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FAQs: COVID-19 and Human Subjects Research Activities

(Updated 3/23/2020; this is a rapidly evolving situation. Please check back for further updates and guidance.)

On March 12, 2020, Research Leadership issued a memo regarding precautions to limit study activities involving external parties (sponsors, CROs, monitors) to those that are essential for participant safety and/or time sensitive. In addition, guidance for screening visitors for risk of COVID-19 was outlined. These FAQs are intended to provide additional information.

Research Administration and the Lurie Children's IRB remain fully functional. The IRB will continue to hold bi-monthly meetings. The IRB email inbox (irb@luriechildrens.org) will continue to be monitored at its current frequency.

1. **Can study activity continue during the COVID-19 crisis?**

   Effective March 20, 2020, all non-essential participant-facing human subjects research activities has been paused.

   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.

   Please refer to the Guidance on Essential Research Activities for more information.

2. **How is my study team expected to screen study participants for upcoming (at the hospital or at home) study visits?**

   Please review the Guidance on Essential Research Activities to determine if your study activities should continue. If your study includes essential research activities, the Study teams must follow all guidance for screening patients and persons accompanying them for respiratory illness by calling prior to the upcoming research visit. It is recommended this be documented within a research note in the patient's medical record or applicable study files:

   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.*

3. Can I conduct my research procedures remotely?

Yes, study procedures that must continue and can be completed without requiring face-to-face interaction with the participant should be conducted remotely. Such changes may include the elimination of/reduction in study visits, a shift from onsite visits to telemedicine or home healthcare by a third party agency, collection of labs offsite, changes in the provision of investigational product (IP), etc.

If the current IRB approved protocol does not allow for this, a modification can be submitted to the IRB. (Not necessary for studies deemed Exempt.) It is understood that study protocols may not be officially amended to reflect all changes. Submit clear documentation (from the sponsor and/or PI) that outlines the changes, the rationale for the changes, the expected duration of the changes (i.e., temporary or permanent), etc. Keep in mind that the IRB needs enough information to assess how the changes impact the risks and benefits to participants.

Alert the IRB staff via e-mail: irb@luriechildrens.org and such modifications will be given priority review. Ensure that relevant communication about altering study procedures is maintained in your regulatory files. If there is an immediate hazard to conducting a study visit in person, changes can be made and then reported to the Lurie Children's IRB within 72 hours.

****IMPORTANT**** To ensure timely review, please *do not include* other changes to your study in these special modification submissions beyond those required to conduct study procedures remotely.

Please note: *It may not be necessary to modify your IRB-approved protocol if it does not specify whether interaction will occur in person or remotely.*

4. Does my COVID-19 related modification require re-consent?

The regulations require initial consent from participants which includes notifying them of significant new findings that may impact their willingness to continue participation. The IRB will determine if reconsent is necessary for modifications or if the new information can be presented to participants in a different format (consent addendum, memo, orally by phone or phone, etc.). It is important for the PI/study team to thoroughly document how participants were informed of the new findings or protocol modifications. The IRB will be flexible and encourage the least burdensome approach for the participant.

5. Can I consent a participant remotely?

If you plan to conduct consent remotely (via phone or by e-consenting), if not previously approved by the IRB, submit a modification prior to implementation. Please reference the IRB Policies and Procedures Manual for information on alternative consent processes:

https://www.luriechildrens.org/globalassets/documents/luriechildrens.org/research/research-management--support/researcher-toolkit/irb-resources/irb-ppmanualsection-11.pdf

For externally sponsored (industry or other multi-site) studies, it is important to have approval from the sponsor (or lead site) first. Ensure that relevant communication about altering patient schedules is maintained in your regulatory files.

6. **Should I prepare to potentially transfer on site study visits to in-home visits due to increased restrictions at Lurie Children's or travel restrictions?**

   For externally sponsored studies, please notify sponsors of current, and the potential for future, restrictions including suspension of research activities. Inquire about plans that are in place, or being developed, for in-home visits or use of community resources (such as local laboratories).

   In order to conduct study visits in home, a licensed agency must be engaged, and a proper legal agreement executed. The study's IRB submission must be updated accordingly. The IRB has established an expedited review process for any such requests to avoid delays. OSP should be contacted to execute the proper agreements.

7. **How do I work with my study's sponsor to communicate and prepare for increased visitor and/or travel restrictions?**

   We recommend that you forward your study sponsor the Lurie Children's Clinical Research Activities Guidance Documents found on the Lurie website for COVID-19 response https://www.luriechildrens.org/en/for-healthcare-professionals/education/2019-novel-coronavirus-2019-ncov-faq-for-lurie-childrens- healthcare-providers/. Work with your study sponsor for a plan to address visit window deviations and/or missed assessments.

8. **Is it okay to send regulatory or study documents via e-mail?**

   If a study monitor and/or sponsor requests regulatory documents to review remotely, you may send documents that do not contain Protected Health Information (PHI).

   Source documents containing PHI should not be sent via e-mail or fax. Health information and study documents that contain any of the 18 HIPAA identifiers are considered PHI. Patient medical records may be shared via EpicCareLink.

9. **What should I do if the study sponsor or lead site temporarily pause study activities?**

   Submit a Modification for acknowledgement in Cayuse IRB. This is not required for Exempt studies.

10. **What resources can I share with participants concerned with exposure?**

Lurie Children's has provided a dedicated webpage for questions about COVID-19 and participants' calls can be directed to this additional information.

11. Should I still submit Incidents to the IRB?

Yes, the regular requirements for reportable events (i.e., an adverse event or protocol deviation that meets the definition of an unanticipated problem; non-compliance, etc.) still apply during this time.

Please track all protocol deviations in your study records. Report only those incidents that negatively impact risks to participants or others and/or study integrity. For example, it is not necessary to report a minor protocol deviation such as a study visit conducted outside of a visit window due to self-quarantine. However, a report to the IRB is necessary when safety assessments are missed.

Study teams are encouraged to keep clear documentation of any and all protocol deviations or failure to comply with normal policies and procedures. Documenting the circumstances of protocol deviations in real time, via a note-to-file, will be useful for reference for later monitoring or auditing.

12. Has the process for single patient emergency use been affected?

The procedure for Single Patient Emergency Use of an experimental drug or device remains the same during the COVID-19 outbreak. All Emergency Use Submissions must be submitted to the IRB by submitting an application in Cayuse IRB.

13. Is my COVID-19-related project considered research?

The Lurie Children's IRB is ready to assist researchers and clinical care providers who are planning COVID-19 research related activities. The IRB can assess the circumstances and provide advice. Contact irb@luriechildrens.org.

14. Is the ORIC Office open?

The Lurie Children's Office of Research Integrity and Compliance remains fully functional. However, all ORIC staff will be working remotely until further notice.

15. Who is the best contact for questions about my research protocols?

Please continue to contact IRB@luriechildrens.org with any research protocol questions.