research activities on the CRU depends on each study team member placing the safety of themselves and the people around them first while conducting their research. All clinical research teams are expected to fully comply with these guidelines. Our compliance will be monitored.