

Research Affiliate Visitor Forms for PI/Managers

Bar Code Identification Form

Please print clearly

Last Name				
First Name				
Email Address				
Affiliation (school or organization)				
Department Name				
Job Title Research Visitor - Affiliate				
Phone Number (hospital ext.)				
Start Date				
End Date (MANDATORY)				
Area(s) of access	Area Name	Floor	Wing	Initial
PI/ Manager Name (Print)				
PI/ Manager Signature				
<i>For renewal only:</i> reason why visitor is being renewed beyond initial end date (1 year max):				

Not Paid by St. Michael's Hospital.

Research Visitor Assignment Form for PIs/Managers

Please complete all fields. It is the Investigator's responsibility to ensure space adequate training and supervision are available to support the research visitors work.

PI Name:	Phone Ext:
Program Manager: (If applicable)	Phone Ext:
Start Date:	End Date:

Please describe why you are engaging this visitor and what they will receive from the experience:
Please describe the specific duties of the visitors:
Please describe all relevant skills or qualifications relevant to the duties:
Will the visitor be working with biological material? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please email Steven Hayes at hayess@smh.ca to follow up on next steps.
Is there any additional training beyond the standard training (i.e. Biosafety, WHIMS, etc.) required?
Which days and what hours will the research visitor be expected to work? Where will the research visitor be located?
Please describe how the visitor will be supervised.
Will the visitor interact with research subjects and/or patients, patient/research data and/or patient/research subject samples? <input type="radio"/> Yes <input checked="" type="radio"/> No <small>* Please be reminded to read the prohibited activities in section 1.8 of the Research Volunteer and Visitor Policy</small> If yes, have you informed or contacted the Research Ethics Board? Yes No http://www.stmichaelshospital.com/research/reb.php
What institution is the visitor affiliated with. If the visitor is a student, what school and program are they enrolled in?
What is the visitor's role or job titled at the affiliated Institution. If the visitor is a student, are they gaining academic credit from this experience? If yes, please refer to http://stmichaelshospitalresearch.ca/staff-services/research-employment/

Will the visitor receive compensation or reimbursements directly from St. Michael's Hospital? Yes No **If yes, please explain.**

Conflict of Interest Disclosure

Is the individual a family member of the supervisor (or the individual responsible for the decision to engage this incumbent)?	Yes No
--	-----------

Is the individual affiliated with an organization in which the supervisor or the supervisor's family member has a financial or ownership interest?	Yes No
--	-----------

(Family Member includes a spouse, domestic partner, child, parent, sibling, grandparent, grandchild or other close relation. For the purpose of this policy (i.e., Research Conflicts of Interest), a family relationship includes biological relationships, adoptive relationships, relationships created through marriage and other relationships in which care-giving or dependency exists. Please note that if you check "Yes", before this hire can be processed this information will be forwarded to the Office of Research Administration for review under the Research Conflicts of Interest Policy)

Will the research visitor be exposed to clinical activities (e.g patient contact) and/or exposed to human blood/body fluids? **Yes No**

*If yes, the visitor is required to complete the Corporate Health and Safety forms in the Student Package. If no, the visitor is **not required** to complete the Corporate Health and Safety forms.

Investigator/Manager Signature	Date Signed (MM - DD - YYYY)
--------------------------------	---------------------------------

Visitor Signature:	Date Signed (MM - DD - YYYY)
--------------------	---------------------------------

If the visitor is international, please answer the additional questions :

We strongly recommend that the PI checks references for international visitors

How did you come to know the Visitor or establish this relationship?

If the Visitor is already in Canada, please describe the type of Visa they have received and provide a copy (Please Attach) : **Yes No**

If the Visitor has been provided with an invitation (email or letter) - please provide us with a copy attached : **Yes No**

Research Visitor Service Agreement

Please read carefully before signing!

Please check each box to acknowledge your understanding and agreement.

The supervisor/PI agrees to:

- Adhere to all responsibilities outlined in section 1.8 of the Research Volunteer and Visitor Policy (see excerpts in Instruction Sheet) (link to full policy: <http://cpps/Default.aspx?cid=1669&lang=1>)
- Provide supervision, training, orientation, supervision and feedback to the visitor specific to their work area/field
- Be accessible to the visitor for input, direction and to share information

The research visitor agrees to:

- Seek direction from supervisor if visitor is unsure
- Always wear ID badge to be clearly visible
- Know the infection control guidelines and understand the importance of hand washing
- Not to exchange contact information – including address, phone numbers, email or social networking information – with patients, study subjects and/or their friends and family.
- Maintain confidentiality
- Review the Research Volunteer and Visitor Policy and other relevant SMH policies within 30days of start date

I Understand and accept the terms of the foregoing Research Visitor Service Agreement.

Date:

Date:

PI/manager (print) name:	Research Visitor (print) name:
PI/manager Signature:	Research Visitor Signature:

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: