

University of Virginia
Guidelines for Return to Clinical Research
As of June 30, 2020

Overarching Goals:

- Clinical research can proceed only to the extent that it can be performed safely.
- 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 participants, caregivers, staff, visitors (monitors, vendors, etc.), and faculty.
- Consistent with the [Governor's Phased Reopening Plans](#), 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 reopening clinical research.
- **Required personnel and core services (CRU, BTRF) must be available.**
- **Failure to follow these guidelines will result in revocation of onsite privileges.**

Timeline for re-opening clinical research:

- **In order to open or re-open clinical research complete the request form at the link given at the bottom.**
- The earliest date to re-open previously halted human subject research studies that includes clinical research is **June 1, 2020** based on staff availability, provider, departmental, institutional and/or Sponsor restrictions, and PPE availability (see Tiers section below for details about opening clinical research).
- Clinical research that was approved to continue in [mid-March 2020](#) may continue and must meet the requirements outlined in these guidelines.
- Clinical Research activities that have been conducted remotely will follow the guidance outlined below for halted clinical research now that on-site visits will be permitted.
- To the extent possible, it is recommended that data collection and non-participant contact studies continue to be performed remotely in order to minimize the number of clinical research staff in research buildings and offices at any time.

Tiered approach to re-opening human subject clinical research:

- **Tier 1 - Effective June 1, 2020:** May continue those studies that were not previously paused, and may now start or restart those studies that do not have a potential for health benefit and require minimal face to face contact with subjects (e.g., a study requiring only a single blood draw within UVA Health or a study being conducted outside of UVA Health of a short time frame (e.g. less than an hour) provided the guidelines below are followed,

- **Tier 2 - Effective June 15, 2020:** In addition to the studies in Tier 1, study personnel may now start or restart those studies that do not provide a potential for health benefit to the subject and that involves only a small number of face to face visits, with each visit lasting a moderate time frame (e.g., less than 4 hours /visit) and require a limited use of core or auxiliary services (e.g., CRU, BTRF).
- **Tier 3 – Effective July 1, 2020:** All other human research studies, including those without a potential for health benefit, including biorepository specimen collections, observation studies, and other non-treatment clinical research may resume. At this time representatives from sponsors for site monitoring or site initiation visits will still not be allowed,

Tier 2 and Tier 3 target dates will be highly dependent on ongoing updates to federal, state, local, and institutional policies related to physical distancing and allowed activities and based on continuous monitoring of the guidelines. All safety measures (e.g. social distancing, wearing masks, taking temperature) are required in Tier 2 and 3 and will continue until further notice.

If there are special circumstances (e.g., the need for certain procedures in restricted periods) you may write to request an earlier restart. Please provide background information and justification to [DHudson@virginia.edu]

Additionally, researchers must maintain plans and be prepared to halt all activities on short notice should this become necessary.

In order for clinical research staff/faculty to return on-site, the following practices must be in place:

- Maximizing opportunities for remote work is critical and should remain in use for the foreseeable future whenever possible.
- Meetings with sponsors/CROs/vendors and collaborators should continue to be conducted virtually until local, state, institutional and facility restrictions are lifted (e.g., visitor restrictions to UVA Health)
- Research visits with participants should be conducted virtually wherever permitted by study protocol or other sponsor guidance until local, state, and institutional restrictions are lifted.
- 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 UVA facilities should develop a plan to ensure enhanced workplace sanitation and disinfection based on CDC and OSHA guidance.
- All clinical research personnel must wear masks while working on-site, including when in contact with research participants and/or staff.
- Clinical research personnel must follow the recommendations on physical distancing and hygiene practices for staff and study participants as required for the specific locations being used.
- When moving around a minimum distance of 6 feet is recommended for social distancing.
- For prolonged work with others (e.g., in shared office space) the space between people should meet relevant guidelines.
- Supervisors must, to the extent practicable, make special accommodations for employees at higher risk for severe illness. Individuals in these high-risk categories have been identified by the [Centers for Disease Control and Prevention](#). Such accommodations shall be coordinated through the Human Resources employee relations team.

Research office visits:

- For outpatient clinical research visits that will be conducted in-person, research personnel should contact participants within 24 hours prior to the visit. Clinical research personnel should verbally confirm and document that the participant is well, and explain the procedures on site for screening. The participant should be informed to wear a mask to the visit and that they will be required to wear a mask throughout the visit.
- Upon arrival, research participants must have their temperature taken and will be asked about symptoms consistent with COVID-19 (up-to-date symptom description from the CDC can be found [here](#)). In UVA Health facilities where this screening is conducted for everyone who enters the building, clinical research personnel do not need to repeat the screening. If the visit is taking place in an academic space (CRU, Memorial Gymnasium, etc.), the study team must document and log the screening results (<https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=H9AEYA3DCC>)
- Research participants should not bring guests to the visit. Children and adults who require assistance may have one caregiver. If a caregiver is present, the caregiver must also be screened prior to the visit as outlined above.
- Throughout the study visit, including during the screening process, clinical research personnel should follow physical distancing guidelines (i.e., 6 feet of physical distancing), except as necessary to complete required procedures.
- Clinical research related activities should be conducted by a minimum number of necessary people, with time limitations and minimal personnel density.
- All clinical research sites must eliminate traditional waiting and common seating areas and utilize non-traditional alternatives (e.g., call ahead registration, waiting in car until called, take participant directly to the research room, etc.).
- Research participants 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).

- Clinical research personnel must also wear eye protection if they need to be within 6 feet of a research participant for prolonged periods. Note: glasses without side protection are not sufficient.
- Should the participant require inhalation treatment or a procedure requiring inhalation (e.g., pulmonary function test), the current guidance for the facility in which this is conducted must be followed.

Industry sponsored clinical research studies:

- For industry-sponsored studies requiring isolation gowns, N95 masks, or other non-standard PPE in a hospital setting beyond the PPE currently in use, the study sponsor must provide PPE for required research staff.
- If the sponsor is unwilling or unable to provide such PPE, the study visit cannot be performed if there are UVA Health restrictions in place to conserve PPE.

Investigator initiated clinical research studies:

- For investigator-initiated studies requiring isolation gowns, N95 masks, or other non-standard PPE in a hospital setting, PIs will be responsible for obtaining required PPE.
- Investigators should minimize the number of research personnel in procedure rooms in order to limit exposure and use of PPE.

Device Representative visits:

Device representatives may enter UVA Health per their guidelines.

NOTE: If the facility in which the clinical research occurs has stricter restrictions than outlined above, the facility guidance must be followed. Failure to follow these guidelines will result in revocation of onsite privileges.

If you have an approved study (or studies) you would like to resume please go [here](#) to complete and to submit the short form.