

Research Visitor – Study Monitor Forms for **Accessing Electronic Medical Records**

Process for Study Monitors to Access Electronic Medical Records (EMR) for Research Purposes

1. With each newly REB-approved study requiring the review of electronic medical records (EMRs), the PI must complete the [Access to Electronic Medical Records \(EMR\) Request Form](#). The PI sends the completed form and a copy of the REB approval letter to Health Records (HealthRecords@smh.ca).
2. Health Records will then set up Research Access and a temporary folder for the specific study. Allow 3 business days for processing.
3. If the PI/coordinator does not have an existing SOVERA User ID for research purposes and is requesting patient chart(s) for the first time, contact Health Records (HealthRecords@smh.ca) to arrange for a training session on how to make a SOVERA Request. A SOVERA User ID and password will be assigned to the PI/coordinator upon completion of the training session.
4. If the Study Monitor is accessing an EMR for the first time, they must first complete mandatory training in SOVERA. The Study Monitor must complete the [Accessing SOVERA for Research Purposes Training Record](#). Please contact Health Records (HealthRecords@smh.ca) in advance to arrange for a training session.
5. Three days prior to a Study Monitor visit, the PI/coordinator must log on to SOVERA using the assigned User ID to request the release of individual patient charts for enrolled subjects. The PI/coordinator notifies Health Records via email (HealthRecords@smh.ca) that a SOVERA Request for patient charts has been made under the assigned User ID. To aid in tracking, include the following information in the email: study title, REB#, MRN(s), date(s) of access and name of study monitor.
6. Health Records will then release the charts requested for research purposes.
7. On the day(s) of the Study Monitor visit, the PI/coordinator will provide the Study Monitor with the SOVERA User ID and password. Upon logging into SOVERA, the Study Monitor will have access only to the specific patient charts that have been released by Health Records. The requested patient charts will be available through SOVERA to the researcher and the Study Monitor only for a limited period of time (default is 10 days).
8. The PI/coordinator is responsible for tracking the name of the Study Monitor, the patient charts that are accessed by the Study Monitor and the dates of access.
9. The PI must ensure that Health Records has a copy of the current REB approval letter when making a request for patient charts.
10. Steps 5, 6, 7, 8 and 9 are repeated for each Study Monitor visit.
11. The PI must also notify Health Records of any additional research personnel and/or Study Monitors throughout the study period using the [Access to Electronic Medical Records \(EMR\) Request Form](#).

Access to Electronic Medical Records (EMR) Request Form

To the Investigator:

This form is to be completed for each newly REB-approved study requiring access to SMH electronic medical records (EMR). In addition, this form can be used to notify Health Records of additions to study staff.

Date of Request: _____ Start Date of Study: _____

Study Title: _____

REB #: _____

Name of Principal Investigator: _____

Study Contact: _____

Name(s) of the research team member(s) who will be accessing EMRs for the study:

Name(s) of external Study Monitor(s) and their affiliation (if available):

Please submit this completed form with a **pdf copy of the current REB approval letter** for the study to: HealthRecords@smh.ca *Attention- Fernando Antunes / Lucy Howie*

Note: Submit a pdf copy of the REB renewal letter to Health Records each year.

Health Records will notify the Study Contact when access to SOVERA for the study becomes available.

Office Use:

Health Records to initiate Research Access and a temporary folder for the study.

Completion Date: _____ By: _____

Accessing SOVERA for Research Purposes Training Record

All **registered** research visitors i.e., Study Monitors may obtain access to SOVERA, the hospital's electronic medical record (EMR) system. Training in how to use SOVERA must be completed prior to their first access to SOVERA for research purposes. Training is currently done by a face-to-face 20 minute session with an Expert User in Health Records.

Date of Training: _____

Name of Trainer: _____

Name of Trainee: _____

Trainee's Department or Affiliation: _____

The following actions were demonstrated during the training session:

- How to log on and log off
- How to select a patient record
- How to navigate, retrieve and review:
 - Patient History
 - Medical Notes
 - Nursing Notes
 - Consult Notes
 - Emergency Department/Trauma Notes
 - Pre-Operative and Operative Notes
 - Diagnostic Reports
 - Laboratory Results
 - Medication Profile

At the completion of the training session, the trainee was able to demonstrate competency in accessing electronic medical records in SOVERA.

Signature of Trainer: _____

Signature of Trainee: _____

Completed Form: One copy for Principal Investigator. One copy for Health Records.