CHEO RESEARCH ETHICS BOARD TERMS OF REFERENCE

The Research Ethics Board (REB) is a standing committee of the Children's Hospital of Eastern Ontario reporting to the Quality and Safety Committee of the CHEO Board of Trustees.

The REB has the authority to:

- approve, require modifications to, place restrictions on, suspend or terminate, or disapprove, any research activity that falls within its jurisdiction;
- conduct continuing review of ongoing research;
- request, receive and share information that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy,
- take any action considered necessary to ensure the protection of human research participants.

The primary purpose of the Board is to ensure that research under its purview meets the highest ethical and scientific standards.

The REB adopts as minimal standards the 'Tri-Council Guidelines on Research with Human Subjects'(TCPS), the 'Good Clinical Practice' (International Conference on Harmonization – E6), and relevant regulations, legislation and guidelines. The REB considers a number of factors in its review of research protocols including: social and scientific merit, the risks and benefits to subjects, subject selection and recruitment, privacy and confidentiality, record keeping, and the consent and assent processes and documents.

Scope of Review

The REB reviews:

- research involving humans conducted by staff of the Hospital or Research Institute; and
- research involving humans identified or recruited at or through the CHEO and the CHEO Research Institute.

Accordingly, the jurisdiction of the REB extends to human research taking place outside the hospital and the Research Institute.

Governance

The CHEO Board of Trustees delegates to the REB the responsibility for the oversight of human research. The REB reports to the Board of Trustees through the Hospital Quality and Safety Committee of the Board. The Chair of the REB reports administratively to the Vice-President, People, Strategy and Performance.

Notwithstanding this reporting and delegation structure, the REB is independent in its decision-making responsibilities. The REB also has the authority to set out its policies and procedures (including SOPs).

The REB terms of reference must be compliant with TCPS and other related ethical guidance, legislation or regulations. For this reason, the document is developed collaboratively between the Quality and Safety Committee and the REB itself.

The REB Chair or delegate shall provide the Quality and Safety Committee, with regular updates on its activities including:

- An annual report
- Performance indicators of REB activities;
- Matters relating to stakeholder groups (e.g., patients/families, investigators, etc.);
- Strategic considerations in ethics oversight (e.g., harmonization between Research Ethics Boards);
- Compliance with ethical and regulatory standards as well as internal policies and procedures (e.g., SOPs, routine internal audits of the REB files);
- Any concern with respect to the independent decision-making of the REB.

Membership
The size of the REB can vary but will always be between 9 – 16 voting members.

Chair and Vice Chair:
In consultation with the Board, the CEO of the Hospital and the CEO of the CHEO Research Institute jointly appoint the REB Chair and Vice Chair for a term of five years; which is renewable. The REB Chair or Vice-chair should normally be an experienced REB member with at least two years of experience on an REB.

Members:

- In consultation with the REB chair, the CEOs of CHEO and the Research Institute appoint the members of the REB.
- Membership should represent as much as possible the different sectors of the hospital and Research Institute, but should always include a Pharmacy representative and a bio-ethicist.
- In compliance with Personal Health Information Protection Act (PHIPA), the membership will include a member with specific knowledge in privacy issues who provides the Board with guidance
- In compliance with Health Canada's Part C, Division 5 of the Food and Drugs Regulations, the majority of the REB members are either Canadian citizens or permanent residents

Term:

- Membership appointments are for a three-year term, which is renewable.
- The membership terms are generally staggered in such a manner as to ensure the continuity of the REB.

REB meetings and review process
The REB convenes monthly (except in August) to review protocols submitted for its consideration. The REB issues monthly minutes which include documentation on its meetings and all other decisions. The REB members ratify the Board minutes at convened meetings.

Quorum &decision-making
The composition of members present at a convened meeting of the REB must allow for a substantive review of the research under consideration. The quorum rule is 50% + 1 of the membership in effect at that time. In addition, the convened REB must consist of at least five members, including both men and women, of whom:

- at least one member who practices medicine or dentistry and who is in good standing with their regulatory body (for regulated clinical trials);
- at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- at least one member is knowledgeable in ethics;
- at least one member whose primary experience and expertise are in a non-scientific discipline;
- at least one member is knowledgeable in the health law (but that member should not be the institution's legal counsel or risk manager);
- at least one community member who has no affiliation with the institution; and
- at least one member who is knowledgeable in considering privacy issues.

In order to adhere to this quorum rule, regular attendance at the monthly REB meetings is expected. If a member's attendance wanes, a meeting with the Chair can be convened to discuss possible solutions. In the event that a solution cannot be agreed upon, the REB member may be asked to forfeit his/her role on the Board.

REB members vote on the disposition of protocols (approve, approve with major/minor modifications, defer judgment or reject). A majority vote of those members who are present and entitled to vote is required in order to approve a protocol.

Any significant minority view (i.e., two or more members) will be noted in the minutes. The Primary CHEO Site Investigator will also be alerted to the ethical issues raised by the dissenting member(s). Further details are outlined in the Standard Operating Procedures of the Board.

Appeal process
Investigators have a right to request reconsideration of REB decisions. These requests should be made in writing and addressed to the REB Chair. The investigator must explain in his/her request for appeal, the procedural and/or substantive reasons for the request. The REB can decide to confirm or revise its original decision. In the event of continued disagreement between the investigator and the REB, the University of Ottawa's Appeal Board can be asked to consider the appeal.

Competing Interests and Interference
The greatest responsibility of the REB is the rights and safety of human research participants. Members must disclose to the Board any competing interest that might interfere, or could reasonably be perceived as interfering, with their appraisal of protocols. These competing interests can be financial or non-financial, professional, or personal.

REB members who are judged by the Board to have a competing interest in relation to a protocol will be asked to recuse themselves from deliberations and will not be included in the REB voting on protocol disposition. A notation will be made in the minutes reflecting that the member excused himself/herself from the room.

In addition, the REB can be subject to interference from external stakeholders (e.g., study sponsor, investigators). The Board will attempt to directly resolve situations, which threaten the independence of the Board. Communication can occur between the REB, CHEO administration, CHEO Research Institute administration and others, as appropriate. Failing such a resolution, the Board can bring these situations to the attention of the Quality and Safety Committee of the CHEO Board of Trustees for further consideration and possible action.

Quality Assurance Inspections
The internal audit program assists the REB in continuing oversight of studies involving more than minimal risk. The audit program provides assurance that research is conducted according to the ethical and regulatory standards. The QA staff will work with the REB to determine if and when a for-cause inspection is required of a research study. The QA staff provides the final audit report to the REB. As required, the REB Chair may provide the findings of the internal audit to the Quality and Safety Committee of the Board of Trustees.

APPENDIX 1: Relationship to Other REBs

In consultation with the CHEO REB, the Quality and Safety Committee may authorize the REB to accept ethics reviews undertaken by an external REB. This authorization should be based on an explicit agreement which specifies adherence to the TCPS, and where applicable, Heath Canada and other relevant regulations and legislation. Studies approved on the basis of cross-institutional agreements should be documented and reported to the full REB, through the Chair.

The following agreements are currently under review:

1. The University of Ottawa – a unilateral jurisdictional agreement recognizing the authority of the CHEO REB by the University.
2. Clinical Trials Ontario (CTO) – reciprocity agreement (pending)
    a. CHEO REB will participate in the rotational review process of multicenter trials submitted to CTO as a designated, qualified REB.
    b. CHEO and CHEO RI will accept REB reviews done under the aegis of CTO for multi-centre trials in which the review is completed by the Hospital for Sick Children.
3. Ottawa Health Science Network Research Ethics Board – reciprocity agreement (in-progress)

Additional agreements may be added as deemed necessary by the CHEO REB, and ratified by the CHEO Quality and Safety Committee.