IWK Research Ethics
Standard Operating Procedures

Document # **RE 9.902**	Title: **Remote Monitoring During a Publicly Declared Emergency**	Effective Date: **February 1, 2023**
Pages: **4**	Responsibility of: **Research Ethics Board**	Date Approved **February 1, 2023**

PURPOSE:

With the activation of SOP 5.503 (REB Review During Publicly Declared Emergencies), the REB may, during a publicly declared emergency "follow a modified review and operations plan". The purpose of this Standard Operating Procedure (SOP) is to inform the processes concerning remote clinical trial monitoring during any publicly declared emergencies such as the COVID-19 Pandemic.

Note: Research teams are to keep abreast of any public health changes to isolation requirement for individuals entering Nova Scotia that could affect their current monitors and/or this SOP.

SCOPE:

This SOP applies to all IWK based research areas, its personnel, regardless of employee status and all institutional support services that are impacted by remote monitoring. Due to COVID-19 restrictions, clinical trial monitors will be required to monitor study data remotely via IWK approved, secure video conferencing platforms.

PROCEDURE:

1. **Sponsor:**
    - Please check with your Sponsor for CTA contract wording. There may need to be a change to include remote monitoring.
    - Please negotiate any increased costs associated with more coordinator time for remote monitoring including cost for access to via IWK approved, secure video conferencing platforms.

2. **Informed Consent:**
    - Please inform all study participants monitoring will be remote and not physically at the institution. There is no change in the commitment and expectation of confidentiality.
    - Consent may be done verbally or as a consent addendum.

3. **Confidentiality:**
    - Ensure all confidentiality agreements are in place and valid
    - Guidance on confidentiality practices and requirements ca be found by visiting the following resources:
    - ICH-GCP 5.15.1 and 5.15.
    - IWK Health Pledge of Confidentiality
    - TCPS2 Chapter 5: Privacy and Confidentiality, A. Key Concepts: Confidentiality

4. One Content Account Holders

- Following standard procedure, identify which patient records will be reviewed and have the appropriate queue updated.
- Keep in mind there will be extra time required from the research team member to be available to bring up the records for viewing.
- Only an account holder for the queue should be assisting the monitor.

5. Electronic Medical Record Users:

- Identify which patient records will be reviewed in your monitoring letter.
- Only the individual having Clinical Portal access for study participant records should be assisting the monitor.

6. Communications:

- Consider writing an SOP or note to file for remote monitoring.

7. Execution:

- Any study documents that contain personal identifying information such as consent forms and demographic pages cannot be scanned and must be reviewed over video (e.g. IWK approved, secure video conferencing platforms.).
- Identifiable source documents must be de-identified with a participant number prior to being sent securely or uploaded for screen sharing.
- Scanned de-identified documents must be sent via IWK secure email platform with the following statement: *The sender certifies that the copy being uploaded has the same information as the original*.
- Scanned source documents that are sent to the monitor should be deleted/destroyed by the recipient after the virtual monitoring meeting.
- Monitoring visit logs will indicate that the visit was done remotely.

Forms/Records:

Form #	Form/Record Name
SOP 902.2	Remote Monitoring During a Publicly Declared Emergency

Revision History:

Revision	Date	Description of changes
0.0	January 8, 2021	Initial Release
1.0	October 26, 2021	Addition of IWK approved video conferencing platform
1.1	November 2, 2021	Addition approved
1.2	February 1, 2023	Updated logo