HSPPO and the UofL IRBs Remain Fully Operational

The HSPPO and the UofL IRBs are fully functional and operating at our standard capacity. We expect this to continue even if the University suspends operations for contagion control purposes. All HSPPO staff are able to work from home, should it become necessary. All HSPPO email addresses continue to be monitored with the same or greater frequency. You may continue to use the phone numbers of your assigned IRB Analyst.

The current differences

- The University announced on 3/15/2020 that all research laboratories and facilities should ramp down non-essential research activities whether on- or off-campus.
- Clinical trials that involve life-threatening illnesses, last resort therapies, and other critical work that must continue need to go through an approval process. By Tuesday 3/17/2020 there will be a review of all clinical trials and documentation of critical life-saving intervention trials that may need to continue. Approval will go through Craig McClain and/or Jason Chesney, depending on the trial. This is a fluid process, as industry sponsors/NIH are constantly updating their guidance. Additional guidance will be available on the CTU web page: https://louisville.edu/research/ctu.
- The HSPPO main phone line, 502-852-5188, will continue to be monitored. It will be checked for messages every 20-30 minutes during standard work hours.
- Highest priority is being given to all inquiries, requests, applications, and modifications related to COVID-19. Please notify hsppofc@louisville.edu or your IRB Analyst for any urgent submissions related to COVID-19.

In-Person Interactions with Study Participants

Recommendations

For essential research that must continue, the HSPPO is suggesting that researchers consider requiring research participants to complete a short screening for exposure to the novel coronavirus or symptoms of illness before they are scheduled for any study-related visits or research activities and in-person interactions. Research participants with possible exposure or symptoms of illness should be scheduled (or re-scheduled) for a date in the future.

In the meantime, HSPPO believes this approach would be a prudent public health precaution for UofL and affiliated institutions, while the novel coronavirus situation and public health authority recommendations are rapidly evolving.

UofL researchers should consider the participant populations and if they are at high risk for COVID-19.

- Over 60 years of age
- Underlying health conditions
- Weakened immune systems
- Pregnant
UofL researchers should consider holding study visits or research activities remotely if feasible and in-person visits are not required to conduct safety monitoring; decreasing the number of protocol-mandated in-person study visits to healthcare facilities; and replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine.

UofL researchers should also consider contacting enrolled participants prior to their research activity or study visit to screen for possible exposure or symptoms of illness. Research participants with possible exposure should not participate in in-person interactions until after the time recommended by the CDC. (This added screening does not require IRB approval).

Screening questions may include, but are not limited to:

- Have you had any of the following symptoms in the past two weeks (fever, cough, shortness of breath)
- Have you had contact with a person who may have COVID-19?
- Have you been out of the country in the past three weeks or traveled to an area with known cases of COVID-19?

In addition, UofL researchers should:

- Follow the recommendations from the Louisville Metro Department of Health and Wellness.
- Follow any guidelines or instructions from a specific facility (e.g., UofL Health and Norton Healthcare, etc.) where participant interaction would occur.
- Consider the participant population (e.g., are they considered “high risk” for COVID-19?) and the setting in which the interaction would occur.
- Develop possible alternatives to in-person study visits that are important for subject safety and participant monitoring.

Is study visit or research activity cancellation recommended?

Things to consider

Clinical trials that involve life-threatening illnesses, last resort therapies, and other critical work that must continue need to go through an approval process. By Tuesday 3/17/2020 there will be a review of all clinical trials and documentation of critical life-saving intervention trials that may need to continue. Approval will go through Craig McClain and/or Jason Chesney, depending on the trial. The UofL IRB does not have a recommendation or requirement about canceling study visits or research activities; however, minimizing in-person interactions should be considered when feasible. You may choose to hold research activities or study visits remotely if feasible for the study and in-person visits are not required to conduct safety monitoring. You may also consider changing the schedule of study visits, changing or canceling non-essential study visits, conducting phone visits rather than in-person visits, conducting focus groups, interviews, other research activities or study visits by Go-To-Meeting or other electronic meeting applications.
You will need to modify the application before implementing any changes (unless they are necessary to eliminate apparent hazards to the participant and there is not time to obtain IRB approval) if the study is not exempt and the application specifies in person visits or research activities. Prior to submission to the IRB, researchers must communicate any proposed changes to the sponsor (if applicable).

You do not need to modify the application in order to hold visits remotely or change the schedule if the study is exempt from federal policy or if the IRB application does not describe whether the visit would be in person or remote or give specifics about visit schedule.

These modifications to procedures should be approved in advance by the IRB, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval. Consult with your HSPPO team at hsppofc@louisville.edu if you have questions. If you do need to change an approved monitoring procedure to eliminate immediate possible danger, please report it to the UofL IRB within 5 days, following the process within iRIS for an iRIS Application/Protocol/Document Change.

COVID-19-Related Activities That May Not Be Research

Consult with HSPPO

HSPPO is ready to assist researchers and clinical care providers who are planning COVID-19-related activities that may intersect or overlap with public health authority activities and/or FDA emergency authorizations for diagnostics. In some cases, IRB approval will not be required. HSPPO can assess the circumstances, provide advice, and issue determination letters (if warranted). Contact hsppofc@louisville.edu or your IRB Analyst.

Temporary halt to study enrollment. What do I do?

Some studies are voluntarily halting or delaying participant enrollment because of COVID-related public health recommendations, facility requirements, study team availability, and/or participants considered to be at high risk for susceptibility to COVID. This does not need to be reported to the UofL IRB unless the study hold is initiated at the request of an external funding agency/sponsor or the study’s Data and Safety Monitoring group (if there is one).

Kentucky COVID19 hotline: 1-800-722-5725