Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Signatory Authority
REB SOP # 018

Issued by: Research Ethics Board Office
Date of Issue: 2016-03-02
Revised: YYYY/MM/DD

Purpose:
This standard operating procedure (SOP) specifies who has the authority to sign documents on behalf of the Research Ethics Board (REB) and describes the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

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

Description:
REBs are accountable for their activities and decisions, and appropriate controls must be applied to ensure that documentation related to REB review and approval of research are signed by a person or persons having the appropriate authority to do so.

Procedure:

1) REB Reviews, Decisions and Other Correspondence with the Investigator:

- For each submission reviewed at a Full Board meeting, the responsible REB Office Personnel records the decision made by the Full Board
- Communication of the REB decision made at a Full Board meeting must be reviewed and authorized by the REB Chair or designee or as otherwise delegated by the REB Chair or designee
- For each submission that undergoes delegated review, the reviewer's decision is documented
- Once a final decision is documented by the REB Chair or designee, the responsible REB Office Personnel may issue the decision or letter
- All activities are documented in the research file
- Any letters, memos, or emails between the REB and Investigators that provide information concerning the review of research (e.g., requests for consent form changes, requests for additional information) and that do not imply or appear to imply approval of the research, may be issued as per delegated signing authority
- All reviews, actions, decisions and signatures are filed within the research file
- All correspondence is retained in the research file

2) Correspondence with External Agencies:

The REB Chair or designee or the responsible Ontario Shores' Official signs all correspondence with agencies of the federal government (Health Canada, OHRP, FDA) and with all funding agencies and/or sponsors

3) Delegation of Signing Authority:

- The REB Chair or designee may delegate signing authority for documents related to REB review and approval
- The REB Chair or designee may only delegate signing authority to REB members or REB Office Personnel with the skill and knowledge necessary for the effective exercise of the authority
- The REB Chair or designee may not delegate his/her signing authority to ad hoc advisors or to independent contractors
- The REB Chair or designee should clearly define the parameters of the delegated authority
- The REB Chair or designee may delegate signing authority for defined periods of time (e.g., for temporary absences)
- Delegation of signing authority must be documented in the REB office file and on the study related file

Responsibility:
All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met. The REB Chair or designee is responsible for signing documents related to REB review and approval of research. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair.

References:

1) N2 CAREB REB SOPs v1 *SOP 106.001* (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)