

Expectations for Resumption of In-Person Clinical Research with the CCTS (Posted June 19, 2020)

We look forward working with investigative teams as they resume their non-essential research visits utilizing CCTS resources. As part of this process, we have developed a series of re-entry guidelines that are meant to ensure a safe and responsible approach in full compliance with university and hospital policies. Implementing these guidelines will require that research teams adhere to certain expectations and responsibilities to ensure that appropriate safety precautions for avoiding COVID-19 exposure are in place.

We recognize that not all possible scenarios will be covered by these written expectations and strongly encourage investigators to reach out to specific CCTS unit leads to clarify any of the procedures as needed:

CCTS Unit Contacts:

Bionutrition: [Orlando Gutierrez](#), MD, MMSc

Child Health Research Unit: [Daniel Feig](#), MD, PhD, MPH

Clinical Resources Support Program: [Meredith Fitz-Gerald](#), BSN, MSN, RN

Clinical Resources Unit: [Jolene Lewis](#), RN, MSN

Specimen Processing and Biorepository Unit: [Jeffrey Edberg](#), PhD

The specific expectations are outlined as follows:

- Prior to any scheduled research visit on the Clinical Research Unit, Child Health Research Unit or any other location that will involve CCTS personnel, staff from the investigator team must perform an in-person or telephone-based screen of the participant for COVID-19 no more than 24 hours prior to the visit. At a minimum, screening will include inquiring whether the research participant has been experiencing any symptoms concerning for COVID-19 infection (cough, fever, shortness of breath, viral prodrome [headache, nausea, vomiting, diarrhea]), whether the participant has been tested for COVID-19 (including results of that test), and whether the participant has had a known contact with an individual who has been tested for COVID-19 (including results of that testing). We encourage research groups to utilize a screening protocol as outlined [here](#) to document the screening. If any participant answers in the affirmative to any of the screening questions, the investigator team will need to contact the CCTS unit site lead prior to the visit to determine whether it is appropriate to continue with the scheduled research visit. Screening is also required when the individual arrives on the campus for the research visit.
- Similar screening provisions will be necessary for a caregiver if one is needed to accompany a participant to the visit.
- All research team members and study participants (and/or caregivers) must follow current masking and social distancing policies for research visits conducted on the Clinical Research Unit, Child Health Research Unit, or any other location that will involve CCTS personnel.

- Participants for studies conducted on the Clinical Research Unit are currently not permitted to park in the 6th Avenue Deck as the number of entry points into the hospital have been reduced to permit screening everyone entering the facilities. Participants may park in the 4th Avenue or TKC parking decks and the CCTS will validate their parking.
- All research team members must complete all applicable training for re-entry and be able to provide documentation of that training prior to requesting access to CCTS resources for non-essential research visits.
- Research visits which require SPAN services will have to adhere to new policies and procedures as outlined [here](#).