# Guidance for Remote Monitoring Requests

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

## 1. BACKGROUND

Given travel restrictions, public health directives, and updated monitoring processes, some sponsors are choosing to conduct monitoring activities remotely. Study participants sign consent forms prior to study enrolment which allow sponsors to access personal health information that are directly relevant to clinical trial conduct and source data verification.

Monitoring is essential to assure the quality of every aspect of a clinical trial and is a fundamental regulatory function in verifying:

- that the rights and well-being of human participants are protected
- that the reported trial data are accurate, complete and verifiable from source documents
- that the conduct of the trial is compliant with the REB-approved protocol/amendment, Good Clinical Practice (GCP) and with all applicable regulatory requirements.

Sponsors, Investigators, Vancouver Coastal Health Research Institute (VCHRI), and the UBC Clinical Research Ethics Board (CREB) look to *Good Clinical Practice: Integrated Addendum to E6 (R1) ICH Topic E6 (R2)* and *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2)* for guidance on the monitoring and oversight of regulated clinical trials.

Remote access to the electronic medical records is not available through VCH and our hospitals. We are therefore offering the following guidance and options for remote monitoring at VCH clinical trials sites.

## 2. SPONSOR RESPONSIBILITIES

Sponsors are responsible for developing a systematic, prioritized, risk-based approach to monitoring. Sponsors develop a clinical trial monitoring plan, and secure agreements with the investigator/institution for direct access to trial-related documentation to monitor the site.

- To facilitate the monitoring activity, VCH has approved certain platforms. See section 4.

- Platforms proposed by the Sponsor will be considered and approved by VCHRI on a case-by-case basis.

    - If a monitoring platform or tool needs to be installed on a VCH device, or an external system/tool needs to connect to a VCH device or system, contact the Research Privacy Advisor in advance to conduct a privacy security review and approval.

    - If there are any additional confidentiality risks that may arise for the participant from their data being entered into the sponsors monitoring tool/system it is the sponsor's responsibility to ensure that those risks are transparent to the participant and, if required, update the Informed Consent Form (ICF), accordingly.

- Participant records should remain stored in Canada. If participant record is to be accessed or stored outside of Canada, the ICF) must be amended to reflect this, and participants must be informed and re-consented.

- If any monitoring is conducted that is different than that in the study protocol, careful documentation will be required to capture:
    - The reason why it was done
    - The method used to collect monitoring information
    - The types of data that were collected
    - Who provided the information
    - How the source of the information was verified

## 3. INVESTIGATOR RESPONSIBILITIES

Investigators and site-level research teams facilitate and help to provide access to essential trial-related documentation to permit monitoring by the Sponsor.

- Ensure that the study participant is aware and consented to monitoring changes.
- Confirm VCHRI and REB approval of monitoring changes.
- Ask the sponsor what they require ahead of time to ensure they only have source documentation that is required (avoid sharing more information than is needed).
- Carefully review and redact documents before monitoring visit.
- Ensure that monitors have completed the Confidentiality Undertaking form (SOP & Tools) before performing any monitoring related tasks. Maintain a copy in the site master file.
- Ensure privacy and confidentiality are maintained during remote monitoring visits.

## 4. VCHRI Approved Tools for Remote Monitoring

A. VCH Zoom Healthcare, VCH Skype for Business, or UBC Zoom
    - Used for supervised visual verification of redacted records and source documents
    - Sessions are not to be recorded
    - Records are not to be uploaded or shared via these tools
    - Screenshots are not allowed at any time during the session
    - Confirm the identity of those that you share your screen with
    - Complete the monitor visit in a private location
    - Turn off automatic notification during screen share to prevent unrelated information from being shared
    - Retain a copy of study documents on file.

B. RealTime Clinical Trial Management System (CTMS) at VCHRI
    - This platform integrates all clinical trial activities into one centralized place for research teams and allows online access for sponsors/monitors to review, track and issue queries on electronic regulatory documents. For more information, see RealTime CTMS at VCHRI.
    - Utilize monitor portal access for remote monitoring

C. UBC Microsoft Teams
- Monitor/Sponsor: Records are not to be downloaded or removed by the sponsor
- Coordinator/Site:
    - Teams can be used to upload study documents.
    - Records are not to be downloaded or removed by the sponsor
    - Sessions are not to be recorded
    - Screenshots are not allowed throughout the sessions
    - Complete the monitor visit in a private location
    - Turn off automatic notification during screen share to prevent unrelated information from being shared
    - Retain a copy of study documents on file.
    - All uploaded documents must be deleted by responsible research team member after the session has been completed.

See UBC Faculty of Medicine Research Technology for more information on Microsoft Teams for research.

## 5. RESEARCH ETHICS

The UBC Clinical Research Ethics Board (CREB) may review ethics applications and study documents that reflect changes in monitoring approach for a regulated clinical trial

The CREB is responsible for approving the monitoring process and Informed Consent Form.

The CREB recommends that sites review the REB approved ICF(s) to ensure there is accurate reflection of the planned remote or on-site monitoring processes.

If it does not:

A. Refer to the BC Common Clinical Informed Consent Template Guidance language which states, “Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected remotely or on-site in the presence of the Investigator or his or her designate by representatives of ***[insert here, if relevant, the name of the sponsoring company or cooperative group conducting the study,] [insert here, if relevant, Health Canada], [insert here, if relevant, the U.S. Food and Drug Administration,]*** and ***[insert name of your REB]*** for the purpose of monitoring the research. If your records are inspected remotely, your information will be accessible via a secure online workspace, where certified copies including for example this informed consent form, may be viewed or uploaded and then permanently deleted following review. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.”

B. Submit an amendment if there are changes to the monitoring process

C. Participants may need to be re-consented or informed (with documentation in the study file) of any changes.

## RELATED DOCUMENTS

Health Canada, Management of Clinical Trials During the COVID-19 Pandemic: Notice to Clinical Trial Sponsors

Health Canada Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects

VCH Confidentiality Undertaking Form for Monitors and Auditors (SOPs and Tools)

Realtime Clinical Trial Management System at VCHRI

## FOR FURTHER QUESTIONS ON:

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