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Research Visitor - Study Monitor - Forms For PI/Managers

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Bar Code Identification Form

Please print clearly

Last Name	
First Name	
Email Address	
Affiliation (school or organization)	
Department Name	
Job Title	Research Visitor – Study Monitor
Phone Number	
Start Date	
End Date (study monitors can be active for up to 1 month, at at time)	
PI/Manager Name (Print)	
PI/Manager Signature	
For renewal only: reason why off-site/remote Study Monitor is being renewed beyond initial end date (1 year max):	

Please go to the site below for access to physical spaces at Unity Health www.rfbms.com/access

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Criminal Check Process and Email Templates for Research Visitors

Dear Research Visitor,

In order to access Unity Health's electronic health records we are reaching out to you to advise you to **read** and **sign off** on the required criminal check information below in order for the check to be completed. Failure to complete this information in a timely manner will impact your access.

PIs/Managers: In order to process your visitor, we will need your AU and Project Account info below. The typical cost of a Canadian Criminal Record Check is $21.

IMPORTANT INFORMATION REGARDING CRIMINAL CHECK PROCESS – PLEASE READ CAREFULLY

- **Your access is contingent on the completion and satisfactory result of a Criminal Check.**
- **In the next few days you will receive an email from our vendor First Advantage. The email address is: applicants@fadv.ca**
- **Keep an eye out for the email and check your junk mail**
- **You will have a deadline of 48 hours to complete the email once sent to you. Failure in responding will result in terminating your access.**
- **ONLY Government IDs are accepted for the Criminal Check process**
- **Previous criminal checks conducted by outside institutions (Police Checks) are NOT ACCEPTED. The consent form from**

_____	_____
Research Study Monitor (Print Name)	Research Study Monitor (Signature)
_____	_____
PI/Manager (Print Name)	PI/Manager (Signature)

_____	_____	_____	_____
Company	AU	Project Number	Percentage

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Research Study Monitor Service Agreement

Please read carefully before signing.
Please check each box to acknowledge your understanding and agreement.

The supervisor/PI agrees to:

- ☐ Provide virtual supervision, training, orientation, supervision and feedback to the Study Monitor
- ☐ Be accessible (via phone/email) to the study monitor for input, direction and to share information.

The Study Monitor agrees to:

- ☐ Maintaining confidentiality as outlined in the "SMH Privacy and confidentiality Agreement"
- ☐ Completing the required training prior to accessing electronic medical records (if needed).
- ☐ Only reviewing medical records of enrolled research participants in the study.
- ☐ Must not copy, take notes of, photograph and/or remove medical records.
- ☐ Must not have direct contact with patients, research participants and/or their family and friends, including the exchange of their contact information.
- ☐ Complying with all appropriate Hospital Policies and Procedures, as needed.

I understand and accept the terms of the foregoing Research Study Monitor Service Agreement.

PI/Manager (print) name:	Research Study Monitor (print) name:
PI/Manager Signature:	Research Study Monitor Signature:

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Remote Monitoring:

Process for Remote Study Monitors to Access Electronic Medical Records (EMR) Off-Site for Research Purposes

Once the study monitor has registered with the Office of Research Administration (ORA), please follow the below instructions for EMR remote training and obtaining SOVERA access.

1. The PI to submit a ShopIT request for access to SOVERA application, and to create SOVERA user account.
2. The PI must complete the following documentation and e-mail to Health Records (HealthRecords@smh.ca):
    a) Access to Electronic Medical Records (EMR) Request Form (provided below) for each newly REB-approved study that requires review of EMRs.
    b) A copy of the current REB-approval letter
    c) List of MRN(s) to access for research purposes
    d) Dates of access for study monitor
    e) **If the remote study monitor is accessing SOVERA for the first time**, please inform Health Records. A remote training session with the Study Monitor will be arranged. The Study Monitor must complete the Accessing SOVERA for Research Purposes Training Record once training is complete (provided below).
3. Once the above documentation is submitted, Health Records will set up research access for the REB-approved study. Allow 3 business days for processing.
4. Upon logging into SOVERA (and completion of the remote training session, if applicable), 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 Study Monitor only for a limited period of time.

Note: 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. The PI must also notify Health Records of any additional research personnel and/or Study Monitors throughout the monitoring period using the Access to Electronic Medical Records (EMR) Request Form.

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Access to Electronic Medical Records (EMR) Request Form

To the Investigator:

This form is to be completed for each newly REB-approved study requiring remote access to 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:

_____

Please submit this completed form with a **PDF copy of the current REB approval letter** for the study to: HealthRecords@smh.ca

Reminder: 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

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Office Use:

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

Completion Date: _____ By: _____

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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 done via a 20 minute remote 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 Records

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.