

PART 1: TERMS OF REFERENCE FOR THE RESEARCH ETHICS BOARD¹

MANDATE

The REB will ensure that research involving the participation of humans meets current scientific and ethical research standards for the protection of human research participants. This will be achieved by the REB:

- reviewing all proposed research from scientific and ethical perspectives before the research is started,²
- promoting research ethics education of the research community.

TERMS OF REFERENCE

The St. Michael's Hospital Research Ethics Board is appointed on behalf of St. Michael's Hospital and maintains an arms-length relationship with St. Michael's Hospital. St. Michael's Hospital mandates the REB to independently approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants or human materials, which is conducted within, or by members of, St. Michael's Hospital.³

Decisions made by the REB are based on the scientific and ethical merits of the research study, and are made independently of other interests of St. Michael's Hospital. St. Michael's Hospital retains the authority to disallow the conduct of research even if approved by the REB.

The REB reports to the Board of Directors of St. Michael's Hospital.

PHILOSOPHY

Research involving human participants must be directed toward the benefit of humanity and the advancement of knowledge. Researchers are to conduct their research as critical and responsible professionals, accountable to those people participating in the research, to the society that supports them, as well as to their colleagues, students and research institutions.⁴

¹ This section was approved by the SMH Research Ethics Board on December 3, 2003.

² See article 1.1(a) of the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans, Medical Research Council of Canada, Natural Sciences and Engineering Council of Canada, and Social Sciences and Humanities Research Council of Canada, August 1998 (hereinafter Tri-Council Policy), also see website <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

³ Tri-Council Policy, article 1.2

⁴ Catholic Health Association of Canada, Health Ethics Guide, 2000 (hereinafter "Catholic Ethics Guide"), article 106, see also website www.chac.ca/publications/ethics/html

The REB is guided by the following principles:⁵

- respect for a person's right for self-determination and autonomy,
- not harming others nor violating a person's fundamental rights of liberty and privacy,
- doing good to others, including society, research participants, researchers, sponsors and institutions,
- recognizing the duty of researchers to disseminate the analysis and interpretation of any significant results to the research community, since silence on negative outcomes may foster potentially harmful clinical practices or wasteful duplication;⁶
- equitable distribution of the benefits and burdens of research.

OTHER GUIDELINES FOR THE REB

The REB is guided in decision-making regarding research protocols by a number of key documents at the local, national, and international level. Most recently the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans has been adopted as a national standard. In addition, the adoption by the Therapeutics Products Directorate of Health Canada of the ICH Good Clinical Practice: Consolidated Guideline provides the REB and researchers with internationally accepted standards to strive toward when working with new drugs.

Therefore, the REB is attentive to local, national, and international trends in research ethics that may bear directly on research carried out at St. Michael's Hospital. Listed below are some key reference documents:

- University of Toronto Guidelines⁷
- Tri-Council Policy Statement⁸
- ICH Good Clinical Practice: Consolidated Guideline (E6)⁹
- Catholic Health Association of Canada, Health Ethics Guide¹⁰
- Canadian and Ontario laws and regulations.¹¹

⁵ Tri-Council Policy, page i.5 (Guiding Ethical Principles)

⁶ Catholic Ethics Guide, article 110

⁷ The University of Toronto, "Guidelines on the Use of Human Subjects", see website <http://www.library.utoronto.ca/rir/tblconhu.html>

⁸ Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans, Medical Research Council of Canada, August 1998, see website <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

⁹ ICH Harmonized Tripartite Guideline, Good Clinical Practice: Consolidated Guideline (E6), Therapeutic Products Directorate, Health Canada, 1997, see website http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/goodclin_e.html

¹⁰ Catholic Health Association of Canada, Health Ethics Guide, 2000, see website www.chac.ca/publications/ethics/html

¹¹ most importantly the Health Care Consent Act, S.O. 1996, c.C.2, http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/96h02_e.htm