Ontario Shores
Centre for Mental Health Sciences

**REB STANDARD OPERATING PROCEDURES MANUAL**

**Name of SOP: Research Requiring REB Review**
**REB SOP # 008**

**Issued by: Research Ethics Board Office**
**Date of Issue: 2015/06/15**
**Revised: YYYY/MM/DD**

**Purpose:**
The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review and research activities that do not.

**Scope:**
This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

**Description:**
All research involving human participants must be reviewed and approved by an REB. No intervention or interaction with human participants in research, including recruitment, may begin until an REB has reviewed and approved the research protocol, consent documents and recruitment materials.

**Research that Requires REB Review:**
The following requires ethics review and approval by an REB before the research commences:
(a) Research involving living human participants,
(b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

**Research Exempt from REB Review:**
Research that relies exclusively on publicly available information does not require REB review when:
(a) The information is legally accessible to the public and appropriately protected by law,
(b) The information is publicly accessible and there is no reasonable expectation of privacy;

REB review is not required for research involving the observation of people in public places where:
(a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,
(b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and
(c) Any dissemination of research results does not allow identification of specific individuals;

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;

The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

**Activities Not Requiring REB Review:**
Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB;

Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes within the organization, do not constitute research for the purposes of this SOP, and do not fall within the scope of REB review; these activities may be reviewed by the REB if they are intended to produce generalizable knowledge or address a hypothesis-driven question.

Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

**Responsibility:**
REB Chair, REB members
REB office

**References:**


1) N2 CAREB REB SOPs v1 *SOP 102* (September 2014) https://oicronca.box.com/s/95k7ydj574579ajvbe06

2) 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/

3) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

4) 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

5) Personal Health Information Protection Act, 2004: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

6) 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

7) 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

8) 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

9) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)