Lawson Health Research Institute - Remote monitoring during the COVID-19 pandemic

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The following guidance has been created for investigators, research staff members and study sponsors. 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 (PI) and study team.

Lawson Health Research Institute values the partnerships we share with sponsors to advance the health of patients around the world. As the COVID-19 pandemic progresses, we must continue to follow provincial directives and facilitate sponsor visits using virtual methods whenever possible to protect the health and safety of our community.

All participants sign consent forms prior to study enrolment which allow sponsors to access personal health records that are relevant to study conduct to perform source data verification. When remote monitoring is performed, the sponsor requires access to the same records they would have access to during an on-site monitoring visit in accordance with contractual obligations.

Our Privacy, Health Information Management (HIM), and Information Technology Services (ITS) teams have approved a process to provide remote access to the Electronic Health Record (EHR).

A secure platform approved by our institution for the sharing of identifiable health data must be used and this must be performed by an authorized member of the research team (not students or trainees).

Research staff members and monitors both have a responsibility to ensure privacy and confidentiality are maintained during these types of visits.

- The videoconference cannot be recorded and screen shots cannot be taken.
- The research staff member and sponsor must both be in a private location when videoconferencing, screen sharing or reviewing confidential documents.

The following methods are currently available at our institution for supporting remote visits with external sponsors. Please note, no other methods or platforms will be permitted.

Cisco Webex, Microsoft Office 365,and Direct Access to the Electronic Health Record

Webex: Webex is intended to be used for meetings between staff and external parties for conducting hospital related business, education and research.

Features include;

- Videoconferencing
- Screen/Application Share function
- Document Sharing (during active sessions only)

Office 365 – Teams/SharePoint: Any files that are normally stored in our hospital environment, are safe to store in Office 365 (accessed by staff via corporate credentials). SharePoint can be used to share documents with authorized external parties.

Features include;

- Videoconferencing (Teams)
- Screen Share function (Teams)
- Document Sharing (SharePoint)
    - External monitors will be provided 24/7 Read-only access to Investigator Site File (ISF) documents. These files will not contain any participant-related information.
    - Restricted access (View-only with print/download/share disabled), limited to the duration of the monitoring visit, will be provided to external monitors for participant source documents. These documents will contain varying levels of Personal Health Information and Personal Information PHI/PI.

Specific participant visits that are to be monitored should be identified in advance and detailed in the Monitoring Visit (MV) confirmation sent to the site at least 1-2 weeks in advance, to allow the coordinator time to upload all the appropriate source documents into the system. A generic request for “all participants and all visits”, particularly for high enrolling studies, is not feasible and cannot be accommodated at this time.

Direct Access to the Electronic Health Record (EHR): This process can be set up by the research team. Requests must be made at least two weeks in advance of the scheduled remote monitoring visit to ensure system access can be granted.

All options described above allow secure access to essential and original/unaltered source documents for source data verification. These processes and programs provided by our institution (London Health Sciences Centre and St. Joseph's Health Care London), meet our hospital Privacy, Risk and ITS requirements to protect confidential information in our hospital environment.

Providing de-identified or redacted copies of participant records

Providing the sponsor with de-identified or redacted copies of participant records for the purpose of remote monitoring may be permitted in limited quantities, however videoconferencing or screen/document sharing via the methods above must be accommodated for regular remote monitoring visits for two reasons:

1. There is a greater risk of a privacy breach associated with transferring of redacted documents outside of the organization. Suspected or known privacy breaches must be reported immediately.
2. Sending redacted documents does not fully satisfy the regulatory requirement for source data verification and therefore the sponsor may be required to review the original source of redacted data once the pandemic restrictions have lifted.

If choosing to provide de-identified or redacted copies of original records, please ensure:

- **Only minimal documentation is sent to support critical data monitoring and safety information**
- To ask the sponsor to be specific about what they require (avoid sending more information than is needed).
- All copies are properly de-identified or redacted (i.e. all identifiers like names, DOB, address, PIN, etc. have been removed). This requires careful review of the entire document and verification by a second person before sending. Do not send or modify original documents.
- The participant's study ID is written on the top of each page.

Data sent off-site must be transmitted via a secure method. Options include secure file transfer (email – File Safe is available at the hospital and can be used by either party as long as the information is being sent or received by a hospital e-mail address), secure fax or uploading to a secure sponsor website. Research staff members must keep a log of all documents that are sent off-site.

On-site sponsor and regulatory visits

On-site visits by research (sponsor or regulatory) representatives may be permitted in **limited** circumstances, when the visit is deemed absolutely **essential** and cannot be performed virtually/remotely.

Investigators/research teams must get prior approval from the Clinical Area Director in accordance with hospital directives. Research representatives will be responsible for complying with all health and safety requirements during their visit.

Please note that Lawson reserves the right to classify an on-site visit as essential and that on-site visits will only be permitted in accordance with hospital and public health safety protocols. As these protocols evolve over time, we may need to update our guidance and policies. Please check our website for our most recent guidance document.

Questions

For more information or questions, please contact Lawson's Quality Assurance and Education team at qaep@lawsonresearch.com.