University of Louisville
Return to Clinical Research Guidelines
May 20, 2020
(Updated May 26, 2020)**

Overarching Goal:

- Clinical research can proceed only to the extent that it can be performed safely.
- UofL research faculty 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 Healthy at Work Phase 1 Reopening Plan, the approach outlined in these guidelines is based on establishing 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.
- **Failure to follow these guidelines will result in revocation of onsite privileges.**

Timeline for re-opening clinical research:

- The earliest date to re-open previously halted Human Subject Research (HSR) (clinical research, clinical trials) is **June 1, 2020** based on staff availability, provider, departmental, institutional and/or Sponsor restrictions, and PPE availability.
- HSR that was approved to continue in mid-March 2020 (what we are now calling Phase 1) may continue and must meet the requirements outlined in these guidelines.
- Research activities that have been conducted remotely during Phase 1 will follow the guidance outlined below for halted HSR now that on-site visits will be permitted.
- It is recommended that data collection and non-participant contact studies continue to be performed remotely in order to minimize the number of HSR staff in research buildings and offices at any time.

Tiered approach to re-opening human subject clinical research:

- Tier 1 - Effective on June 1, 2020: Existing interventional studies prior to COVID-19 suspension may resume research activities with currently enrolled participants (evaluate staff availability, provider resources).
- Tier 2 - Target date June 15, 2020: Existing studies may enroll new participants. New interventional studies may be initiated (evaluate staff availability, provider resources).
- Tier 3 - Target date June 29, 2020: All human research studies, including biorepository specimen collections, observation studies, and other non-treatment clinical research may resume.
- Investigators wishing to re-initiate an existing study or open a new study prior to the timeline outlined above must receive approval according to the process established during Phase 1 of the COVID-19 suspension. Requests can be submitted using ULink user name and password.

- 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.
- Additionally, researchers must maintain plans and be prepared to halt all activities on short notice if this becomes necessary.

In order for HSR employees to return to on-site work, the following practices must be in place:

- Remote work is recommended for those employees who can perform their duties off campus in alignment with the university remote-work policy (currently through June 30th).
- Meetings with sponsors/CROs/vendors and collaborators should continue to be conducted virtually until local, state, institutional and facility restrictions are lifted.
- 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.
- When returning to work on campus for the first time, or as soon as practical thereafter, all faculty and staff must complete the Attestation of Self-Assessment Requirements and submit the confirmation to their immediate supervisor. PRIOR to returning to work each day, all personnel must conduct a daily health assessment as outlined in the Attestation of Self-Assessment Requirements.
- 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.
- Temperature checks on all participants and other visitors must be performed prior to entering HSR spaces.
- Employees or others with a temperature ≥100.4 F will not be permitted to enter HSR spaces. Employees who develop a fever while at work should go home immediately.
- All HSR units should develop a plan to ensure enhanced workplace sanitation and disinfection based on CDC and OSHA guidance.
- All HSR personnel must wear masks while working on-site, including when in contact with research participants and/or staff.
- All HSR personnel must follow the state recommendations on physical distancing (i.e., 6 feet of physical distancing) and hygiene practices for staff and study participants.
- To the extent practicable, the University will make special accommodations for employees at higher risk for severe illness from COVID-19, based on guidance from the Centers for Disease Control and Prevention. Such requests for COVID-19 accommodations should be made to your immediate supervisor who, if you are faculty, will coordinate with your department chair, dean and Provost Office of Faculty Affairs (eells@louisville.edu), or if you are staff, will coordinate with your department head and Human Resources via the employee relations team at emrelate@louisville.edu.

Research office visits:

- For outpatient HSR visits that will be conducted in-person, research personnel should contact participants within 24 hours prior to the visit. HSR staff should verbally confirm and document that the participant is well, and explain the procedures on campus for screening. The participant and any participating caregiver must be informed 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 (symptom description from the CDC). In healthcare facilities where this screening is conducted for everyone who enters the building, HSR personnel do not need to repeat the screening.
- 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, research personnel should follow physical distancing guidelines (i.e., 6 feet of physical distancing), except as necessary to complete required procedures.
- HSR related activities should be conducted by a minimum number of necessary people, with time limitations and minimal personnel density.
- All HSR units 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).
- 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.
- ** For contact tracing purposes, PIs and research teams should make a note in the research file (for all subjects with on-site study visits) of the individuals that interacted with the subject and any caregiver. This information may then be accessed later, if needed, to facilitate contact tracing.

Industry sponsored clinical research studies:

- For industry-sponsored studies requiring isolation gowns, N95 masks, or other non-standard PPE in a hospital setting, 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 due to hospital restrictions that are in place to conserve PPE.
- Approved studies in which PPE was required prior to COVID-19 and for which sponsors are providing PPE may continue.

Investigator initiated clinical research studies:

- For investigator-initiated studies requiring isolation gowns, N95 masks, or other non-standard PPE in a hospital setting, the PIs must communicate with the facility research office to obtain approval for PPE use.
- Investigators should minimize the number of research staff in procedure rooms in order to limit exposure and use of PPE.

Sponsor visits:

- In-person sponsor visits may not occur until restrictions are lifted by local and institutional authorities.

- The University of Louisville has a contract with Veeva SiteVault system. If you are interested in converting your study to remote monitoring, please send an e-mail to ctu@louisville.edu.

NOTE: If the facility in which the HSR 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.