

UNIVERSITY HEALTH NETWORK

Research Ethics Board

Terms of Reference

INTRODUCTION

The University Health Network Research Ethics Board (REB) exists to ensure that all research involving human subjects (hereafter referred to as “Research”) conducted under the auspices of the University Health Network meets the highest scientific and ethical standards.

Ethics are principles of right conduct guiding “what ought to be done”. In the context of the Tri-Council Policy Statement: Guidelines on Research Involving Human Subjects, the REB subscribes to the 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 University Health Network REB is invested with the authority and responsibility to approve, modify or reject Research protocols, monitor ongoing Research projects, and to suspend or terminate any ongoing Research involving human subjects being carried out within the University Health Network. Included within the jurisdiction of the University Health Network REB are the staff of the Toronto General Hospital, Toronto Western Hospital, Princess Margaret Hospital, and the Toronto Medical Laboratories who are carrying out Research as a member of the University Health Network within these institutions. Additionally, the University Health Network REB has similar authority over investigators from other institutions who wish to carry out Research on University Health Network premises or with University Health Network patients.

The University Health Network REB is responsible for:

- Ensuring that all Research proposals involving human subjects being conducted by members of the University Health Network or by others at the University Health Network meet the highest standards of scientific rigor and ethics
- 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 the University Health Network to ensure that ethical standards are maintained throughout the course of the investigations

- Recommending policies and procedures governing ethical conduct of Research at the University Health Network
- Acting as a resource on matters of research ethics for the University Health Network

AUTHORITY

The authority for decisions made by the REB is delegated by the Board of Trustees through the Medical Advisory Committee (MAC) of the University Health Network. While the REB is a subcommittee of the MAC, in accordance with current standards for REBs outlined in the Tri-Council Policy Statement, the REB is an administratively independent body within the University Health Network and operates at arm's length from administrative, programmatic, and research structures within the University Health Network. The University Health Network 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, Vice-President (Research) or other administrative entity at the University Health Network 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 Research Ethics Board reports monthly to the Board of Trustees through the MAC. Administratively, the Chair of the REB reports to the Vice President (Research). The Chair of the REB has the additional responsibility to liaise with the University of Toronto on research ethics matters as specified under the current affiliation agreement between the University Health Network and the University of Toronto. The Chair of the REB is a member of 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 the University Health Network. 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

The Research Ethics Board is responsible for reviewing all Research protocols. To ensure that Research proposals are reviewed in accordance with Tri-Council standards and in a timely manner, the University Health Network will establish multiple REBs. The REB office will coordinate the ethics review process and all related activities for all REBs. All REBs will be chaired by the incumbent in the role of the "Chair" of the REB. Where necessary, subcommittees of the REB will be established such as the Human Tissue Review Committee. Each REB, however, will also have a Vice-Chair appointed by the Chair.

CHAIR OF THE RESEARCH ETHICS BOARD

The Chair of the REB is an administrative position within the University Health Network and reports to the Vice-President (Research). The Chair of the REB will appoint a Vice-Chair for each REB and, as necessary, Chairs for subcommittees.

REB MEMBERSHIP

Each Research Ethics Board 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 5 Members from the following areas:

- at least three members who have broad expertise in 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 who 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 is 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 based on the guidelines in the Tri-Council Policy Statement under Article 1.3.

Potential members of the REB will be nominated by the relevant Hospital leaders (usually Department/Division Chairs) to the MAC. In cooperation with the Chair of the REB, the MAC will nominate members for membership on the REB and will search for replacement 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 Vice-President (Research). Members of the REB will normally serve for a term of two (2) years. By mutual consent between the REB member and the Chair of the REB, the REB member 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. Meetings will be held monthly 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. Protocols will only be approved if sufficient and appropriate expertise is available at the meeting to ensure adequate review as determined by the REB. Members will be assigned protocols in an equitable fashion to review.

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 on the REB. In the event that an REB member fails to meet these criteria, the appropriate member of the MAC will be notified by the Chair of the REB so that a suitable replacement can be obtained for the REB.

DECISION PROCESS

The University Health Network REB will provide proportionate review for all Research protocols as detailed in the Tri-Council Policy Statement. For protocols that do not qualify for an expedited review process carried out by the Chair and the staff of the REB office, 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. All documentation and communication will be through the REB Chair and REB 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. All decisions made by the REB will be reported monthly to the MAC.

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. 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 or further requests for modification to the investigators. All such actions of the Chair of the REB 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. The approval of a Research submission by the REB will be valid for 12 months (unless otherwise stipulated).

CONFLICT OF INTEREST

Members of the University Health Network 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

In the event that the REB rejects a submission, an appeal of the REB decision may be made to a standing Appeal Committee. The Appeal Committee will decide whether or not to hear the appeal. If the Appeal Committee decides to hear the appeal, it will review the REB process by which the REB reached its decision. The Appeal Committee may dismiss the appeal or may direct the REB to reconsider its decision based on their findings of the Appeal Committee. The Appeal Committee will provide the REB and the person appealing with a written decision documenting the reasons for its decision.

The Appeal Committee will be composed of the current Chairs of the Hospital REBs (University Health Network, Hospital for Sick Children, Sunnybrook Health Sciences Center, Women College Hospital, the Center for Addiction and Mental Health, St. Michael's Hospital and the Baycrest Centre for Geriatric Care). This committee will also include a lay person from the community and a member knowledgeable in relevant law. The Appeal Committee will draw on necessary expertise from the scientific community within the University of Toronto and affiliated Hospitals as necessary to carry out its review.

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. In regard to the qualifications of the Investigator, the REB relies on the Division/Department Head to attest to the qualifications of the Investigator to carry out the specific study. 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. These minutes are forwarded to the MAC on a monthly basis. 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 (or stipulated) period without applying for a renewal of the 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 any 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 UNIVERSITY HEALTH NETWORK 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 – Ethical Conduct for Research Involving Humans (September 1998) 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.