

Research Ethics Board Terms of Reference

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PURPOSE AND SCOPE:

The primary and clear purpose of the Markham Stouffville Hospital (MSH) Research Ethics Board (REB) is to protect the rights, safety and well-being of human subjects at MSH. The MSH REB is responsible for a) ensuring that research protocols meet with current safety, scientific, ethical and privacy standards; and, b) making certain that all MSH research activities are aligned with the best interests of MSH.

The role of the MSH REB is to “*approve, reject, propose modification to, or terminate any proposed or ongoing research involving humans*” (TCPS2 Article 6.3).

POLICY STATEMENT(S):

The MSH REB acts in compliance with all laws, policies, standards and guidelines governing human research, which are applicable to a submitted research study, including but not limited to: the International Conference on Harmonization for Good Clinical Practice (ICH/GCP) Guidelines, as set forth in Part C Division 5 under the Canadian Food and Drugs Act, the Tri-Council Policy Statement (TCPS2), “Ethical Conduct For Research Involving Humans”; the Declaration of Helsinki; and the Personal Health Information Protection Act (PHIPA), 2004, in accordance with generally accepted clinical practices.

The TCPS2 sets forth standards for the conduct of research involving human subjects. The MSH REB is responsible for overseeing the rights, welfare, protection and dignity of human subjects participating in research conducted at MSH.

The MSH REB reports to the Vice President, Medical Operations.

PROCEDURE:

1. REB Membership

The REB will consist of at least 10 members, including both men and women, from the following areas:

- At least two members who have broad expertise in the scientific methodology, health science research and medicine;
- At least one member who is knowledgeable in ethics;
- At least one member who is knowledgeable in relevant law;
- At least one member who is knowledgeable in privacy legislation and/or risk;
- At least one member who has no affiliation with the institution and preferably recruited from the community served by the institution;
- At least two members representing the profession of medicine;
- At least one member representing the profession of pharmacy;
- At least one member representing the profession of nursing and/or allied health; and,

- Ad hoc members as required

All members will have 1 vote, with the exception of MSH administrators and the Office of Research staff.

All members must have a documented ‘Certificate of Completion’ of the online tutorial for TCPS2 guidelines. Copies of the TCPS2 ‘Certificate of Completion’ and each member’s current curriculum vitae (dated and signed) are kept on-file in the Office of Research.

REB members must participate in continuing education organized by the Office of Research in matters relating to research ethics and the use of human participants in research.

2. Terms of Service

The Chair of the MSH REB is appointed annually by the Medical Advisory Council. The Vice-Chair of the MSH REB is also appointed annually by the Chair. Under normal circumstances members of the MSH REB will not serve more than five years. The terms of service will be staggered to ensure continuity.

3. Quorum

At least 6 (50% +1) members will constitute a quorum and include men and women and at least one of each of the following members:

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|---------------------------------------|----------|----------------------------------------|----------|--------------------------------------------------------------------|----------|--------------------------------------------------|----------|-------------------------------------------------------|----------|--------------------------------------------------------------|
| 1 | + | 2 | + | 3 | + | 4 | + | 5 | + | 6 |
| An independent community member | | A member knowledgeable in ethics | | A member knowledgeable in privacy legislation and/or risk | | A member knowledgeable in the relevant law | | A physician with relevant expertise in research | | A non-physician with relevant expertise in research |

4. Meetings & Attendance

The REB shall meet every month, at least 10 times per year. More than 3 unexplained absences by members should be construed as a notice of resignation.

DEFINITION(S):

Not Applicable.

REFERENCE(S):

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. www.pre.ethics.gc.ca
2. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Good Clinical Practice. www.ich.org
3. The Personal Health Information Protection Act. www.ipc.on.ca

RELATED DOCUMENTS:

Not Applicable.

RESPONSIBILITY:

| Required Endorsements | Sponsor | Approval Authority |
|-----------------------|--------------------------------|-----------------------|
| | Manager, Office of Research | Research Ethics Board |

DOCUMENT HISTORY:

| Type | Individual/Committee | Date | Outcome |
|-------|-----------------------|------------|------------------------|
| Draft | Research Ethics Board | 23/07/2018 | New Document; Approved |

APPENDICES:

Not Applicable.