



Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

**Name of SOP: Principles, Guidelines and Regulation
References**

REB SOP # 001

Issued by: Research Ethics Board Office

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Purpose:

The purpose of this reference document is to list the principles, guidelines and regulations utilized in the standard operating policy and procedure (SOP) established by Ontario Shores' Research Ethics Board (REB) for reviewing the research protocols..

Scope:

This SOP pertains to Research Ethics Boards (REB) that review and oversee research involving human participants and/or human biological materials in compliance with national standards, applicable regulations and guidelines.

Description:

Ontario Shores Board of Directors acknowledges the importance of facilitating investigative research in the pursuit of new knowledge and understanding in mental health care to improve quality, safety and patient outcome. Ontario Shores REB is accountable to the Board of Directors (Board) and shall report directly to the Board or at the Board's discretion, indirectly, through a Board committee designated by the Board. The REB Chair shall submit annual reports to the Board or its designated committee. The Board of Directors authorizes the Research Ethics Board at Ontario Shores to review the ethical acceptability of research involving humans, their personal health information and/ or human biological materials and approve, reject, propose modifications to, or terminate any such proposed or ongoing research. The institution recognizes the autonomy of the Research Ethics Board in their decision making authority in regards to the ethical review of research involving humans.

Principles, Guidelines and Regulation References: The REB is guided by the fundamental basic value of "Respect for Human Dignity". Respect for human dignity is expressed through the following three core ethical principles which are reflected in the Tri-Council Policy Statement (TCPS 2, 2014):

- Respect for Persons
- Concern for Welfare
- Justice

The REB's actions shall be in accordance with the guidelines and regulations listed in the reference section below.

Responsibility:

REB Chair, REB members
REB office
Senior Management
Board of Directors

References:

- 1) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, December 2010: (short name: TCPS 2) <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
- 2) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) <http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf>
- 3) Health Canada: Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials: Part C: DRUGS (Division 5) http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/ctdcta_ctddec-eng.php
- 4) Personal Health Information Protection Act, 2004: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm
- 5) Quality of Care Information Protection Act, 2004: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm
- 6) Public Hospitals Act, 1990: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p40_e.htm
- 7) Mental Health Act, 1990: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90m07_e.htm
- 8) Health Care Consent Act, 1996: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm
- 9) Regulated Health Professions Act, 1991: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_91r18_e.htm
- 10) US http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>
- 11) U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
- 12) U.S. Department of Health and Human Services (HHS): Office for Human Research Protections (OHRP) Policy & Guidance Library <http://www.hhs.gov/ohrp/policy/index.html>
- 13) Other applicable provincial or federal Statutes and Regulations
- 14) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)
- 15) Research Ethics Board Standard Operating Procedures, *REB-SOP-I-02.01* St Joseph's Care Group (May 2012)