MARKHAM STOUFFVILLE HOSPITAL CORPORATION	**Research Ethics Board Review Procedures**
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PURPOSE AND SCOPE:
The purpose of the 'REB Review Procedures' policy is to provide a structure, system, process and procedure to ensure that the scientific, ethical, safety and privacy review is conducted by the Markham Stouffville Hospital (MSH) Research Ethics Board (REB) prior to and during the conduct of clinical studies that impact the internal MSH patient and staff populations, including but not limited to, admitted patients and outpatient visits in hospital clinics.

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.

PROCEDURE:
1. All research that involves human subjects or involves human remains, cadavers, tissues, biological fluids, embryos or fetuses and is conducted at MSH, requires MSH REB written approval before the study may commence (TCPS2 2.1), except as specified below:

    - Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes (TCPS2 2.5).

2. All investigators are required to submit proposals as outlined in the attached Appendix 1. Incomplete applications will not be processed.

3. All MSH REB approvals are for one year, following full approval. Investigators are required to submit an Annual Report for projects that last longer than one year. An annual submission

that is 8 weeks overdue will be interpreted to mean that the study is discontinued. The MSH REB study file will be deemed closed.

4. A final report is required for all study projects, upon completion.

5. The MSH REB has adopted a proportionate approach to REB review as indicated in TCPS2 Article 6.12. Full review by the MSH REB shall be the default requirement for all research involving human subjects, as follows:

   Full REB Review:
   - All new study applications, except research protocols that involve no more than minimal risk, as indicated in Delegated Review criteria.
   - All major study amendments.
   - All significant adverse events (SAEs) – Note, detailed reports regarding local SAEs must be submitted to the Chairperson within 7 days of the event. Delayed submissions will be investigated by the MSH REB and actions will be taken accordingly.
   - All annual renewals, of more than minimal risk research, which involves new interventions to current participants and has active enrollment.

   Delegated Review:
   The following reviews involve minimal risk and may be approved by (2) REB members as follows: the chair and the research manager OR the research manager and a designated member of the REB:

   - Protocol revisions responding to conditional REB approval.
   - Minimal risk interventions, such as education of MSH employees, following departmental approval.
   - Health Record Research (ie. secondary use of data), adhering to privacy legislation and following health record departmental approval.
   - All annual renewals of approved minimal risk research

   Delegated approvals are reported to and considered for ratification at the next REB meeting, to enable the REB to maintain surveillance over the decisions made on its behalf (TCPS2 6.12).

   Departmental Review:
   Ethics review of research that is conducted by undergraduate students, as part of their course work, is delegated to departmental level approval. The Department shall have written policies and procedures and in compliance with TCPS2 Article 2.5. Departments are encouraged to consult with the office of research regarding policy development.

6. When the REB is reviewing research in which a member of the REB has a personal interest in the research under review, conflict of interests principles obligate that the REB member not be present when the REB is discussing or making its decisions (TCPS2 Article 7.3).

Research Ethics Board Review Procedures

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 Harmonization 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 (REB)

DOCUMENT HISTORY:

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

APPENDICES:
Appendix A: Research Ethics Board Application Process

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