

MEMO

RE: Monitor/Auditor Access to AHS Patient Records

Due to technological limitations and privacy considerations, Alberta Health Services (AHS) is unable to provide clinical trial monitors/auditors with direct access to AHS electronic medical record (EMR) systems. AHS is working on the implementation of EMR functionalities that will enable external view-access for study monitoring purposes.

In the interim, to meet sponsor regulatory requirements for source verification, research teams have the following options:

1. **Over the Shoulder Access:** Study coordinators may use their AHS system log-in to access the electronic medical records of consented trial participants. The monitor/auditor sits with the study coordinator to review the source data while the coordinator navigates through the electronic medical record of the participant. *Note: Monitors/auditors cannot be left unattended at any time while reviewing patient medical records.*
2. **Certified Copies:** Study coordinators may provide monitors/auditors with certified hard copies of the study participants' medical record for the duration of their site visit. GCP E6 (R2) defines a Certified Copy as "A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original." This will allow the monitor to review the patient records (while on site only) without supervision by the research team.

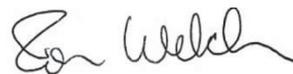
If certified copies are provided, it is also permissible for the monitor/auditor to ask for source validation to a subset of the data through an over shoulder access to the AHS EMR (see option 1).

For further clarifications, please contact the NACTRC team at NACTRC@NACTRC.ca or AHS Provincial Research Administration at Research.Administration@ahs.ca.

Thank you,



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