UNITY HEALTH TORONTO

Caring hearts. Leading minds.

Remote monitoring for clinical trials

Background

Study Monitors are external representatives of the Sponsor who oversee the progress of a clinical study, and ensure that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures, Good Clinical Practice and applicable regulatory requirement(s).

Unity Health Toronto is currently not allowing on-site monitoring for clinical trials due to the ongoing COVID-19 pandemic. Study teams have been asked to transition all sponsor monitoring to remote alternatives.

Privacy and Security

Individuals are not permitted to use solutions that have not been endorsed by Privacy and or Security such as free cloud-based videoconferencing platforms, third-party vendor endorsed software, personal email, or other unencrypted solutions. These platforms raise serious privacy and security risks for Unity Health and the participants within the study.

The following list of solutions has carefully and successfully undergone a privacy and security assessment to ensure compliance. The use of one or a combination of any of the tools is acceptable.

This document provides an overview of those remote monitoring options and best practices.

Options for remote monitoring

There are currently several options available to study teams for remote monitoring:

Tool	Instructions	Restrictions
Zoom Healthcare ONLY (No other platform is currently endorsed)	• The host must be a Unity Health employee with a Zoom Healthcare account • Contact ZoomResearch@unityhealth.to to have a Zoom Healthcare account set up under a Unity Health email address • Use the screen-sharing tool to share documents and other information with monitors remotely • Alternatively, share documents and other information by holding them up to the screen	• You must disable the local recording feature. You can learn how to do that here: https://support.zoom.us/hc/en-us/articles/201362473-Local-Recording • No photos or screenshots are permitted to be captured • Users should not send or forward meeting links to anyone outside of the meeting, or post meeting links on websites and social media sites
Remote access to EMRs for monitors	• Review this page for guidelines (for the full instructions see here) • Monitors can register and can access to	• Monitors will only have access for 30 days at a time (renewals can be requested)

	SOVERA directly • Complete the Unity Health Privacy and Confidentiality Training module and Sign the Unity Health Toronto Privacy and confidentiality Agreement	• Only review medical records of enrolled research participants in the study • Must not copy, take notes of, photograph, and/or remove any medical records • Following the research plan and only using personal health information as outlined in the research protocol • Do not share log in and password credentials
Shared Research Drives	• Study Teams should submit a SHOP IT request to set up a new shared folder on the Unity Health network. Study team should indicate who on the team should have access to the drive and specifically indicate if the person requires read or write access to the folder. Study monitors should be given read access only to the shared folder. • If they study monitor has not been set up with a Unity Health user name and password please contact Cordelia Cooper (Cordelia.Cooper@unityhealth.to) • Study team should upload only the relevant information into the shared network folder for monitors to see/review	• Monitors should have read-only access to folder • Monitors should only have access to drives for a limited period of time (this corresponds to their barcode end date when set up) • No study documentation is to be sent outside of Unity Health's network e.g. sending via unprotected email

Note: Study teams should **NOT** meet monitors off-site as a remote monitoring option. The tools listed above have been implemented to ensure the safety of our scientists, staff and trainees, and to ensure that monitoring can be completed without in-person contact

The study monitor must agree to:

- Maintaining confidentiality as outlined in the "SMH Privacy and confidentiality Agreement"
- Follow the research plan and protocol
- Only reviewing medical records of enrolled research participants in the study
- Must not copy, take notes of, photograph, and/or remove any medical records
- Must not have direct contact with patients, research participants, and/or their family and friends, including the exchange of their contact information
- Complying with all appropriate hospital policies and procedures, as needed
- Use only the secure approved methods above for any transmission of personal health information

Terms of Informed Consent, Protocols and Contracts

A reminder that most protocols, informed consent forms and study contracts currently state that personal health information will stay on-site or will only be sent to the coordinating centre. We should avoid sending data to the sponsor unless it was part of the original plan, even in de-identified form. Once the data is sent Unity Health loses all custody and control of the data which puts our research participants at risk. These secure methods above ensure that original terms of the informed consent form, protocol and the current contract are followed.

Please contact the individuals below for more information about:

- Privacy: Sydney.Dingwell@unityhealth.to
- Research ethics: Sharon.Freitag@unityhealth.to
- Clinical restart approvals: Olivia.Lavery@unityhealth.to
- ZOOM Healthcare: ZoomResearch@unityhealth.to
- Setting up Study Monitor with UHT username and password: Cordelia.Cooper@unityhealth.to