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

March 20, 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
Patrick C. Seed MD PhD, Division Head Infectious Diseases & Associate Chief Research Officer for Basic Sciences
Cassandra Lucas PhD, Chief Operating Officer, Stanley Manne Children's Research Institute
Matthew M. Davis, Interim President and Chief Research Officer, Stanley Manne Children's Research Institute and Interim Chair, Department of Pediatrics

This guidance updates prior documents on conduct of all participant-facing research in and outside of the Clinical Research Unit.

Re: Effective March 20, 2020---Definition of essential participant-facing research activities during COVID-19

Essential research includes ongoing research that, if paused, would harm research participants. The risk of harm to participants must be balanced with the risk of health care facility and community spread of COVID-19. Study teams must notify sponsors to identify procedures that can safely be delayed or performed remotely. Principal investigators are ultimately responsible for participant safety and risk: benefit decisions.

For **interventional research,** harm may occur if studies are paused and

- enrolled participants do not have access to experimental therapies or safety monitoring/assessments
- recruitment is paused for potential participants who have limited treatment options for a severe and rapidly progressive disorder (for example, phase II and III clinical trials) or
- where above criteria are met and timely access to experimental treatments may be critical to avoid loss of time and safety data (for example, phase I clinical trial).

For **observational research**, in-person recruitment for participant-facing studies not embedded in clinical care must be paused.

Enrolled participants seen in patient care settings AND whose care is deemed essential under current COVID-19 guidance may have research procedures if they are

- feasible AND

- can be conducted by the staff already essential for the patient's clinical care (no extra personnel involved).

To continue in-person recruitment for participant-facing studies embedded in clinical care you must obtain approval in advance.

- Approval will be limited to those in which harm may occur if studies are paused because data collection is critical to the development of new treatment strategies for severe disorders with limited treatment options AND
- Are feasible without exposure of staff who are not essential to the patient's clinical care AND
- Require only minimal data collection (for example, use of medical records, bio-banking of specimens that do not require additional procedures, patient and family surveys).
- Requests for approval must be sent by email to Drs. Susanna McColley (SMcColley@luriechildrens.org) and Leon Epstein (LEpstein@luriechildrens.org). Drs. McColley and Epstein are available by pager at all times.

Please continue to look out for further updates regarding research in and 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 participant-facing clinical and behavioral research at the Stanley Manne Children's 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.