

MEMO

July 28, 2023

RE: Monitor/Auditor Access to AHS Patient Records

To meet sponsor regulatory requirements for source verification of health information, research teams have the following options:

- 1. External Study Monitor (ESM) access to the Connect Care Provider Portal (CCPP):**
Research study monitors will be able to request ESM access to the CCPP by completing the [HSA intake form](#). If your monitor or auditor has additional questions about how to access the CCPP, please direct them to these [instructions](#).
- 2. Over the Shoulder Access:** Study coordinators use their AHS system log-in to access the electronic medical records of trial patients. The monitor/auditor sits with the study coordinator and reviews the source data while the coordinator navigates through the electronic medical record of the consented trial patient. **Note:** *Monitors/auditors cannot be left unattended at any time while reviewing trial patient's medical records on the coordinator's AHS system log-in.*
- 3. Certified Copies:** Study coordinators provide monitors/auditors with certified hard copies of the study participants' medical record. Monitors/auditors have access to the certified copies 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 data on their own (while on site only) so you can get some of your own work done.

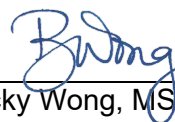
If certified copies are provided, the monitor/auditor will also typically ask to validate a subset of the data through CCPP ESM access or an over shoulder check of the actual AHS electronic medical record (see Options 1 and 2 above).

For further clarifications, please contact jldobry@ucalgary.ca.

Thank you,



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