nova scotia health	Remote Access of Source Data for Verification containing Personal Health Information by a Sponsor Representative.	Effective Date: March 1 2021
Clinical Trials Standard Operating Procedures		Version: V1.0
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SOP Owner: Research Quality		

1. **Purpose:**
   This Standard Operating Procedure (SOP) describes:
   A. The process for the site to obtain access Zoom for Healthcare platform for remote access by a Sponsor representative to facilitate source data verification that contains personal health information of the study participant.
   B. The process to prepare for the remote monitoring visit that facilitates remote access to source data though screen sharing.
   C. The process to provide requested source data documents to the monitor and/or Sponsor.

2. **Definitions:**

   Clinical Trial Agreement (CTA):
   Legally binding contract between a sponsor, site, and researcher and outline each party's responsibilities and obligations for the clinical trial.

   Personal Health Information (PHI):
   Identifying information, (i.e. information that identifies or could reasonably be used to identify an individual either alone or with other information), whether living or deceased, and in both recorded and unrecorded forms, if the information relates to:
   - The physical or mental health of the individual, including information that consists of the health history of the individual's family,
   - The application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,
   - Payments or eligibility for health care in respect of the individual,
   - The donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
   - The individual's registration information, including the individual's health-card number,

- Identification of an individual's substitute decision-maker

- Any other information about an individual that is included in a record containing personal health information.

Source data:
All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

Substitute Decision Maker:
Person(s) who can legally make health care decisions for another person who does not have capacity to make their own decisions at that given time.

Zoom for Healthcare:
A secure, web-based virtual care video conferencing platform used in NSHealth.

3A.Procedure for ZOOM Healthcare access:

Obtain access for Zoom for Healthcare platform.
3.1 Visit Zoom for Healthcare website:
Zoom for Healthcare | Nova Scotia Health Authority - Corporate (nshealth.ca)
3.2 Complete the Zoom for Healthcare Request Form:

- For the Service Area, enter 'Other" and add "Research Approved-Remote Monitoring"
- Save the form
- Submit form by email to VirtualCare@nshealth.ca

3B. Procedure for preparation for the remote monitoring visit

3.B.1. Confirm the Clinical Trial Agreement with Sponsor has the provision for remote monitoring prior to first remote monitoring visit.
3.B.2. Confirm required confidentiality agreements (NSHealth and if applicable, Sponsor) are present and valid prior to the first remote monitoring visit and as needed.
3.B.3. Confirm with Sponsor what process to take in the event of a study participant declining consent to allow remote monitoring of PHI prior to the first remote monitoring visit and as needed.
3.B.4. Confirm the study participant or Substitute Decision Maker has been informed and consented to having source data verification done remotely instead of the monitor being on site prior to the first monitoring visit.
3.B.5. Request the required medical records study participants.

OneContent account holders

- ✓ Identify from the monitor correspondence the study participants' medical records to be viewed during the remote monitoring visit.
- ✓ The account holder updates the queue assigned to the clinical trial, if required, as per Health Information Services process.
- ✓ Only an account holder for the queue assigned to the clinical trial can

facilitate the monitor to view the content.

- ✓ The monitor can only view the medical records of the study participants that were identified in the monitoring letter prior to the remote visit.

Clinical Portal/Meditech access holders.

- ✓ Identify from the monitoring correspondence which study participants' medical records will be viewed during the remote monitoring visit.
- ✓ Only an access holder to Clinical Portal/Meditech can facilitate the monitor to view the content.
- ✓ The monitor can only view the medical records of the study participants that were identified in the monitoring letter prior to the remote visit.

3C. Procedure to provide requested source data verification documents to Sponsor representative

3.C.1. Provision of source date verification documents to monitors or sponsors is only permissible using the following mechanisms:

- ✓ All documents containing PHI are de-identified preventing the identification of the study participant, institution, physician, other personnel providing care, and any other information that may could provide tracing ability (bar code ID from test reports, etc.)
- ✓ Scan hard copies of de-identified documents and sharing via SEND secure email using an NSHA-issued device.
- ✓ Mailing hard copies of de-identified documents by courier.
- ✓ Soft copies of de-identified documents sent using Adobe Pro or other approved software via SEND secure email using an NSHA-issued device.

Guidance on confidentiality practices and requirements:

- ICH-GCP 5.15.1 and 5.15.2
- NSHA confidentiality agreements
- TCPS2 Chapter 5: Privacy and Confidentiality, A. Key Concepts: Confidentiality.

References:

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Version:	Effective:	Approved by:	What's changed:
Original	2021-03-01	M.Chappell A. Dean K. Hornberger	N/A
[Revised / Reaffirmed]	YYYY-MM-DD	[Sponsor or Issuing Authority	[Brief description]