# TERMS OF REFERENCE: HUMBER RIVER HEALTH RESEARCH ETHICS BOARD

## 1. INTRODUCTION

The Research Ethics Board (REB) of Humber River Health exists to ensure that all research involving human participants conducted under the auspices of Humber River Health meets the highest ethical and acceptable scientific standards, in accordance with the spirit of the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2).

Ethics are principles of right conduct guiding "what ought to be done." In the context of the TCPS2, the REB subscribes to following ethical principles that are commonly held and valued by diverse research disciplines:

- **Respect for Persons** which recognizes the intrinsic value of human beings and the respect and consideration that they are due; considers how people of all ages are treated as research participants; incorporates the moral obligations to respect autonomy; and protects those with developing, impaired, or diminished autonomy.

- **Concern for Welfare** which considers the impact on individuals of factors including physical, mental and spiritual health, as well as their physical, economic and social circumstances; encompasses factors including privacy and control of information about the person and the assessment of foreseeable risks and benefits; and the treatment of data and human biological materials according to the free, informed and ongoing consent of the person who was the source of the information and materials.

- **Justice** which recognizes the obligation to treat people fairly and equitably.

## 2. TERMS OF REFERENCE

From a research ethics perspective, the Humber River Health REB is vested with the authority and responsibility to approve, modify or reject protocols for research involving human participants, monitor ongoing research projects, and to suspend or terminate any ongoing research involving human participants being carried out within Humber River Health.

Research to be considered by the REB is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation." Such research includes not only intervention studies of possible therapeutic benefit but also minimal risk studies involving questionnaires, focus groups, chart reviews, secondary use of data, use of tissue and blood samples, and use of confidential information. Included in the jurisdiction of the Humber River Health REB is research carried out by the staff and physicians of Humber River Health, and investigators from other institutions who wish to carry out research on Humber River Health premises or with Humber River Health patients and/or HRH resources.
The Humber River Health REB is responsible for:

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

## 3. AUTHORITY

The authority for decisions made by the REB is delegated by the Board of Directors through the Transformation and Innovation Committee of the Board. In accordance with current standards for REBs outlined in the TCPS2, the REB is an administratively independent authority within Humber River Health and operates at arm's length from administrative, programmatic, and research structures within Humber River Health. Humber River Health 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 Directors nor other administrative bodies within Humber River Health 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 an Appeal to review the decision process and documentation that formed the basis of the decision.

## 4. REPORTING RELATIONSHIP

The REB reports to the Board of Directors, through the Transformation and Innovation Committee. The reporting relationship is through the Board of Directors 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 Humber River Health and the University of Toronto.

## 5. ACCOUNTABILITY

The REB will be accountable to the Board of Directors, through the Transformation and Innovation Committee, of Humber River Health. The REB is also accountable to the President of the University of Toronto with regards to research ethics matters for staff holding University appointments.

## 6. RESEARCH ETHICS BOARD

Humber River Health will have one REB responsible for reviewing protocols for all research carried out at

Humber River Hospital, HRH Finch campus, HRH Chruch campus, HRH Research Institute, and Schulich Centre for Family Medicine. 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 Research Ethics Office (REO) will coordinate the ethics review process and all related activities for the REB. Where necessary, subcommittees of the REB will be established. The Chair may appoint a Vice-Chair of the REB who can act in place of the Chair and at times when the Chair may have a conflict of interest.

## 7. CHAIR OF THE RESEARCH ETHICS BOARD

The Chair of the REB is an administrative position within Humber River Health and reports to the CEO or delegate. The Chair of the REB may appoint a Vice-Chair for the REB and, as necessary, Chairs for subcommittees.

## 8. RESEARCH ETHICS OFFICE

The REB will be supported by the Research Ethics Office (REO), which will be staffed as required to effectively support the functions of the REB. The duties of the REO staff will be to support the Chair and the work of the REB. In addition, the REB staff will advise researchers on their applications for ethical review and be part of the review process. The REB staff will be responsible to the Chair and will liaise routinely with other research administrative bodies within Humber River Health.

## 9. 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 5 members from the following areas:

- at least two members who have broad expertise in the scientific methodology, health science research, and medicine (for regulated clinical trials, this will include at least one member who practices medicine or dentistry);
- 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, institution, or immediate family member of 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;
- a member who is knowledgeable in privacy legislation.

In addition to the members listed above, the REB will not be comprised of members of a single gender and will include a diverse representation of lived and living experience, as well as adequate representation of physicians and non-physicians. With regards 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 TCPS2 and other relevant legislation (e.g.: PHIPA in Ontario).

Potential members of the REB will be nominated to the REB by the relevant Hospital leaders (usually Department/Division Chairs) and/or recruited from the hospital community. 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 not fill more than two representative capacities during a full board meeting.

To ensure the independence of the REB decision making, institutional senior administrators shall not serve on the REB.

## 10. TERMS OF SERVICE

The Chair of the REB serves at the discretion of the CEO or delegate in consultation with the Board of Directors, but this term will normally be three 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.

## 11. MEETINGS AND ATTENDANCE

Meeting dates shall be set by the Chair through the REO. Humber River Health's REB will generally meet once a month though the Chair may call additional meetings if the need arises. For the review of US-regulated studies, quorum will consist of a simple majority of Research Ethics Board (REB) members (50% + 1), who collectively have sufficient expertise in the scientific, methodological, and clinical areas of the research under review and are knowledgeable about relevant ethical and legal matters. The quorum will include at least one community member and a member whose primary experience and expertise are in a non-scientific discipline. Quorum includes REB members participating by telephone or video conference. Quorum also includes alternate REB members substituting for regular REB members in the same membership category.

For meetings during which no US-regulated studies are under review, 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 based on the TCPS2 and other relevant legislation (e.g.: PHIPA in Ontario). 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 may result in loss of membership on the Board. If 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.

## 12. DECISION PROCESS

The Humber River Health REB will review protocols for all research conducted at Humber River Hospital as detailed in the TCPS2. For protocols that do not qualify for a delegated review process carried out by the Chair or delegate, a fully detailed review will take place and the REB will meet to review such proposals. Votes will be carried out for each study under review, and the numbers of members voting for, against or abstaining will be documented in the minutes of the meeting. All documentation and communication will be through the REB Chair and REO to the 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 delegated review, and to review, modify and approve such delegated 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 or delegate 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 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).

## 13. CONFLICT OF INTEREST

Members of the REB must disclose any real or potential 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.

## 14. APPEAL PROCESS

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

## 15. RECORDS AND DOCUMENTATION

All records for submissions will be maintained by the REO. 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 or designate and the REO. Minutes of each REB meeting shall be prepared by the REO, and these minutes will document relevant discussions and decisions by the REB. Submissions that are either delegated or approved based on an adequate response by the investigator to REB concerns will be reported at the next REB meeting.

## 16. 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. 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.

## 17. REFERENCE GUIDELINES OF HUMBER RIVER HEALTH REB

The REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection. These include, but are not limited to, the Food and Drugs Act and applicable Regulations, the International Council on Harmonization Good Clinical Practice Guidelines, the Declaration of Helsinki, the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans, and where applicable, US Federal Regulations.