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Hospital Centre

ST. MARY'S HOSPITAL CENTER ✧ RESEARCH REVIEW OFFICE
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FORM A - RESEARCH PROTOCOL REGISTRATION FORM

PURPOSE: This form is to be completed for all research protocols at St. Mary's Hospital Center.

INSTRUCTIONS:

Section A - Administrative Information

1. The Principal Investigator (PI) is the person responsible for carrying out the research. If the PI is not affiliated with St. Mary's Hospital Center (SMHC), then a SMHC Site Investigator (SI) must be appointed who will be responsible for all activities related to the research project at SMHC. Please note that the PI (or SI) cannot be a trainee (please see question #3).
2. If you would like copies of project correspondence sent to a project coordinator, please include his/her email.
3. Trainees (e.g. undergrad students, graduate students, postdoctoral students, residents, and fellows) are NOT eligible to submit protocols as PI. The PI can be the trainee's supervisor (e.g. thesis reviewer etc.)
4. This should only be completed if the PI is not affiliated with SMHC. A site investigator from SMHC must agree to be the person responsible for all aspects of the project at SMHC.
7. Specify the dates when you anticipate starting and ending the project. Note: you must submit an Interim Report one month prior to the expiration of the approval period, and a Termination Report when you complete the project.
8. The purpose of this question is to determine what hospital resources are required for the research. Do not include use of resources that patients would normally receive as part of standard care. Include letters or signatures of support from corresponding department heads with the Registration Form. Letters should indicate that they are aware of the research project, the demands it will make on their departmental resources, and that they support the project. To see further instructions, refer to section G.
9. If your project will require the use of medical records, indicate if the patient will be giving signed consent for access to their medical file. If not, you will need permission from the Vice President of Professional Services, see section F #4.

Section B - Financial Information

3. If your funds are to be held at SMHC, or if any expenses will be incurred at SMHC a detailed budget and justification have to be submitted. If you are not sure as to whether a budget is necessary, please verify with the Research Review Office. Please use the SMHC budget justification template, available on the SMHC research website.
4. If your study involves a contract, a copy must be submitted at the time of registration. Research activities may not begin until the contract has been signed by the Director General and CEO of the Hospital. It is also important to note that there cannot be a contract between a PI and another party. Contracts must always be between SMHC and the other party, and, if applicable, the PI.

Section C - Personnel Information

2. This information can be sent after full institutional approval, however, it must be sent for approval by the Vice President of Operations and Nursing before the staff can have patient contact at SMHC.

Section D - Scientific Review Information

1. Specify whether you have submitted your protocol to an organization that carries out a peer-review, and whether your protocol was accepted by such an organization. If it is a trainee project, the supervisor/thesis committee must approve the project before it can be registered. Please ensure that the supervisor signs the registration form as well (section F #2). If prior scientific review has not been conducted, provide the name(s) of 1 or 2 potential scientific reviewer(s) with no conflict of interest, and with knowledge of both the project's substantive and methodological components.

Section E - Research Ethics Information

1. Please specify the type of research involved, as this will facilitate the review of projects through the appropriate channels. Depending on the type of study involved, some research projects may be eligible for expedited review by the Research Ethics Committee (REC) Chair. Minimal risk means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests”.
2. Specify the number of human subjects you are hoping to recruit in total (if conducting a multicenter trial) and, if applicable, the number to be recruited at SMHC. Indicate what type of subjects you will be recruiting for your study and from which departments in the hospital
4. If consent forms will be used in your study, please ensure that the consent form fulfils the requirements listed in the document "Consent Form Checklist", available on SMHC's website or from the Research Review Office. All consent forms should be bilingual. You may submit the consent form for approval in one language, however, once your study has been approved the Research Review Office will require you to submit a second consent form in either French or English. For further information regarding consent form submission, please see chapter 4.4.1 of the Regulatory Framework.
If any materials (e.g. diaries, questionnaires, etc.) will be used to conduct your study, please indicate and enclose a copy for review. All advertisements that will be used to recruit patients must be in both English and French and will have to be approved by the Public Relations department of SMHC (before you post them in the hospital) once you have received full institutional approval. For further information please see chapter 4.4.3 of the Regulatory Framework.
7. It is important that the REC be aware of any arrangements that may create a conflict of interest or the appearance thereof. Financial interest in the sponsoring company and other potential conflicts must be brought to the Committee's attention, and a letter detailing these potential conflicts must be attached to the Registration Form. If there is any doubt as to the possibility of a conflict of interest, the onus is on the investigator to discuss the situation with the Chair of the Research Ethics Committee.

Section F- Signatures

1. The PI, SMHC site investigator, and supervisor of trainee (if applicable) must sign the Registration Form. These signatures confirm that all these individuals have reviewed the form and approve of the submitted protocol. In addition, the PI's (or SMHC site investigator) administrative supervisor/department head, must also sign the Registration Form to confirm that they are fully informed of and support the research proposal.
2. The supervisor of the trainee must sign the registration form to consent that he/she has reviewed the trainee's study and feels that the study is appropriate to be conducted by the individual at SMHC.
4. **Approval of Vice President of Professional Services for access to Medical Records**
Projects that require the review of patients' medical charts (e.g. active, archived and electronic patient records), and for which no patient consent is being obtained, will need the authorization from the Vice President of Professional Services (DPS). Before authorizing such access, the DPS must make sure that (1) the intended use is not frivolous and the ends contemplated cannot be achieved unless the information is communicated in nominative form and (2) that the personal information will be used in a manner that will ensure its confidentiality.

Section G - Resource Approval

1. Depending on the resources required to carry out the proposed research project, it may be necessary to obtain authorization from various department heads. Projects that require the assistance of nursing staff will need the authorization of the Vice President of Operations and Nursing. Projects that involve the use of drugs will need the authorization of the Chief of Pharmacy. Projects that involve the use of laboratory tests (e.g. biochemistry, cytology, haematology, histology, microbiology, vascular) will need the authorization of the Head of the Laboratory Department. Projects that involve the use of pathology slides or specimens will need the authorization of the Head of the Pathology Department and projects that involve the use of x-rays (MRI, ultrasound, CT scan, mammography, etc.) will need the authorization of the Head of the Radiology Department.



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DATE: -----/-----/-----
(yyyy/mm/dd)

FORM A - RESEARCH PROTOCOL REGISTRATION FORM

A. Administrative Information:

1. Principal Investigator: _____
 Title/Position: _____ Institution: _____
 Department: _____ SMHC Dept. Head/ Admin. Supervisor : _____
 Mailing Address: _____ Postal Code: _____
 Tel: _____ Ext: _____ Fax: _____ Email: _____
2. Project Coordinator email (if applicable): _____
3. Name of trainee: _____ Program of study: _____
 Name of supervisor (if different from PI): _____
 Title/Position: _____ Institution: _____
 Tel: _____ Ext.: _____ Fax: _____ Email: _____
4. SMHC Site Investigator (if PI is not a SMHC staff member):
 Title/Position: _____ Department: _____
 SMHC Department Head/ Admin. Supervisor: _____
 Tel: _____ Ext.: _____ Fax: _____ Email: _____
5. Complete protocol title: _____

 Brief protocol title (70 characters max): _____
6. Is this protocol an add-on or continuation of a previously approved protocol? No Yes [if yes, indicate which below]
 Protocol #: _____ Title: _____
7. Projected Start Date (yyyy/mm/dd): _____ Projected End Date (yyyy/mm/dd): _____
8. Does your study involve any of the following SMHC resources? Check those that apply below and write a brief description. Include letters of support or signatures from corresponding department heads (see section G).

Equipment	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____
Labs	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____
Pathology	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____
Nursing	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____
Pharmacy	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____
Radiology	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____
Other	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____

9. Does your project require access to medical records? No Yes [if yes, check one of below]
- Access will be requested with a patient consent form
- Patient consent will not be requested [in this case, Director of Professional Services signature required in section F #4]

B. Financial Information:

1. Funding source (check one and specify):
- Not funded [skip to section C]
- Government granting agency: _____
- Industry: _____
- Other private source (including foundations): _____
- Other: _____
2. (a) Amount: \$ _____
- (b) This amount is: Total Per patient
- (c) This amount has been:
- Already awarded [include copy of approval/award letter]
- Requested [promptly inform the Research Review Office of funding decision, when made]
3. Funding/grant period from (yyyy/mm/dd): _____ to _____ Not Applicable
4. Indicate where the funds will be held:
- St. Mary's Hospital Center [if SMHC, include a detailed budget and justification]
- McGill University
- Other (specify): _____
5. Will any project expenses be incurred at SMHC? No Yes [if yes, include a detailed budget and justification]
6. Does your project involve a contract? No Yes [if yes, submit a copy]

C. Personnel Information:

1. Will there be research staff (paid or unpaid, including Principal and Site Investigators) working on your project at SMHC? Yes No [if no, skip to section D]
2. Will any of your research staff...
- a. ... interact with SMHC patients? (i.e. interviews, focus groups, telephone calls) Yes No
- b. ... have direct, physical contact (i.e. blood procurement, physical examination) with SMHC patients? Yes No
- c. ... be performing procedures involving equipment? (i.e. CT scan, MRI) Yes No
- [If you answered yes to any of the above questions, please attach the job description, CV & professional license of the research staff]

D. Scientific Review Information:

1. Has (or will) this protocol receive(d) a scientific review (check one)? Attach documentation for any previous scientific review.
- Submitted to or accepted by a peer review committee, or trainee's supervisor/thesis committee (specify): _____
- Other independent scientific review, specify: _____
- No [name a potential scientific reviewer who does not have a conflict of interest below]
- Potential scientific reviewer's name: _____
- Address: _____
- Tel: _____ Ext.: _____ Fax: _____ Email: _____
2. Attach the most recent version of the PI's CV. If applicable, include a list of co-investigators; for each, indicate whether they are from SMHC or not. Attached

F. Research Ethics Information:

1. Type of research (check all that apply):
- No human subjects involved [if no human subjects, proceed to question #5]
 - Analysis of previously collected research data
 - Data collection from pre-existing records or databases (e.g. chart review)
 - New data collection from human subjects: minimal risk
 - New data collection from human subjects: more than minimal risk
 - Phase I, II or III clinical trial (safety / efficacy drug studies); circle phase: I II III
 - Other clinical trial, specify intervention: _____
 - Other study, specify: _____
2. If your study involves a clinical trial, have you registered it with ClinicalTrials.gov? No Yes Not applicable
3. (a) How many subjects do you plan to recruit and/or how many charts do you plan to review across all study sites?
- Number of research subjects: _____
- Number of chart reviews: _____
- (b) How many subjects do you plan to recruit and/or how many charts do you plan to review at SMHC?
- Not applicable [if N/A, skip to question #3]
- Number of SMHC research subjects: _____
- Number of SMHC chart reviews: _____
- (c) What type of subjects and from which departments do you plan to recruit at SMHC (check all those that apply)?
- Inpatients Department(s): _____
 - Outpatients Department(s): _____
 - Staff Department(s): _____
 - Other (specify): _____
4. Does this study involve (check one)? Children Mentally incompetent adults Neither
5. Indicate if you will use any of the following materials (check all those that apply). For all those checked, enclose a copy.
- Not applicable
 - Consent form
 - Investigators brochure
 - Subject diaries
 - Questionnaires
 - Advertisement material/brochures
 - Other materials distributed to subjects: _____
6. List below any submissions to this or other research ethics boards (REBs) regarding this project that have resulted in either 1) refusal of ethics approval or 2) where a major modification of the study protocol was required (e.g. to therapeutic procedures). Attach additional sheets as necessary. For each submission listed below, attach a copy of that REB's decision letter. Not applicable
- | <u>REB</u> | <u>Decision</u> |
|------------|--|
| _____ | <input type="checkbox"/> Refused <input type="checkbox"/> Major modification |
| _____ | <input type="checkbox"/> Refused <input type="checkbox"/> Major modification |
| _____ | <input type="checkbox"/> Refused <input type="checkbox"/> Major modification |
| _____ | <input type="checkbox"/> Refused <input type="checkbox"/> Major modification |
7. Is your project multi-site? No Yes [if yes, include a list of all project sites in your protocol submitted to REC]

8. Does this study put you, members of your research team or SMHC in any actual, perceived or potential conflict of interest (financial, professional or other nature) that could threaten the ethical or scientific validity of your project?
 No Yes [if yes, attach an explanation with a proposed mechanism for addressing it]
9. The following questions apply only to industry-funded projects. Not applicable
- (a) Do you, your immediate family or research team members have any financial, professional or other interest in the funding source?
 No Yes
- (b) Will there be any investigator payments or 'finders fees' for subject recruitment or referral? No Yes
- (c) Are there any restrictions on publication of research results? No Yes
- (d) Are there any professional, financial or other benefits promised to you or SMHC? No Yes
- (e) Do research subjects receive payment above compensation for their participation? No Yes
- (f) If you answered 'yes' to any of questions (a)-(e) above, append a report with a justification. Not applicable

E. Signatures of Principal Investigator and Site Investigator (if applicable):

1. Investigator declaration:

I have reviewed this form and approve the attached research protocol entitled _____

I agree to carry out and will be responsible for this research according to policies and procedures described in the St. Mary's Hospital Center Regulatory Framework in Health Research.

Principal Investigator	Signature	Date (yyyy/mm/dd)
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SMHC Site Investigator	Signature	Date (yyyy/mm/dd)
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2. Signature of supervisor of trainee (if applicable):

I am the supervisor of the trainee and I approve the above-mentioned protocol to be conducted at SMHC.

Supervisor of trainee	Signature	Date (yyyy/mm/dd)
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3. Signature of the PI's or SMHC site investigator's administrative supervisor:

I have been fully informed of the above research and I support it. I have reviewed and approved the following (check all that apply):

- Protocol Budget Human Subjects Review Summary (methods of recruitment) Use of hospital resources
 Involvement of hospital staff Contract (e.g. clinical trial agreement) Consent form

I have reviewed the CV of _____ and feel that he/she is scientifically competent to conduct the above-mentioned protocol at SMHC.

Name	Signature	Date (yyyy/mm/dd)
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Title/ Position	Department
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4. **Approval of the Vice President of Professional Services for access to medical records needed for this study**

*I have been fully informed of the research protocol entitled _____ and grant
_____ access to medical records as described in the Human Subjects Review Summary:*

Vice President of Professional Services

Signature

Date (yyyy/mm/dd)

G. Resource Approvals:

1. *I have been fully informed of the research protocol entitled _____ and authorize use
_____ of my department resources for the protocol.*

Equipment (specify) respective chief of dept.

Signature

Date (yyyy/mm/dd)

Chief of Laboratories

Signature

Date (yyyy/mm/dd)

Vice President of Nursing & Operations

Signature

Date (yyyy/mm/dd)

Chief of Pharmacy

Signature

Date (yyyy/mm/dd)

Chief of Radiology

Signature

Date (yyyy/mm/dd)

Chief of Pathology

Signature

Date (yyyy/mm/dd)

Other (Specify) respective chief of dept.

Signature

Date (yyyy/mm/dd)