



March 12, 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
Cassandra Lucas PhD, Chief Operating Officer, Stanley Manne Children's Research Institute

Re: Effective March 13, 2020---**suspension of routine visits for study oversight by external persons**

Given the rapidly evolving circumstances with COVID-19, we are providing this guidance document relating to the external visitors involved in conduct and oversight of clinical and behavioral research at Manne Research Institute/Lurie Children's Hospital. Research Administration and the IRB remain fully functional and are available for questions. All study teams should regularly review and always adhere to current institutional policy for infection prevention and control.

- a. Site Visits (Including but not limited to Site Qualification, Site Initiation, Monitoring, and Close-out Activities):
External persons involved in studies may not visit Lurie Children's facilities, including the hospital, clinics or offices, except for pre-approved visits requiring their presence as noted in section 2.
 - a. Visits may be rescheduled or conducted remotely in compliance with all applicable regulations and institutional policies (i.e., HIPAA). Please contact the IRB (IRB@luriechildrens.org) with any regulatory compliance concerns.
 - b. If telemedicine tools and services are needed for required monitoring, please contact Christy Anton (canton@luriechildrens.org)
- b. In unusual circumstances in which a critical procedure requiring an external person is necessary for participant health and safety
 - a. A written request must be sent to Drs. Epstein (lepstein@luriechildrens.org) and McColley (smccolley@luriechildrens.org) and Ms. Anton. Drs. Epstein and McColley are available by pager for urgent or after hours needs
 - b. After approval, study teams must ask and document screening questions to confirm absence of risk factors before external persons enter the institution:
 - i. Have you or your close contacts travelled internationally in the last 14 days or plan to do so prior to your scheduled visit? **External persons who have travelled internationally within 14 days may not visit Lurie Children's Hospital.**
 - ii. Have you or your close contacts been in close proximity to a person with a confirmed or suspected case of COVID-19? **External persons exposed to suspected or confirmed COVID-19 within 14 days may not visit Lurie Children's Hospital.**
 - iii. Are you experiencing fever, cough, stuffy or runny nose, sore throat, or shortness of breath? **External persons with any of these symptoms may not visit Lurie Children's Hospital until 48 hours after symptom resolution.**



- iv. Are any of your close contacts experiencing fever, cough, stuffy or runny nose, sore throat, or shortness of breath? **External persons with close contact with others with these symptoms may not visit Lurie Children's Hospital until 14 days after last exposure.**

We will update this guidance as required based on this rapidly evolving situation.