Guidance for Remote Monitoring Requests

BACKGROUND

Sponsors, investigators, and Research Ethics Boards (REBs) look to *Good Clinical Practice: Integrated Addendum to E6 (R1) ICH Topic E6 (R2)* for guidance on the monitoring of clinical trials regulated by Health Canada.

For sponsors, they develop the approach to adequately monitor a clinical trial (monitoring plan) and secure agreements with the investigator/institution for direct access to trial related documentation to monitor the site.

For the investigator, they provide direct access to trial related documentation to permit monitoring by the Sponsor.

Island Health REBs, may review the application and study documents that reflect changes in monitoring approach for a regulated clinical trial.

SPONSOR

1. Sponsor Responsibilities

- Ensure that any tool/system they are using has reasonable security arrangements in place.
- Ensure that they are aware of and have met the applicable standards for appropriate security arrangements.
- Provide Island Health information on the privacy and security arrangements of any tool/system they are using as this may be required to support the ethical or operational review of the study.
- May only store or access participant data from outside of Canada if the ICF has informed participants this will occur and aligns with the level of identifiabililty of the data the monitoring requires.
- If a monitoring tool needs to be installed on an Island Health device, or an external device needs to connect to an Island Health device or system, please contact the Privacy Office, as this will require review and approval by Island Health.

2. Sponsor Provided Tools

- Remote monitoring tools provided by the sponsor will be considered on a case-by-case basis.
- Any sponsor tool or proposed use or disclosure of health records must comply with the study ICF including what jurisdiction information is stored in and the level of identifiabililty of the data leaving the Island Health site.
- 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 ICF, accordingly.

RESEARCH ETHICS

For monitoring, the Research Ethics Board's (REB) responsibility is to review the Informed Consent Form (ICF) to ensure it contains:

- Monitoring activities and
- Associated data flow

In general, the REB will acknowledge (not approve) requests for either:

- remote monitoring or
- resumption of on-site monitoring

The REB 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:

- 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 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. 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."
- Participants may need to be re-consented or informed (with documentation in the study file) of any changes
- Submit to the REB a summary of any changes to the ICF(s) and outline how participants will be informed of any changes
- Submit an amendment if new documents/procedures need to be approved
- If there are no changes to documentation, submit a Non-Local Safety Report for REB acknowledgement

PRIVACY

The following is for the remote monitoring of clinical trials that will be accessing or requesting disclosure of information from Island Health systems.

1. Island Health Supported Tools

At this time, Island Health does not allow direct access to the Electronic Health Record for clinical trial monitors.

Island Health can support access for remote monitoring by using one or a combination of the following Island Health approved tools:

- Video conferencing tools (e.g. Zoom Healthcare):
  - Used for supervised visual verification of de-identified study records, redacted or identifiable source records.
  - Good Practice Tips:
    - Sessions are not to be recorded
    - Documents are not to be uploaded or disclosed via these tools
    - Confirm the identify 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

- Island Health Secure File Transfer Protocol (SFTP) (e.g. Kiteworks):
  - For disclosure of de-identified study records or redacted copies of source records.
  - Disclosure (not just review/access) of identifiable records may only occur if there is clear consent for identifiable records to leave the Island Health site in the participant ICF.

- Review of records in a secure system supported by Island Health (e.g. Clinical Trial Management System):
  - Secure systems can be used for access to de-identified study documents and redacted or identifiable certified copies of source records.
  - Identifiable records are not to be downloaded or removed from these systems unless there is clear consent for disclosure of identifiable records to the sponsor in the participant ICF.
  - Depending on the system, monitors may need to contact Research & Capacity Building to establish further agreements or accounts to enable access.

RELATED ISLAND HEALTH GUIDANCE

- Guidance for the use of virtual tools in research specific to Island Health requirements

FOR FURTHER QUESTIONS ON:

Privacy

a. Email: Shannon.May@viha.ca , Research Privacy Specialist

Good Clinical Practice and other clinical trial regulations, guidance, and policies

b. Email: Tracy.Wong@viha.ca , Research Compliance Facilitator

Clinical Trial Research Ethics reviews

c. Email: Karen.Medler@viha.ca , Research Ethics Coordinator, Clinical REB

Conducting clinical trials

d. Email: Sheilah.Frost@viha.ca , Clinical Research Manager