MOUNT SINAI HOSPITAL
Research Ethics Board
Terms of Reference

INTRODUCTION

The Research Ethics Board (REB) of Mount Sinai Hospital exists to ensure that all research involving human subjects conducted under the auspices of Mount Sinai Hospital meets the highest ethical and acceptable scientific standards, in accordance with the spirit of the Tri-Council Policy Statement 2: Guidelines on Research Involving Human Subjects.

Ethics are principles of right conduct guiding "what ought to be done". In the context of the Tri-Council Policy Statement 2, the REB subscribes to following ethical principles that are commonly held and valued by diverse research disciplines:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits

TERMS OF REFERENCE

From a research ethics perspective, the Mount Sinai Hospital REB is invested with the authority and responsibility to approve, modify or reject protocols for research involving human subjects, monitor ongoing research projects, and to suspend or terminate any ongoing research involving human subjects being carried out within Mount Sinai Hospital.

As a general definition, research to be considered by the REB includes all systematic collection of data from human subjects that is intended as generalizable knowledge. Such research includes not only intervention studies of possible therapeutic benefit but also minimal risk studies involving questionnaires, chart reviews, use of tissue and blood samples, and use of confidential information. Included in the jurisdiction of the Mount Sinai Hospital REB is research carried out by the staff of Mount Sinai Hospital, and investigators from other institutions who wish to carry out research on Mount Sinai Hospital premises or with Mount Sinai Hospital patients.

The Mount Sinai Hospital REB is responsible for:

- Ensuring that all research involving human subjects being conducted at Mount Sinai Hospital meet the highest ethical and scientific standards
- Ensuring that all protocols have a favorable risk/benefit ratio for research subjects, respect the rights, dignity, and autonomy of research subjects, and equitably distribute the benefits and burdens of research
- Monitoring on-going research activities at Mount Sinai Hospital to ensure that ethical standards are maintained throughout the course of the investigations
- Recommending policies and procedures governing ethical conduct of research at Mount Sinai Hospital
- Acting as a resource on matters of research ethics for Mount Sinai Hospital.

AUTHORITY

The authority for decisions made by the REB is delegated by the Board of Trustees and the Medical Advisory Committee (MAC) of Mount Sinai Hospital. In accordance with current standards for REBs outlined in the Tri-Council Policy Statement 2, the REB is an administratively independent authority within Mount Sinai Hospital and operates at arm's length from administrative, programmatic, and research structures within Mount Sinai Hospital. Mount Sinai Hospital retains the authority to deny the implementation of REB-approved research protocols for reasons other than research ethics (such reasons may be administrative, programmatic, philosophical, or resource-based in nature). However, neither the Board of Trustees, MAC or other administrative bodies within Mount Sinai may override a decision of the REB to reject a research project. If a research protocol is rejected by the REB, the principal investigator may request a hearing by an Appeal Committee to review the decision process and documentation that formed the basis of the decision.

REPORTING RELATIONSHIP

The REB reports to the Board of Trustees, through the MAC and liaises with the Research Council. The reporting relationship is through MAC rather than the Research Council to minimize the potential for conflict of interest in discussion of REB decisions. The Chair of the REB reports administratively to the CEO or delegate and has the additional responsibility to liaise with the University of Toronto on research ethics matters as specified under the current affiliation agreement between Mount Sinai Hospital and the University of Toronto. The Chair of the REB is a member of the Research Ethics Board Committee organized by the Office of Research Administration at the University of Toronto.

ACCOUNTABILITY

The REB will be accountable to the Board of Trustees, through the MAC of Mount Sinai Hospital. The REB is also accountable to the President of the University of Toronto with regard to research ethics matters for staff holding University appointments.

RESEARCH ETHICS BOARD

Mount Sinai Hospital will have two REBs responsible for reviewing protocols for all research carried out at Mount Sinai Hospital. To ensure that research proposals requiring ethics review are reviewed in a timely manner, an appropriate meeting schedule will be organized by the Chair of the REB. The REB office will coordinate the ethics review process and all related activities for the REB. Where necessary, subcommittees of the REB, such as a Human Tissue Review Committee, will be established. The Chair will appoint a Vice-Chair of the REB who can act in place of the Chair and at times where the Chair may have a conflict of interest.

CHAIR OF THE RESEARCH ETHICS BOARD

The Chair of the REB is an administrative position within Mount Sinai Hospital and reports to the CEO or delegate. The Chair of the REB will appoint a Vice-Chair for the REB and, as necessary, Chairs for subcommittees.

RESEARCH ETHICS OFFICE

The REB will be supported by four full-time REB staff: Two Research Ethicists, one Ethics Coordinator and an Administrative Coordinator. Their duties will be to support the Chair and the work of the REB. In addition, the REB staff will advise clinicians on their applications for ethical review, and assist the review process. The REB staff will be responsible to the Chair and will liaise routinely with the Mount Sinai Hospital Coordinator of Clinical Research.

REB MEMBERSHIP

The REB will have a majority of members who are Canadian citizens or permanent residents under the Immigration and Refugee Protection Act and will consist of at least 10 members from the following areas:

- at least three 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 Canadian laws relevant to the biomedical research to be approved
- at least one member whose primary experience and expertise are in a non-scientific discipline
- at least one member who has no affiliation with the sponsor or the institution where the study is to be conducted and preferably recruited from the community served by the institution
- a member representing the profession of nursing and the allied health professions

In addition to the members listed above, the REB will have adequate representation from both genders as well as adequate representation of physicians and non-physicians. With regard to the above configuration of the REB membership, every effort will be made to keep the community representatives proportionate to the size of the REB, and to have appropriate representation from the membership at each convened meeting based on the Tri-council policy and other relevant legislation (eg: Bill 31 in Ontario).

Potential members of the REB will be nominated to the MAC by the relevant Hospital leaders (usually Department/Division Chairs). It shall be the responsibility of Department/Division Chairs to nominate members as needed and to replace members as required. It is the responsibility of the Chair of the REB to recruit at least one representative from the community. Members may serve in more than one capacity such as representing both a Department/Division and a profession.

TERMS OF SERVICE

The Chair of the REB serves at the discretion of the CEO or delegate in consultation with the MAC, but this term will normally be two years. Members of the REB will normally serve for a term of two years. By mutual consent between the REB member and the Chair of the REB, the REB members may be appointed for additional terms. The terms of service will be staggered to ensure continuity.

MEETINGS AND ATTENDANCE

Meeting dates shall be set by the Chair through the REB office. Bi-monthly meetings will be held twice a month though the Chair may call additional meetings if the need arises. A quorum shall consist of at least 5 members of the REB and include at least one physician and one non-physician. Members will be assigned protocols in an equitable fashion to review. Protocols will only be approved if sufficient and appropriate expertise is available at the meeting to ensure adequate review as determined by the MAC.

Since attendance at REB meetings is crucial to the success of the review procedure, failure to attend two-thirds (66%) of the REB meetings will result in loss of membership to the Board. In the event that a REB member fails to meet these criteria, the appropriate Hospital leader will be notified by the Chair of the REB so that a replacement can be obtained from that Department/ Division.

DECISION PROCESS

The Mount Sinai Hospital REB will review protocols for all research conducted at Mount Sinai Hospital as detailed in the Tri-Council Policy Statement 2. For protocols that do not qualify for an expedited review process carried out by the Chair, a fully detailed review will take place and the REB will meet in a face-to-face forum to review such proposals. Decisions will be made by consensus: only in exceptional circumstances will decisions be made by majority vote at the discretion of the Chair. All documentation and communication will be through the REB Chair and office to investigators. Decisions by the REB will be communicated to the investigator by the REB based on the documentation and deliberations at the REB meeting.

The Chair of the REB is mandated on behalf of the full REB to determine which research protocols qualify for expedited review, and to review, modify and approve such expedited protocols. Such protocols may include those which have received full ethics review by the University of Toronto Human Subjects Review Committee or one of the University of Toronto affiliated hospital REBs. On behalf of the full REB, the Chair of the REB is delegated the authority to review and approve amendments and monitor reports of serious adverse events. Finally, for protocols that have been reviewed by the full REB, the REB may delegate the responsibility to the Chair of the REB to assess responses from investigators to concerns raised by the REB and issue approval of further requests for modification to the investigators. All such actions of the Chair will be reported to the full REB at the next available opportunity.

Submissions to the REB may receive approval, approval pending revision and clarification, deferral to obtain further information or consultation, or rejection (as submitted). If a submission is rejected, the REB will provide the investigator with a detailed list of the deficiencies so that any resubmission will meet the standards needed for an appropriate REB review. Applicants will be notified of the REB decision as soon as possible after the meeting. The REB approval of a research submission will be valid for 12 months (unless otherwise stipulated).

CONFLICT OF INTEREST

Members of the REB must disclose any real or apparent conflict of interest regarding a proposal under review. Members may not be present for any REB discussion regarding a proposal in which they have any vested interest and may not participate in the decision process regarding such a proposal.

APPEAL PROCESS

The REB will follow the appeal policy as defined in TAHSN.

RECORDS AND DOCUMENTATION

All records for submissions will be maintained by the Research Ethics Office. In order for a protocol submission to be approved, all documentation must be complete including the most current Investigator's Brochure for clinical trials, the budget for the proposed research, and, where necessary, the qualifications of the investigator to carry out the proposed research. All correspondence with the investigator will go through the Chair and the Research Ethics Office. Minutes of each REB meeting shall be prepared by the Research

Ethics Office and these minutes will document relevant discussions and decisions by the REB. Submissions that are either expedited or approved based on an adequate response by the investigator to REB concerns will be reported at the next REB meeting.

MONITORING

The approval of any study will remain in force for a 12 month period unless otherwise stipulated. The investigator must seek a renewed approval for a further 12 months prior to the expiration of the current approval. The investigator cannot continue with the study after the 12 month period without applying for a renewal of REB approval. Depending on the nature of the research, the REB may require more frequent reporting and more rigorous monitoring. As well, the REB may, at any time, audit an ongoing study to ensure compliance with ethical standards. If the REB becomes aware of any new information that alters the risk/benefit ratio in the study, the REB may suspend previous approval of the study until the REB can assess the safety implications of this new information.

REFERENCE GUIDELINES OF MOUNT SINAI HOSPITAL REB

The REB is guided in its decisions on research protocols by a number of key documents at the local, national and international level. As the Tri-Council Policy Statement 2 – Ethical Conduct for Research Involving Humans (2010) has been adopted as a national standard, at a minimum the REB will be in compliance with the standards set forth in this document. The REB is responsive to changing "best practices" in research ethics and will attend to developments at the local, national and international levels, including the ICH Good Clinical Practice Guidelines, Food and Drug Administration (FDA) Policy and interpretations, the Office for Protection from Research Risks (OPRR) directives and international declarations such as the Helsinki Declaration on research ethics. To the extent that such guidelines enhance the protection of research subjects, the REB will adopt such practices.