Guidance for Research at Le Bonheur Hospital during COVID-19 Pandemic

As of March 20, 2020

Note-These guidelines are fluid and subject to change as information becomes available.

Research Activity	Guidance
On-site Monitoring/Auditing for Industry Sponsored Trials	Campus is closed to all on-site study monitoring until further notice. In the short term, ask study monitors to delay on-site visits if possible. If delay is not ideal, remote monitoring is an option. For remote monitoring, hard copies of the source documents can be provided to the study sponsor provided all PHI is removed/blacked out. -We are working to set up a process for sharing Microsoft office OneDrive folders for this. This would allow time sensitive access to de-identified records. - Send redacted data via email using ENCRYPT method. Note- We are exploring the option of using a web based go to meeting to allow the study team to review source docs while the study monitor looks on via WebEx or Zoom or some other platform-this is under discussion with IT because we need to ensure the security and privacy of the data. More details to follow as we learn more.
Screening and enrolling of new subjects at Le Bonheur in already open and active clinical trials	For interventional studies with little to no direct patient benefit, hold all new enrollment and notify the IRB and study sponsors. Please contact Kerry Moore or Marie Jackson in CFRI for guidance on interventional studies providing treatment for illness where the study benefits outweigh the added COVID-19 risk to subjects and providers. Non-interventional studies, including standard of care reviews, databases, research specimen collections and retrospective chart reviews are on hold during the COVID-19 pandemic to allow needed resources for clinical duties. A notice to the IRB and study sponsors might be required.

Initiation or Submission of New Clinical Trials	New studies with significant patient benefit will be considered on a case-by-case basis. Please contact CFRI to discuss (Kerry Moore or Marie Jackson).
Submission of New Studies to UTHSC IRB	Refrain from submitting new studies to the IRB until further notice (unless the new study offers significant patient benefit), as all resources are working to assist researchers in COVID-19 research treatment and managing changes to existing active clinical trials to ensure subject safety and to minimize harm.
Inpatient research visits	Continue research visits as there is no increased risk to patients or providers.
Subject follow up visits	Cancel all non-essential research visits (not related to patient safety or study objectives) If the sponsor or subject requests study visits be done, explore options including telemedicine or face-time. Subjects needing safety labs can have this done at another facility. Contact Thomas Hobson for billing procedures prior to scheduling to ensure the subject does not get billed.
Study subjects tests positive for COVID-19	In consultation with the study sponsor and investigator, decide if subject should continue with study or be withdrawn from participation.
Study Drug/Investigational Products	Some sponsors have requested study medication be shipped to subject homes. CFRI along with LB pharmacy are discussing options and how to facilitate. Sponsors have also recommended that the sponsor will directly ship IP to the subject.
IRB Reporting if changes are made to a study related to COVID-19	1. Please note all changes to the study related to COVID-19 must be reported to the appropriate IRB to ensure proper documentation. 2. To suspend or place a study on hold due to COVID-19. Please contact the study sponsor and IRB. and document discussion and plan for your study records. 3. For changes in study procedures (changing visits to phone calls, changing method of study drug delivery or telemedicine) submit a form 2.

	4. All missed study visits and/or protocol deviations that include safety procedures (Labs, physicals, etc.) will need to be reported to the IRB (on a form 4). 5. The study team can make changes and submit with a prepared document and attach to the form 2 instead of making multiple changes to section 925 in the application. In section 925, state see attached for COVID -19 changes/procedures. Consent changes can be made by creating a consent addendum to inform subjects of changes needed related to COVID-19 instead of revising the entire consent form.
Documentation	1. Document the discussion of management of the clinical study during COVID-19 and place in your study records. 2. Create a note-to-file of COVID-19 protocol deviations and file in the regulatory binder. This should include all study deviations, such as delayed visits. 3. Any missing data points should be documented and filed in the study record.

Please contact Kerry Moore Kerry.moore@lebonheur.org or Marie Jackson marie.jackson@lebonheur.org for questions related to COVID-19 and research.

Sources:

1. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic. March 2020.
2. WCG. Webinar. Clinical Trials in the Era of COVID-19: The Changes You Need to Make Now on 03/18/2020