Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Duties of REB Members
REB SOP # 004

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Purpose:
This standard operating procedure (SOP) describes the duties of the members of the Research Ethics Board (REB).

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

Description:
Each REB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, REB members must be versed in regulations governing human participants' protection and biomedical research ethics, and policies germane to human research participant protection.

Attendance: Regular REB members are expected to attend the regularly scheduled REB meetings. REB Members may be asked to step down if they consistently miss a specified percentage of the scheduled REB meetings; REB members must notify the REB office if they will be absent for an REB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place.
Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member; REB members are expected to be available for the entire REB meeting, not just the sections for which they have been assigned as reviewers.

Terms of Duty: All members of the REB, including the REB Chair and Vice-Chair, will be appointed for a term as specified by organizational policy.
Duties: All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, to submit comments in advance of the REB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting; Each REB member is expected to fulfill specific duties based on the role as outlined below. More than one REB member may fulfill each role;

Scientific members: are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits and standards of practice. These members should also advise the REB if additional expertise in a scientific or non-scientific area is required to assess whether the research adequately protects the rights and welfare of human participants;

Non-scientific members: are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Non-scientific members should advise the REB if additional experience in a non-scientific area is required to assess whether the research adequately protects the rights and welfare of participants and to comment on the comprehension of the consent document;

Community member(s): are expected to provide input regarding their knowledge about the local community

and be able to discuss issues and research from that perspective;

Member(s) knowledgeable in relevant law: are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB;

Member(s) knowledgeable in ethics: are expected to guide the REB in identifying and addressing ethics issues related to the research under review;

Ad hoc advisors: individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the REB meeting to lend his/her expertise to the discussions;

REB Chair: The REB Chair or designee provides overall leadership to the REB.

- The REB Chair can delegate any of his/her responsibilities, as appropriate to a Vice-Chair or other qualified individual(s)
- Any responsibilities that are delegated by the REB Chair must be documented
- The REB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines. The REB Chair or designee determines the level of risk of each research project. The REB Chair or designee monitors the REB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion
- The REB Chair or designee ensures that all REB members are free to participate in discussions during the REB meetings. The REB Chair or designee can ask a substitute REB member to attend an REB meeting in order to draw his/her expertise in an area that may be relevant to the REB's review and deliberations of the research
- The REB Chair or designee determines the appropriateness of a Full Board or delegated review of the research
- The REB Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review
- The REB Chair or designee signs off on all REB decisions in writing
- For REB approval of clinical trials approved by Health Canada, the REB approval letter which includes the REB attestation, is signed by the REB Chair or designee
- The REB Chair or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the Full Board. The REB Chair or designee can suspend the conduct of the research if he/she determines that a Researcher is not adhering to the REB approved protocol or to the REB's policies and procedures
- The REB Chair or designee will report on the activities of the REB to the organization on an annual basis
- The REB Chair or designee, in conjunction with the REB Office Personnel and other organizational representatives as applicable, ensures the REB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the organization on policies and procedures related to research conduct
- The REB chair, in conjunction with the REB Office Personnel, shall assess the educational and training needs of the REB members and Office Personnel, and will address any gaps identified
- The REB Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards

REB Vice-Chair: The REB Vice-Chair or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so:
- The REB Vice-Chair performs all responsibilities assigned by the REB Chair
- The REB Vice-Chair assists with the overall operation of the REB.

Primary and Secondary Reviewers: REB members will act as primary and/or secondary reviewers for assigned research projects at Full Board meetings. The primary and secondary reviewers present their findings resulting from review of the REB submission materials and provide an assessment of the soundness and safety of the research and recommends specific action to the REB. They lead the discussion of the research project during the REB meeting. The primary and secondary reviewers review additional material(s) as requested by the REB for the purpose of approval of the research.

Training and Education: REB members are expected to follow training and education procedures.

Conflict of Interest: REB members are expected to follow conflict of interest procedures.

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 clearly articulating all required duties associated with membership to the REB to potential and current REB members. REB members and alternates are responsible for fulfilling their duties as specified in this SOP.

References:

1) REB Shoreline intra
https://shoreline/departments/REB/Pages/default.aspx

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
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) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.108, 46.115
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108; 21 CFR 312, 812
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

6) OHRP Guidance on Written IRB Procedures
http://www.hhs.gov/ohrp/policy/index.html