memorandum

To: Nova Scotia Health Research & Innovation Community

From: Dr. Adrian MacKenzie, Director, Research
Ms. Michele Chappell, Program Manager, Quality

Date: January 18, 2021

Re: **Remote Monitoring of Clinical Trials – Updated**

As a result of recent changes in isolation requirements for individuals entering Nova Scotia from New Brunswick, clinical trial monitors residing within Nova Scotia, Prince Edward Island, or Newfoundland and Labrador may continue monitoring visits on-site at Nova Scotia Health while abiding by COVID-19 guidelines. Any change in provincial regulations will be announced immediately.

Nova Scotia Health is continuing to support remote monitoring through the Zoom for Healthcare platform.

Please provide ample time for Health Information Services to process your requests for OneContent queue updates.

We continue to work with IMIT on the development of a Virtual Desktop platform to allow monitors to access their OneContent accounts remotely. Updates on progress will be provided as they become available.

Guidelines:

Zoom for Healthcare access:

Please fill out the form available by visiting our Zoom for Healthcare website. On the form for the column Service Area enter "Other" and for the column If Other, enter Service Area enter "Research Approved – Remote Monitoring", and submit to VirtualCare@nshealth.ca.

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 Zoom for Healthcare.

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 with a note to file or as a consent addendum or update through an amendment to the REB. the method that you choose will depend on your recruitment stage.

Confidentiality:

- **Ensure all confidentiality agreements are in place and valid.**

Guidance on confidentiality practices and requirements can be found by visiting the following resources:

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

OneContent 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.

Electronic Medical Record Users (i.e. Clinical Portal/Meditech or others):

- 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.

Communication:

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