

GUIDANCE DOCUMENT: GUI014

Principles for Managing On-Site Visits by Research Representatives (Sponsor, Regulatory or Lawson Vendors/Contractors) During a Pandemic

1.0 PURPOSE

Mirroring the approach for patient care and family/caregiver presence at London Health Sciences Centre and St. Joseph's Health Care London, leaders should divert Research Sponsor or Regulatory Representative (Research Representative) activity to virtual/remote platforms unless on-site visits are deemed essential and cannot be delayed. This will likely necessitate creative thinking, innovation, process changes, and/or different use of approved technology.

The safety of the Hospital environment is critical to our patients, families/caregivers, staff, researchers, learners and physicians, and cannot be compromised. Any breach or contravention of this safety by external Research Representatives may be met with denial of entry, expulsion, and/or severing of the contractual/service arrangements.

2.0 SCOPE

This guidance document outlines the processes for permitting Research Representatives to come on-site for clinical research sponsor or regulatory visits that cannot be conducted virtually. It is applicable to all Investigators and research personnel who are hosting Research Representatives such as Sponsor monitors and auditors; Regulatory inspectors; or other vendors contracted by Lawson.

3.0 RESPONSIBILITIES

- Sponsor visits should be conducted virtually when possible
- All research representatives must maintain physical distancing while on-site
- Research Representatives must be fully immunized at least 14 days prior to coming on-site and must comply with hospital directives while on-site. (See section 5.0)
- **Parkwood Only** - PI/research personnel must obtain pre-approval from Lawson's Interim Chief Operating Officer (Cory Gosnell) at a minimum 5 days in advance of a proposed on-site visit.
(See section 4.0 for procedure)

PARKWOOD SITE ONLY

4.0 PROCEDURE – All on-site visits at Parkwood must have Lawson Pre-Approval

PI/Research Personnel Process (Requestor)

- At minimum **5 days prior** to the proposed on-site visit date:
- Email Cory Gosnell, Interim Chief Operating Officer (Lawson), at Cory.Gosnell@LawsonResearch.Com
 - **Email must include the following:**
 - Date(s) of the visit – indicate all dates if on-site for multiple days within same visit;
 - Names of individual(s) expected to visit on-site;
 - Name of the company they work for (Sponsor/Contract Research Organization (CRO));
 - Purpose of the visit – details should be specific. (i.e., Monitoring visit for Dr. Smith's study ABC);
 - Campus and location; including unit/room number (if known), of where they will be conducting their visit;
 - If visiting multiple departments, please include this information;
 - Statement Confirming Research Representative is aware of the immunization requirement and has agreed to comply with hospital directives while on-site.
- Research Personnel are also responsible to coordinate with support departments, as applicable, to ensure capacity and availability to support the on-site visit.
- For questions about your request, please contact Cory.Gosnell@lawsonresearch.com or Lawson's Quality Assurance and Education Program at qaep@lawsonresearch.com

Lawson Interim Chief Operating Officer (Cory Gosnell) Process (Approver)

- Receive and approve on-site visit requests in a timely manner.
- Forward the Approval to the appropriate door screener and copy the Requestor.

5.0 Instructions for On-Site Research Representatives – All LHSC and St. Joseph's sites

- All Research Representatives attending Hospital premises/property must show proof of double vaccination with a Health Canada approved vaccine.
- As of September 7, 2021, any research representative/vendor who has not provided proof of vaccination against COVID-19 will not be permitted on-site.
- Research Representatives attending Hospital premises/property must present at a designated patient/visitor entrance or contractor entrance (Research team to provide details).

- Research team member must meet the Research Representative at the designated entrance and escort them to the appropriate work space/location.
- All Research Representatives must show government issued identification to be permitted entry. They may also be required to show employee ID/company badge.
- All Research Representatives will be required to show verifiable proof of two acceptable doses of vaccine administered greater than 14 days prior to arrival.
- All Research Representatives will wear appropriate PPE if required, as follows:
 - Face masks are to be worn at all times throughout the Hospital
 - Any work conducted in clinical areas requires surgical masks with eye protection/shield, gloves, and gowns if applicable
- All Research Representatives must practice appropriate hand hygiene using hand sanitizer upon entry and exit of Hospital premises, at a minimum.
- All Research Representatives must practice appropriate 2m physical distancing while on Hospital premises or property.
- All Research Representatives must restrict their activity while in Hospital premises to the activities required to be on-site in the given location. Loitering and/or visiting others is not permitted.
- Any potential challenges complying with the above should be proactively raised, discussed, and resolved with Hospital leadership prior to arriving on-site.
- The safety of the Hospital environment is critical to our patients, families/caregivers, staff, researchers, learners and physicians; and cannot be compromised. Any breach or contravention of the above may be met with denial of entry, expulsion, and/or severing of the contractual/service arrangement.

6.0 DEFINITIONS:

- **Research Representative (Research Sponsor or Regulatory Representative):** Includes Research Sponsor/CRO employee or contracted representative, Health Canada Inspector or another regulatory agency inspector.
- **Vendor:** Includes any person, businesses or entities operating on or providing services on the hospital's premises; and any person, business or entity whom Lawson/HMMS has a contracted with to perform the work

7.0 CONTACTS:

Lawson's Quality Assurance and Education Program (QAEP) team is available for any questions regarding this guidance document. QAEP team members can be reached at qaep@lawsonresearch.com or ext. 72377.

8.0 REFERENCES:

[Coronavirus disease \(COVID-19\): Symptoms and treatment - Canada.ca](#)

[Fully vaccinated travellers entering Canada during COVID-19 - Canada.ca](#)

[Ontario Makes COVID-19 Vaccination Policies Mandatory for High-Risk Settings | Ontario Newsroom](#)

9.0 VERSION HISTORY

Document Name/Code	Effective Date	Pages	Type/Summary of Changes
GUI014	21Sep2020	8	Original Version
GUI014	29Oct2021	6	V2
GUI014	13Jan2022	4	V3
GUI014	23Aug2022	4	V4