Research Visitor – Study Monitor Forms for **PI/Managers**

St. Michael's

Inspired Care.
Inspiring Science.

Bar Code Identification Form

- Please wear your I.D. Badge at all times while on St. Michaels Hospital premises.
- You will need an I.D. Badge to obtain access to a secure room and/or access to electronic medical records.
- Return your I.D. Badge to your PI at the end of each visit.

Please print clearly

Last Name				
First Name				
Email Address				
Affiliation (organization)				
Job Title	Research Visitor – Study Monitor			
PI's Department Name				
Phone Number (hospital ext.)				
Start Date				
End Date (**MANDATORY**) -1 year max				
Area(s) of access	Area Name	Floor	Wing	Initial
PI Name (Print)				
PI Signature		Date (MM-DD-YY):		
For renewal only: reason why study monitor is being renewed beyond initial end date (1 year max):				

St. Michael's

Inspired Care.
Inspiring Science.

Study Monitor Service Agreement

The following is a service agreement between the St. Michael's Principal Investigator (PI) and the Study Sponsor representative, referred to as the "Study Monitor" (This also applies to a Study Sponsor's Auditor).

Please read carefully before signing.

Please check each box to acknowledge your understanding and agreement.

The PI/Manager Agrees to:

- ☐ Ensuring that all research participants are informed (via a signed informed consent form) that the study sponsor's representative may review their medical records
- ☐ Ensuring that all Study Monitors are registered with the Office of Research Administration (ORA)
- ☐ Arranging for an ID badge for each Study Monitor
- ☐ Arranging for access to SMH secure rooms (with start and end dates), as needed
- ☐ Arranging for any network or computer access and required training for accessing/viewing St. Michael's electronic medical records, as needed
- ☐ Ensuring that access to St. Michael's medical records is restricted to enrolled research participant(s)
- ☐ Being accessible to the Study Monitor and providing supervision during the visit, as needed
- ☐ Providing the Study Monitor with appropriate Hospital Policies and Procedures, as needed
- ☐ Reporting any incidents and injuries in compliance with the SMH incident reporting system

The Study Monitor Agrees to:

- ☐ Maintaining confidentiality as outlined in the "SMH Privacy and Confidentiality Agreement"
- ☐ Wearing the SMH ID Badge at all times while on hospital premises. The SMH ID badge **must** be returned to the PI/delegate on the last day of each visit
- ☐ Completing the required training prior to accessing electronic medical records, as needed
- ☐ Only reviewing medical records of enrolled research participants in the study
- ☐ Not copy, not taking notes of, not photograph and/or not remove medical records
- ☐ Not have direct contact with patients, research participants and/or their family and friends, including the exchange of their contact information
- ☐ Only being present in the hospital during regular business hours, with notice
- ☐ Complying with all appropriate Hospital Policies and Procedures, as needed

I understand if I fail to comply with these obligations, the Hospital may terminate my relationship or affiliation with the Hospital and that I may be subject to legal action taken against me by the Hospital and others, and/or to report to the appropriate college or regulatory body.

PI/Manager Name (Please print)	Signature	Date (mmm-dd-yyyy)
Study Monitor Name (Please print)	Signature	Date (mmm-dd-yyyy)

Observing Patients and accessing Patient Data for Research - Acknowledgment

Please carefully review and acknowledge your understanding of the following:

The hospital is committed to respecting and protecting our patient's privacy and personal health information while balancing the need to foster an environment for academic learning and shared knowledge.

Research personnel (including but not limited to research visitors, volunteers, KRSS students, post-doctoral fellows, graduate students and medical students here for research purposes) **will not be permitted** under any circumstances independent access to patients nor will they be able to participate in direct patient care.

Observing Patients in Clinic

Research personnel are **not** allowed to observe or shadow in a specific hospital clinical environment unless the following conditions are met:

1. The observation must be directly related to their research project and approved by the researcher/PI supervising the research.
2. The patient's attending physician has authorized the observation for research purposes
3. The patient's prior express consent has been obtained to allow the research personnel to observe:
    a. Written consent should be filed in the patient's chart.
    b. Oral consent should be documented, by the attending physician, in the patient's chart.
    c. The consent should include the research purpose for the observation, the date/time of the observation, the observer's name and the observer's relationship with St. Michael's Hospital
4. The researcher/PI supervising the research personnel has obtained permission from the Department Chief, Program Director or Delegate for which that hospital clinical environment would report to.

Depending on circumstances further conditions may be required.

When observing, research personnel must be accompanied at all times by the attending physician.

Research personnel wishing to explore their eligibility to complete an Educational Observership will be subject to and required to comply with the Student Registration and Administration Policy.

Observing Patients in the Operating Room

Research personnel wishing to observe in the Operating Room will be subject to and required to comply with the Visitors as Observers in OR policy. Safety is the first priority in the Operating Room and therefore not all requests will be granted. Requests will be considered providing the following conditions are met.

1. The observation must be directly related to their research project and approved by the researcher/PI supervising the research.
2. The attending Surgeon must approve the request and obtain the patient's written consent and noted on the patient's chart. Consent should include the research purpose for the observation, the date/time of the observation, the observer's name and the observer's relationship with St. Michael's Hospital
3. The research personnel must be screened for communicable diseases
4. An observer request form must be completed at least 2 weeks in advance of the surgery

Depending on circumstances further conditions may be required.

When observing, research personnel must be accompanied at all times by the attending physician. Please note that during the observation you may be requested by any member of the surgical team to leave the operating room due to unforeseen circumstances and you must comply with the request.

Access to Patients Data through Electronic Systems (e.g., Soarian) & Patient Charts

Research personnel may get access to electronic medical records or charts providing it is required and justified for the research project they are working on and the following conditions are met:

1. The research personnel is working on an Research Ethics Board (REB) approved research study, which requires access to electronic medical records or charts stored by the hospital
2. The research personnel has been added to the research team of the approved REB research study.
3. The supervising researcher/PI to ensure that the research personnel is trained appropriately on patient privacy and the electronic system before accessing electronic medical records or patient charts.

Depending on circumstances further conditions may be required.

The research personnel should never access electronic medical records through someone else's account.

Once the above requirements have been met, the supervising researcher/PI can submit a ShopIT request for access to the electronic medical records.

Requirements for Research Personnel and their Supervising Researcher/PI

Research Personnel with access to electronic medical records or while observing patients in clinic or the operating room as well as their supervising researcher/PI must always be aware of their boundaries and role descriptions.

You (research personnel and supervising researcher/PI) are responsible for all of the following:

- Ensure adequate training and certification to conduct the activities in accordance with the research protocol
- Understand and follow appropriate hospital policies and procedures
- Report any breaches of privacy to the Privacy Office and REB
- Provide clearly defined activities consistent with the research protocol
- Ensure oversight to research personnel with access to medical records stay within the activities consistent with the research protocol
- Ensure the REB is informed of all study changes, including personnel changes or additions, for research projects
- Ensure all patient health information transcribed/abstracted will remain on the hospital's secure network and put the appropriate controls in place if data is being transferred to offsite sponsor/collaborator etc. (e.g., contract, described in research ethics application etc.).
- Ensure the registration process has been completed through the Office of Research Administration and a valid SMH ID Badge has been obtained

And that You (research personnel and supervising researcher/PI) **DO NOT** do any of the following:

- Share, lend, or allow others to use your access log in to medical records or patient systems
- Share, remove, or discuss patient health information
- Violate any privacy or confidentiality guidelines and/or legislation, including the "Personal Health Information Protection Act" of Ontario
- Do not access or use any shared system (e.g. ConnectingOntario, PRO, OLIS, eCHN, RM&R, HDIRS, IAR) for research purposes
- Violate any research ethics guidelines
- Engage in any activities beyond those specified in the research protocol or beyond the researcher personnel's role at any time
- Engage in any research activities prior to receiving REB and other required approvals
- Engage in any research activities prior to completing all research training certification
- Allow patient health information or data transcribed/abstracted for research purposes to leave the hospital or to be stored anywhere other than the hospital's secure network

I acknowledge, understand and accept the terms regarding access to hospital patients and their data which is limited to a specific research purpose. I understand that I may be audited by the Hospital at any time.

Date:	Date:
PI/Manager (print) name:	Research Personnel (print) name:
PI/Manager Signature:	Research Personnel Signature: