Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Qualifications and Responsibilities of Principal Investigator
REB SOP # 007

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Purpose:
This standard operating procedure (SOP) describes the qualifications and responsibilities of the Principal Investigator (PI) who engages in research involving human participants.

Scope:
This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

Description:
Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The REB must have assurance that the qualifications of new PIs, for the conduct of research, are appropriate. PIs are required to conduct the research in compliance with applicable regulations and guidelines, and to comply with all REB policies.

PI's Qualifications:
The Principal Investigator must make available to the REB his/her current CV and medical license number (if applicable) and his/her relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the PI's qualifications, if necessary;

If applicable (as in the case of clinical trials involving drug or device interventions), the PI must be a physician or a dentist with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;

The PI must have completed appropriate training regarding the requirements of conducting and overseeing research; If applicable, all specified Organizational Officials must approve the application to the REB; The organizational approver's signature attests that:

- He/she is aware of the proposal and supports its submission for REB review
- The application is considered to be feasible and appropriate
- Any internal requirements have been met
- The PI is qualified and has the experience and expertise to conduct this research
- The PI has sufficient space and resources to conduct this research

Any concerns raised in the REB review of the PI's qualifications will be communicated to the PI and must be satisfied prior to REB approval of the application.

PI Responsibilities:
The PI is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the PI's responsibility to comply with all applicable regulations and ensure that (if applicable):

• He/she and his/her staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for protection of human research participants
• He/she has adequate resources to properly conduct the research and conducts the research following written SOPs,
• All real, potential, or perceived conflicts of interest are declared to the REB at the time of the initial application, and as they arise,
• The REB review and approval is obtained before engaging in research involving human participants,
• All necessary documentation is signed by the responsible PI, as applicable,
• Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) approved by the REB (as applicable),
• He/she personally conducts or supervises the described investigation(s),
• The research is conducted in compliance with the approved research and applicable reporting criteria are reported to the REB, including deviations, serious, unexpected adverse events and privacy breaches,
• Any changes in the approved research are not initiated without REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s),
• Premature termination or suspension of the research is reported to the REB;
• Accurate and complete records are maintained according to applicable regulatory requirements,
• Written summaries of the research status are submitted to the REB at least annually, or more frequently if required by the REB, and an application for continuing review is submitted to the REB prior to the expiration of REB approval,
• Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the REB,
• The REB is notified if there is a change in PI,
• The REB is notified immediately if his/her medical or dental license or hospital privileges are suspended, restricted or revoked (if applicable) or should his/her qualifications otherwise no longer be appropriate,
• The REB is notified when the research is complete;

Note: (if applicable) The obligations of a PI holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-PI) include both those of a sponsor and those of a PI.

Responsibility:
All Principal Investigators and Researchers
REB Chair, REB members
REB office

References:

1) N2 CAREB REB SOPs v1 *SOP 801.001* (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) 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)