Ann & Robert H. Lurie
Children's Hospital of Chicago®

March 13, 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---**Guidance for study teams and utilization of Clinical Research Unit (CRU)**

Given the rapidly evolving circumstances with COVID-19, we are providing this guidance document relating to the conduct 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.

1. Study teams must follow ambulatory visit guidance for screening patients and persons accompanying them for respiratory illness.

2. Study teams must follow all guidance within the hospital for visitor limitation, personal protective equipment conservation, and any additional communications.

3. Notify medical monitors and CRAs regarding restrictions for CRU usage and the potential for a CRU closure. Utilize sponsor resources to define alternatives for critical safety measurements and drug distribution. When appropriate, utilize phone and telemedicine services for required monitoring. If telemedicine tools and services are needed for required, please contact Christy Anton (canton@luriechildrens.org)

4. Cancel screening visits for therapeutic or observational studies. If delays in screening may put participants with a serious illness at high risk discuss with Dr. McColley or Dr. Epstein. 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.

5. Limit CRU use to visits for therapeutic trials.

6. Notify sponsors and IRB of planned protocol deviations based on participant symptoms and to promote social distancing

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