

COVID-19 AND RESEARCH AT DUKE

March 11, 2020

The DUHS IRB and Duke University School of Medicine Administration (DUSOM) wish to assure the Duke research community that the safety of research participants and study teams is paramount during the COVID-19 outbreak. Because information and processes involving the outbreak are quickly evolving, please monitor the Duke COVID-19 [Resource page](#) and expect further notifications from Duke Health, Duke University, DUSOM, and/or the DUHS IRB.

Mandatory Screening for COVID-19 Exposure

Effective immediately, study teams should begin screening research participants at any interaction, whether in person or by phone. Screening should be an ongoing process with each subsequent encounter, subject to further notice from DUSOM. **The DUHS IRB does not need to be notified of, or approve, the incorporation of mandatory screening into research protocols.**

Research staff will have access to the Travel Screening Job Aid in Maestro Care for Duke patients and a paper version will be made available for research participants who are not DUHS patients or when the Travel Screening Job Aid is not easily accessible via Maestro Care. Duke Health has provided versions on the [COVID-19 resource](#) website. The paper version and additional Maestro Care screen shots for research staff will be posted on the research.duke.edu website by March 12, 2020 and will be updated as needed. For Duke patients, use of Maestro Care to screen patients is encouraged so that the screen results are recorded and when applicable the high-risk travel is documented, and flag created.

Triage and management of participants who screen positive is outlined for Duke Health Patients in the [DUHS Triage and Management of Potential COVID-19 cases](#) document which is in the Clinical Guidance and Forms folder of the Document Library. For all non-Duke Health participants additional triage and management guidance has been developed and will be posted to the Office of the Vice President Research website and will be updated as needed.

Deferral of On-Site Research Monitoring Visits

Effective today we recommend all planned in-person onsite clinical research monitoring visits be postponed until after April 20, 2020 or changed to remote monitoring when feasible. If there is an urgent need to maintain an in-person visit, please contact Susanna Naggie for approval. We will continue to reassess the need for this restriction or potential extension of the April 20 date.

Preparation for Potential Study Holds/Revision of Study Activities

As knowledge about COVID-19 continues to develop, Investigators should prepare contingency plans for active research projects. Plans should consider:

- Temporary holds on enrollment or other study activities for non-essential studies
- Necessary modifications to the approved research protocol
- Distribution of Investigational products (for drugs, consult with Duke's IDS)
- Ongoing review of research data, such as lab results or other testing
- Coordinating with collaborators and/or collaborating institutions
- Ongoing oversight on research activities

In preparation for more restrictive measures, particularly for non-essential studies, PI's should consider alternative plans for conducting research activities if staff are reduced. This applies not only to direct

interactions with research participants but also data and safety monitoring. For example, please consider the appropriateness of substituting phone calls or videoconferencing for study visits. The DUHS IRB is available for consultation on these issues. Contact information for the IRB is listed below.

Sponsor/Funding Notifications

If you plan to temporarily suspend or revise any part of your study (enrollment, interventions, data/safety monitoring) due to COVID-19 (*multiple bullets may apply*):

- For federally funded studies, please contact your grant officer;
- For all externally-funded studies, please contact the funding source or the overall PI;
- For any studies for which a Duke PI holds the IND/IDE, please contact Duke ORAQ at oraq@duke.edu;
- For Duke-funded studies, please inform your CRU Director via email.

IRB Approval

For the purposes of this policy, ‘deviations’ shall be considered to be deviations from the IRB-approved protocol that do not affect data integrity or subject safety, rights, or welfare. Examples of deviations include missed study visits, out-of-window visits, elimination of minor assessments, changing the platform under which data is collected or safety is monitored (such as changing from clinic visit to phone call), and home-delivery of drugs/devices. **The DUHS IRB does not need to be notified of, or approve, deviations from the IRB-approved protocol due to COVID-19 at this time; however, please internally track these deviations in the event that an accounting is required at a later time.**

Any other revisions to the IRB-approved protocol (change in the frequency of safety monitoring, elimination of critical study visits, change in drug/device administration or composition), require submission of an amendment to the IRB. Please put “COVID” in the amendment title. These amendments will be given priority for IRB review/approval.

COVID-19 Research Studies

Should Duke investigators wish to submit research studies specifically focused on COVID-19, please email the following IRB personnel: Jody Power, Executive Director; Sharon Ellison, Lead Chair; and Joe Austin, Director of Research Review, to alert them of the submission. Please alert your CRU reviewers of the urgency of the protocol. All COVID-19 studies will be placed at the top of the IRB’s review queue.

IRB Operations

Please be assured that DUHS IRB operations will continue uninterrupted during the outbreak. Office personnel and Chairs will continue to be available even if working remotely. Contingency plans are already in place to conduct convened IRB meetings remotely should it become necessary.

Contact Information

Staff and Chairs will still be available via email and regular office telephone numbers during normal business hours even if working remotely.

If you need to consult with the IRB specifically about COVID-19 and its effect on your research, please call the IRB’s main line at 919-668-5111 from 8:30am to 4:30 pm Monday through Friday and ask for an IRB Chair or the IRB Executive Director. If calling after hours or on weekends, please call 919-668-5111 and follow the contact instructions for the Chair-on-call.