Guidance for Re-opening Research at CCH 1-19-2021

During this phase of re-opening, in-person research visits, including recruitment and new enrollments, are no longer limited to therapeutic studies, i.e. those providing medications or other interventions to treat or prevent illnesses. Studies that are purely observational and other non-therapeutic in-person research may resume at this time. In-person focus groups and community-based research are still not open at this time. Investigators may submit a plan to the IRB on for these studies on how they will keep staff and participants safe for consideration in opening in this phase. On-line and remote study activities are encouraged for all studies.

Compliance with Infection Control Guidelines and Policies to Minimize Exposure

Research staff should comply with all CCH Infection Control Guidelines that govern patient care, including (but not limited to):

- use of face masks at all time
- use of gloves for direct patient care
- use of eye protection for all direct participant interaction
- performance of hand hygiene prior to and after all patient encounters
- screening staff and participants for COVID symptoms and fever each day/each visit
- separating participant visits in time, to minimize overlap
- minimizing wait room time by showing participants to a room to wait for study procedures whenever possible

Prior to conducting in-person visits, public health screening questions about COVID-19 symptoms can be conducted by text or phone. In-person, registration, or research staff may triage for signs/symptoms of COVID-19 prior to commencing study visit using the CCH screening protocol.

Research Staff

All CCH workplace social-distancing regulations apply to research personnel. Investigators are responsible for assuring that all research staff have workplaces that comply with social-distancing regulations and that all staff have training in:

- standard infection control measures
- donning and doffing of PPE should a participant have COVID signs or symptoms
- procedures for participants who have suspected COVID including where the participant will be taken for initial evaluation within the research area, where the participant will be taken if ill, how the participant should be safely guided out of the building if not ill, how to arrange for testing, appropriate protective equipment for staff and participant
- procedures for downtime/appropriate cleaning after environmental exposure to known or suspected COVID+ person

Other Restrictions

- Research procedures that involve aerosolization of pharyngeal, nasopharyngeal or respiratory secretions are not allowed

- Monitor visits and other regulatory and funder visits should be performed remotely whenever possible

IRB Reporting & Documentation

Changes made to the protocol because of COVID-19 restrictions may need to be submitted to the IRB depending on their nature and severity. These changes can include among others, visit changes, including location, procedures, and/or data collection; changes to the investigational product (IP) management, how the IP is dispensed, tracked, and/or accounted for; and changes in research staff.

- Changes that are minor, temporary, and do not increase the risk of harm to participants or adversely impact the data do not have to be submitted to the IRB. Major deviations may impact participant safety and make substantial alterations to the risks of participant. These should be reported to the IRB. Protocol deviations, may or may not rise to the level of an adverse event requiring reporting. This will be a judgment call. Please see the Guide for Investigators available on the Research & Regulatory Affairs website for guidance on adverse event reporting, link below.
- Permanent protocol changes, including temporary protocol changes that may continue indefinitely, should be reported as an amendment to the IRB.
- Investigators should consider whether updated consent forms or other materials are needed to include information about COVID-19 related precautions, testing, and tracing and submit to the IRB accordingly.
- Investigators should document how COVID-19 restrictions led to changes in study conduct, including duration of changes, which subjects were impacted, and how long they were impacted.
- Investigators should always follow their sponsor and FDA requirements.

Resources

Guidance for all of these procedures is available on CCH Intranet
https://vpn.cookcountyhhs.org/+CSCO+1h756767633A2F2F7070757661676 56E6172672E70707575662E7962706E79++/Intranet/Main.aspx?tid=592

- Infection Control Department staff are available for guidance or training.

Remote Consenting Procedures for COVID-19 Research Studies are available on the Research & Regulatory Affairs website: https://cookcountyhealth.org/wp-content/uploads/Remote-Consent-Procedures-for-COVID-19-Studies-FINAL.pdf

https://cookcountyhealth.org/education-research/research/office-of-research-regulatory-affairs-irb/

For questions, please contact CCHHSIRB@cookcountyhhs.org