MOUNT SINAI HOSPITAL
RESEACH ETHICS BOARD GUIDELINES FOR
RESEARCH ETHICS REVIEW INVOLVING HUMAN SUBJECTS

All research involving human subjects must be submitted to the Mount Sinai Hospital Research Ethics Board for review and approval before research can begin. Division Heads are responsible for ensuring that all such research is submitted for ethics review. The Application form has 4 sections: Identification and Division Approval, Ethics Issues, Funding Issues, and an Executive Summary detailing the key issues in the study.

The application forms for all projects submitted for review will require the signature of the Division Head. Applications should be signed only if the research is judged to be scientifically sound and is supported by the Division. Electronic or paper Application Forms are available from the Research Ethics Board Office listed below. If the study impacts on other areas of the hospital (Nursing, Pharmacy, Imaging, Pathology & Labs, Medical Records, etc), the **Principal Investigator is responsible for obtaining all appropriate administrative approval signatures from Hospital departments and reimbursing costs**.

Full Board Review:

The Mount Sinai Hospital Research Ethics Board meets monthly to review submissions in the order of their arrival at the Research Ethics office.

The principal investigator should provide the names of two suitable reviewers. If possible, the reviewers should not be from the same hospital Division as the principal investigator. Two members of the Mount Sinai Hospital Research Ethics Board will serve as primary and secondary internal reviewers and will present the study to the Board for recommendations.

All relevant sections of the application form must be completed and proper signatures obtained. A detailed research proposal should be submitted with this application. It is essential to summarize your proposal in lay terms on the form. Please provide:

- **Protocol (7 copies)**
- **Full Application Form (7 copies)**
- **Consent Form (7 copies) - should be in it's final form (as it will be seen by the patient/subject) including letterhead**
- **Budget information (7 copies) - should provide the details of study expenses**
- **Investigator's Brochure (5 copies) (for drug studies only)**

Expedited Review

A discussion with the Research Ethics Board prior to submission of expedited review is encouraged.
Some studies may be considered for expedited review. This applies to research which is considered either minimal risk and non-invasive (e.g. retrospective chart reviews, questionnaires or surveys, non-invasive assessments, use of tissue), or studies involving only current standards of care, or studies which have had prior approval from a recognized Research Ethics Board. For these studies, submit:

- **Protocol (2 copies)**
- **The relevant sections of the application form (2 copies)**
- **Consent Form (2 copies)(where relevant)- should be in it's final form (as it will be seen by the patient/subject) including letterhead**
- **Budget information - should provide the details of study expenses**
- **Investigator's Brochure (1 copy) (for drug studies only)**

If a study has received prior scientific or ethical review, include a copy of the approval letter, approved consent form and all relevant reviewer and Research Ethics Board's correspondence. Studies that have been reviewed by other Research Ethics Boards are NOT considered for expedited review unless the relevant

documentation is provided. If the Research Ethics Board determines that the submitted protocol cannot be expedited, the investigator will be informed immediately in order to provide a full submission.

PLEASE COLLATE DOCUMENTS PRIOR TO SUBMISSION. THANK YOU.

Applications for ethics review should be sent to:

Dr. Ron Heslegrave
Chair, Research Ethics Board
Mount Sinai Hospital
Room 1003B
600 University Avenue
Toronto, ON M5G 1X5

Research Ethics Board Office: Tel: (416) 586-4875 Fax (416) 586-4715

Application forms (electronic or paper), REB Terms of Reference and Operating Procedures, Guidelines for Consent Forms, and copies of the "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans" are available from the REB Office. Forms are also available at the following URL: http://info/reb

CONTRACTS / STUDY AGREEMENTS (Industry Sponsored Studies Only):

Contracts should be sent to the office of the Tamara Birkenheier, Research Contracts Specialist for review and signature:

Tamara Birkenheier
Research Contracts Specialist
Office of Technology Transfer & Industrial Liaison
Samuel Lunenfeld Research Institute
Tel: (416) 586-8444
Fax: (416) 586-3110
Email: tamara@mshri.on.ca

MOUNT SINAI HOSPITAL (MSH) RESEARCH ETHICS BOARD (REB)
APPLICATION FOR REVIEW OF RESEARCH PROPOSALS INVOLVING HUMAN SUBJECTS

TITLE OF STUDY:

PRINCIPAL INVESTIGATOR(S)

Name	Dept/Division	Program

Address (Room Number)	Telephone	Fax	Email

CO-INVESTIGATOR(S)

Name	Dept/Division	Program

Address (Room Number)	Telephone	Fax	Email

MSH Contact Staff if PI is outside of MSH:

Name	Dept/Division	Program

Address (Room Number)	Telephone	Fax	Email

FUNDING SOURCE _____ **(Include Study Budget)**

EXPECTED START DATE _____ **TOTAL STUDY DURATION**_____

PRINCIPAL INVESTIGATOR AGREEMENT - I assume full responsibility for the ethical conduct of the study as described in the submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Human Subjects.

_____ _____
Signature of Principal Investigator(s) Date

DIVISION APPROVAL
I have reviewed this proposal and consider it to be scientifically sound. Appropriate on-going monitoring will be in place. I support its submission for ethics review.

_____ _____ _____
Division/Department Head Signature Name (PRINT) Date

Date Received:_____ MSH Protocol #:_____ Date of Approval: _____

ETHICS

Has this proposal received prior scientific peer review? **YES** _____ **NO**
If YES, identify where and attached any relevant reviewer comments.

Has this proposal received prior ethical review by another hospital Research Ethics Board affiliated with UofT? If YES, include all correspondence related to the ethical review. **YES** _____ **NO**

SUBJECTS:
Number to be enrolled at MSH _____ Total study enrolment _____
Will this research involve any of the following:

___pregnant women ___infants/children ___ healthy volunteers ___students ___staff
___genetic research ___tissue samples ___ incompetent subjects ___excludes women of child-bearing potential

STUDY LOCATION: Where will this research take place?
___ MSH Other Institutions _____
___ Inpatient _____ ___ Outpatient _____ Other _____
Floor Clinic

RECRUITMENT and CONSENT:
a) Describe how potential subjects will be identified? (e.g. by primary physician, medical records, data bases, advertisements)

b) Who will initially approach subjects (or authorized third party) about the study?

c) How will consent be obtained? By whom?

d) How much time will subjects be given to review the information before being asked to give consent?

e) Is there a relationship between the investigator and the subjects? **YES**___ **NO**___
If **YES**, explain (e.g. treating physician, employee)

f) Will this research involve incompetent individuals or individuals who are temporarily unable to provide an informed consent (unconscious, psychotic, emergency)? **YES** ___ **NO** ___
(If **YES,** attach a summary which justifies the need to include these individuals, how incompetence will be determined, how the subjects interests will be protected, how surrogate consent will be obtained, and what plans are in place to obtain consent if the individual later becomes competent to provide informed consent.)

Ethics (continued)

REMUNERATION: Will subjects receive any remuneration (e.g., stipend, parking and transportation costs) for participating in this study? **YES** ___ **NO** ___

If **YES**, provide information on the amount of remuneration and the justification for that remuneration.

NEW DRUGS OR DEVICES:

NEW: Investigator driven studies involving drugs for an unapproved indication requires Health Canada approval.

Does this study involve the use of any investigational new drugs or devices or the use of an approved drug for a new indication*? **YES** ___ **NO** ___

If **YES**, please provide a copy of the approval from Health Canada or indicate when such an approval is expected.

CONFIDENTIALITY. How will confidentiality be protected? Describe how the data will be stored, who will have access to the data, what will happen to the data at the end of the study (e.g. anonymized), and who will have access in the future.

CONFLICTS OF INTEREST:

Does the principal investigator(s) or any co-investigators involved in this research study:

- function as an advisor, employee, officer, director or consultant for the study sponsor? **YES** ___ **NO** ___
- have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study? **YES** ___ **NO** ___
- receive an honorarium or other benefits from the sponsor (apart from fees for service)? **YES** ___ **NO** ___

If the answer is **YES** to any of the above conflicts, append a letter detailing these activities to the Chair of the REB.

PUBLICATION: Does the funding agency or sponsoring company place any restrictions on publication of findings or reporting of interim results? **YES** ___ **NO** ___

If **YES**, indicate and explain any restrictions.

FUNDING AND IMPACT

FUNDING SOURCE:

Has funding been:

Obtained _____ Applied for _____
Source Source and Expected Date of Decision

Covered by existing grants/other funds (specify) _____ No costs_____

BUDGET: Attach a copy of a budget detailing expenses for the study (e.g. salaries, investigator payments, tests, equipment, compensation , overhead, administrative costs) and the amount of funds received. Include overhead of **30%** for industry sponsored studies.

CONTRACT – Has the research agreement been sent to Tamara Birkenheier, Research Contracts Specialist, for review and signing (see instruction page 1)? YES___ NO___

Does the sponsor have liability insurance? **YES**___ **NO** ___

If the subject suffers an injury as a result of participation in the study, does the sponsor agree to cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided? **YES**___ **NO** ___

STUDY IMPACT: Does the study impact on other hospital departments such as (Nursing, Pharmacy, Pathology & Labs, Imaging, etc.) or need specialized committee approval? **YES** ___ **NO**___

If **YES**, have appropriate approvals been obtained from affected departments? **YES** ___ **NO** ___
(List departmental approvals and obtain appropriate signatures)

Departments/Committees	**Impact**	**Departmental/Divisional Approval Signature** If yes, please obtain signatures
Pharmacy	Yes___ No___	_____
Pathology & Lab Medicine	Yes___ No___	_____
Microbiology	Yes___ No___	_____
Diagnostic Imaging	Yes___ No___	_____
Nursing Services	Yes___ No___	_____
Radioactive Materials	Yes___ No___	_____
Biosafety Committee	Yes___ No___	_____
Research Support Services (ECG, pulmonary function…)	Yes___ No___	_____
Other_____	Yes___ No___	_____
Nursing Research Utilization Committee ***(for research conducted by nurse only)***	Yes___ No___	_____

Date Received:_____ MSH Protocol #:_____ Date of Approval: _____

The following questions MUST be answered in order for the Research Ethics Board to properly evaluate your submission. If these questions are not applicable to your study, please indicate N/A in the applicable sections:

1. What is the usual standard of care at MSH for these patients?

2. How is the usual standard of care MSH altered in this study?

3. What are the incremental risks over the usual standard of care associated with the study?

4. If a placebo control is used, how is this justified?

5. What Phase is the clinical trial (Pilot, I, II, III, IV, Open-label, not applicable)?

6. Is there a safety monitoring board and is it independent of the sponsor?

EXECUTIVE SUMMARY

THE APPLICATION WILL NOT BE CONSIDERED WITHOUT A COMPLETED EXECUTIVE SUMMARY

Please provide a brief synopsis (**in lay terms**) of the key aspects of your submission in sufficient detail for the REB to review your proposal. The critical features of most studies are listed below. The Abstract below may be used to provide MSH administration and the Research Institutes more detailed information regarding studies being carried out at MSH.

Abstract (50-100 words):

Rationale and Hypothesis:

Study Design:

- design
- subjects/controls (selection and most important inclusion/exclusion criteria)
- interventions
- primary outcome measures
- study endpoints for withdrawal
- sample size rationale

Significance of the study:

Risk/Benefit Estimates:

External Review Process

The principal investigator should provide the names of two suitable scientific reviewers. If possible, the reviewers should not be from the same hospital Division as the principal investigator. If the submission has been previously peer reviewed, provide the correspondence associated with those reviews.

REVIEWER (1)

Name: _____

Department: _____

Institution: _____

Address: _____

Wing/Room Number: _____

City: _____ Province: _____ Postal Code: _____

Phone: _____ Fax: _____ Email: _____

REVIEWER (2)

Name: _____

Department: _____

Institution: _____

Address: _____

Wing/Room Number: _____

City: _____ Province: _____ Postal Code: _____

Phone: _____ Fax: _____ Email: _____