Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: REB SOP Procedures Maintenance
REB SOP # 024

Issued by: Research Ethics Board Office
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Purpose:
This standard operating procedure (SOP) describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel

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

Description:
Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner

Procedure:

1) Development, Review, Revision and Approval of Policies & Procedures:

The qualified REB Office Personnel will review the SOPs at least biannually. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs

SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to REB or administrative practices

The qualified REB Office Personnel will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of "DRAFT version date" and removal of the previous "Final Version Date";

The revised SOP(s) will be circulated to the REB Office Personnel and REB Chair or designee, as well as REB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date

Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the "Final Version Date". The history of revisions will be recorded in the 'SOP History' section of each SOP

Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

2) Distribution and Communication:

New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the 'Responsibilities' section of each SOP

The SOPs will be available to Investigators and Investigator sites, Sponsors and Regulatory Authorities as required

Qualified REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policy and or relevant procedure, as applicable

Each new REB member must review the applicable policies and procedures prior to undertaking his/her responsibilities as an REB member

Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking his/her responsibilities with the REB office

Evidence of training must be documented

The REB office shall maintain all documentation of SOP training

3) Forms, Memos and Guidance Documents:

Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled

Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP

Memos and guidance documents will be made available to the Investigators and Investigator sites as applicable

The qualified REB Office Personnel and/or REB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents

Responsibility:
All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

References:

1) N2 CAREB REB SOPs v1 *SOP 108.001* (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) 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

5) 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

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