



March 15, 2020

To: All clinical and behavioral study investigators and research staff

From: Susanna A. McColley MD, Associate Chief Research Officer for Clinical Trials
Leon Epstein MD, Medical Director, Clinical Research Unit
Christy Anton, CCRC, Director, Clinical Trials Office
Larry Kociolek MD, Associate Medical Director of Infection Prevention and Control
Patrick C. Seed MD PhD, Division Head Infectious Diseases & Associate Chief Research Officer
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Cassandra Lucas PhD, Chief Operating Officer, Stanley Manne Children's Research Institute

Re: Effective March 16, 2020---Guidance for study teams performing participant-facing research outside of the CRU

As the circumstances with COVID-19 continue to evolve and the healthcare system encounters additional challenges to keeping staff, patients, and families as safe as possible, the guidance for the conduct of clinical and behavioral research requires re-evaluation and modifications. This document provides updated guidance for the conduct and oversight of clinical and behavioral research at the Stanley Manne Research Institute and Lurie Children's Hospital. Research administration and the IRB are fully functional and available to assist all investigators and staff. All staff should review this document and regularly review current institutional policies for the prevention and control of COVID-19 and other infectious risks.

1. Study teams should familiarize themselves with Lurie Children's information and policies regarding COVID-19: <https://www.luriechildrens.org/en/for-healthcare-professionals/education/2019-novel-coronavirus-2019-ncov-faq-for-lurie-childrens-healthcare-providers/>
2. Study teams must follow all guidance for screening patients and persons accompanying them for respiratory illness.
3. Study teams must follow all guidance within the hospital and other Lurie sites for visitor limitation, personal protective equipment conservation, and all additional measures implemented.
4. All measures should be taken to reduce research staff exposure to patients with respiratory illness. This may require suspension of study activities that are otherwise currently permissible.
5. Recruitment of patients who present for ambulatory, emergency department, or procedural visits and inpatient stays may continue if the patient does not meet institutional requirements for PPE and isolation. Patient volumes, waiting times, and other factors may require suspension of these activities. All institutional guidance must be followed. Otherwise, decisions regarding



- the volumes and waiting times should be made by area leaders who may include medical directors, clinical practice directors, nurse managers, or other supervisory personnel.
6. Study visits that are embedded within ambulatory, procedural, or inpatient visits may also continue with limitations as required, as outlined in #3.
 7. Visits for recruitment (including combined recruitment/enrollment) of participants that require a visit to a Lurie facility that is not embedded in clinical care must be suspended unless this poses a risk to potential participants (for example, a therapeutic intervention). In these cases, send a written request to Dr. McColley (SMcColley@luriechildrens.org) and Christy Anton (CAnton@luriechildrens.org).
 8. Activities requiring home visits by research teams to currently enrolled participants may continue. Participants and their household contacts should be screened for recent and current respiratory illness or international travel before research staff members conduct home visits:
 - a. Has the participant or a member of the household traveled internationally in the last 14 days?
 - b. Has the participant or a member of the household been in close proximity to a person with a confirmed or suspected case of COVID-19?
 - c. Is the participant or a member of the household experiencing fever, cough, stuffy, OR runny nose, sore throat, or shortness of breath?
 - d. Has the participant or a member of the household been in close contact with someone with fever, cough, stuffy or runny nose, sore throat, or shortness of breath?
- If the answer to any of these questions is yes, the visit should be postponed for a minimum of 14 days.** New screening must be performed before conducting any postponed visit.
9. Research activities requiring that patient or community participants convene together in a group (for example, focus groups) must be suspended.
 10. If telemedicine tools and services are needed for required visit activities, please contact Christy Anton (CAnton@luriechildrens.org).
 11. Recruitment activities at community events are strongly discouraged to promote social distancing.