# Lawson Health Research Institute - COVID-19 Frequently Asked Questions (FAQ) for Sponsors

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*This is a living document that is subject to change at any time. Sponsors are encouraged to discuss study-specific action plans with the principal investigator and study team.*

Lawson Health Research Institute values the partnerships we share with sponsors to advance the health of patients around the world. While we must address the rapidly evolving pandemic, we remain committed to working collaboratively with our sponsors.

In alignment with London Health Sciences Centre (LHSC) and St. Joseph's Health Care London, Lawson is currently taking actions to reduce the transmission of COVID-19. Our top priority is the safety of the research participants and patients that we serve, as well as our staff, researchers, physicians, learners and sponsors. As such, Lawson research activity is now limited to essential studies until further notice. While each of our studies play an important role in advancing health care, we must prioritize projects that cannot be delayed in protection of participant safety and/or data integrity.

The below frequently asked questions (FAQs) address how this may impact study sponsors.

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## 1. Is Lawson allowing on-site monitoring visits at this time?

Lawson is currently unable to accommodate on-site monitoring visits at any of our sites across LHSC and St. Joseph's. External monitors often travel from institution to institution and from city to city. To protect the health of research participants and patients, as well as staff, researchers, physicians, learners, volunteers and external monitors, no on-site monitoring visits will take place until further notice. This measure aligns to the directives of our hospitals and public health recommendations of social distancing to prevent the risk and spread of COVID-19.

## 2. Is remote monitoring available?

At Lawson, remote access to the electronic medical record (EMR) is not possible. Transmission of redacted source documents will be limited to key eligibility criteria only. There is a risk of protected health information (PHI) being released when source documents are sent offsite. Sponsors are encouraged to perform remote monitoring and data management review in lieu of on-site visits. Telephone calls with staff during regular business hours are also possible.

## 3. Does your site have any plans of stopping recruitment activities?

Lawson is currently only recruiting for studies that provide a potentially essential treatment option with a time-limited enrollment window. For non-essential and non-therapeutic research studies, recruitment is suspended until further notice.

The safety of our participants is of primary importance. Investigators have been asked to use professional judgment by considering the risks and benefits for participants; the ability for successful recruitment and retention; as well as the ability to confirm eligibility, oversee safety and conduct timely study procedures/evaluations. In cases where recruitment remains active, sponsors should anticipate a reduction in the overall rate of enrollment.

## 4. What should be expected for any patients currently in screening?

For any patient currently in screening, the patient may continue to be screened/enrolled based on the investigator's judgment for what is best for the patient.

## 5. How are active participants affected? Will study visits continue?

We will continue providing essential treatment to patients on active trials. Investigators will use all reasonable efforts to manage the patient according to the protocol, but patient safety will supersede protocol compliance.

Lawson investigators have been advised to collaborate with sponsors to consider whether their active research protocols could be modified or delayed in order to limit personal contact, laboratory visits or trips to clinics and hospitals. Specifically, we've advised that in-person interactions should be reduced and/or replaced with telephone or online communication wherever it is possible to maintain the protocol's scientific validity.

Select study visits may be completed remotely or, if necessary, omitted. In cases where all protocol requirements can be reasonably completed, priority will be placed on collecting the protocol elements for safety and end point measures. Sponsors should expect missed data due to missed visits and deviations resulting from changes in how patients are being evaluated (e.g. telephone calls rather than on-site).

## 6. Is there an increased possibility that patients will not be able to travel to hospital for their visits?

Yes. LHSC and St. Joseph's serve patients from across Southwestern Ontario. It is possible that patients may be unable to commute to the hospitals due to their own illness, a caregiver's illness or concerns about entering a hospital site. The investigator and study team will make every effort to support the patient and will collaborate with sponsors to source alternative solutions to complete the protocol requirements where appropriate. However, sponsors should expect missed data due to missed visits and deviations resulting from changes in how patients are being evaluated (e.g. telephone calls rather than on-site).

## 7. What are some of the possible contingency plans in cases where a patient is unable to come into hospital for a research visit?

In cases where a patient can not or should not be coming to hospital, sponsors may be consulted about the following options to ensure completion of clinical trial protocol requirements:

1. **Oral investigational product (IP) dispensing**: Delivery to the patient's home by courier based on product stability and cost recovery availability.
2. **Oral accountability**: Routine phone calls with the patient for verbal confirmation of accountability and pill diaries with reconciliation once the patient is able to return to the site.
3. **Safety labs**: In cases where lab tests are typically completed on-site at LHSC or St. Joseph's, tests may be completed at a community lab. In cases where lab tests are central, sponsor permission may be requested to allow select tests to be collected at a community lab.
4. **Medical imaging**: CT, MRI and PET scans will continue to solely be provided at Lawson for clinical trial purposes. Select other imaging (e.g. x-ray or ultrasound), if delivered as per standard practice, may be assessed for delivery at a local lab.
5. **Quality of life questionnaires**: In cases where a patient does not require additional on-site activities, quality of life assessments will be completed remotely by mail or electronically.

## 8. Do you anticipate any delays with initiating new studies?

Delays in initiating new studies are anticipated. Recognizing we may experience a reduction in resources due to COVID-19 infection, self-isolation or redeployment to support hospital operations, we will be reducing the volume of new activations. During this period, we will be focusing on clinical trials that deliver a potentially essential treatment option with a time-limited enrollment window or those related to COVID-19. Non-essential trials or studies will not be activated. Any trial not selected for activation will be activated as efficiently as possible once resources are available.

## 9. Will there be any impact on submitting protocol amendments to your Research Ethics Board (REB)?

Western University's Health Sciences Research Ethics Board (HSREB) are prioritizing amendments to ongoing research projects and expediting review of new projects related specifically to COVID-19. As a result, there may be a delay in the review and approval of other submitted applications.