

HSPPO and the UofL IRBs Remain Fully Operational

The HSPPO and the UofL IRBs are fully functional and operating at our standard capacity. 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 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.
- As defined in the March 24th, 2020 memo from the EVPRI, Thursday, March 26, all non-essential research activities were suspended and all researchers were requested to stay away from on-campus workspaces/laboratories with limited exceptions approved by your Dean/VP to carry out essential research activities as follows:
 - Activity that if discontinued would generate significant and irreplaceable data and sample loss
 - Activity that if discontinued would pose a safety or health hazard
 - Activity that maintains critical equipment in facilities and laboratories that would otherwise become damaged
 - Activity that maintains existing critical or irreplaceable samples, animal populations and other research materials.
 - COVID-19 related activity that has a timeline for deployment that could address the current crisis
 - Activity that has U.S. government-mandated security and access requirements, cannot be performed remotely, and whose activity is deemed critical by the U.S. government
 - Activities specifically requested by a U.S. Government sponsor to continue during this emergency situation
 - Clinical trial activity that if discontinued or not started would negatively impact patient health, safety or survival

All research activities that do not meet the criteria listed above and that have not been approved to continue by the cognizant Dean/VP (or their designee) were to have been ramped down and stopped by March 26. Research Service Centers and Core Facilities were to have been ramped down by March 26, unless services are being provided to research programs performing approved, essential research activities. Non-essential research studies and experiments that have not yet started should be immediately postponed. Additional guidance will be available on the CTU web page: <https://louisville.edu/research/ctu>.

- Any research that can be safely conducted under remote conditions can continue, regardless of if the research is deemed essential (as defined in the March 24, 2020 memo) or non-essential.

In-Person Interactions with Study Participants

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?

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 Microsoft Teams or other allowed video/teleconferencing applications.

You **must submit an amendment to the IRB** before implementing any changes. Prior to submission to the IRB, researchers must communicate any proposed changes to the sponsor (if applicable).

If the study is not amended with the IRB, the principal investigator must review all **protocol/study deviations** to determine if any deviation related to the COVID-19 crisis is minor or major. Please track all minor deviations and report them at the next continuing review, per normal process. Major deviations must be reported following the [IRB event reporting policy](#).

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.

If you must make changes to study procedures to eliminate immediate possible danger, you must report it to the UofL IRB within 5 days by submitting the Application/Protocol/Document Change form in iRIS.

Consult with your HSPPO team at hsppofc@louisville.edu if you have questions.

Video/Teleconferencing

Microsoft Teams® is the university's supported and approved communication and collaboration platform. Teams is part of the university's contract with Microsoft which includes a Business Associate Agreement (BAA). University Leadership does not support the use of Zoom. Zoom is not approved for interactions that involve any form of sensitive information or discussion. This includes student (FERPA, GLBA), patient/customer (HIPAA, PCI, HB5) or any other university sensitive information. Zoom is not an ITS supported or recommended platform.

Per university policy and the procurement process, 3rd party vendors whose application stores, accesses or transmits university sensitive information must be appropriately reviewed, approved and contracted with prior to purchase or use. If you have questions regarding enterprise solutions or options, contact [Information Technology Services \(ITS\)](#). For questions regarding existing or new vendor contracts, contact university procurement; for security or compliance questions please contact the [Information Security Office](#).

COVID-19-Related Activities That May Not Be Research

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).

Resources

Kentucky COVID19 hotline: 1-800-722-5725

University of Louisville's response to COVID 19 can be accessed [here](#)

University of Louisville Executive Vice President for Research and Innovation COVID 19 can be accessed [here](#)

The Council on Governmental Relations (COGR) has compiled institutional and agency responses to COVID-19, which can be accessed [here](#). This is a convenient, "one-stop shop" for information regarding a sponsor's policies in response to COVID-19. This link includes FDA, OHRP, DOD, NIH, NSF, etc..