Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: REB Composition
REB SOP # 003

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Purpose:
This standard operating procedure (SOP) describes the membership composition requirements of the Research Ethics Board (REB).

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

Description:
Individual members of an REB must be qualified through education, training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles, and applicable regulations, guidelines and standards pertaining to human participant protection. To promote complete and adequate review of the type of research commonly reviewed by the REB, the REB must include appropriate diversity; therefore, selection of members must include a consideration of professional expertise (including both scientific and non-scientific) to assess the research submitted for review. Important consideration are also race, sex, cultural backgrounds, clinical and research experience, organizational affiliation, and sensitivity to such issues as broad representation from organizations served by the REB.

Selection of REB Members: In selection of REB members, equal consideration shall be given to qualified persons of both sexes. No appointment shall be made solely on the basis of sex;
The REB will make every effort to include cultural and ethnic minorities to represent the population from which research participants are recruited, within the scope of available expertise needed to conduct its functions.

Composition of the REB: The REB membership will not consist entirely of members of one profession; REB members will be selected based on the needs of the REB as outlined below and per applicable regulations, guidelines and standards.

- The membership of the REB will be in compliance with the Food and Drugs Act and applicable Regulations, the Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans, the International Conference on Harmonization of Good Clinical Practice Guidelines, Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013), and the US Code of Federal Regulations
- The REB Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions
- The REB will include at least five members represented by the following categories:
  a) At least two members who have expertise in relevant research disciplines, field and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body)
  b) At least one member who is primarily experienced in non-scientific disciplines
  c) At least one member who is knowledgeable in ethics

d) At least one member who is knowledgeable in the relevant law. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research, and
e) At least one community member who has no affiliation with the organization or the sponsor, and who is not part of the immediate family of a person who is affiliated with the organization

- A member may not fulfill more than two representative capacities or disciplines
- Members will include men and women, a majority of whom are Canadian citizens or permanent residents, and who collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed research
- Membership, when required, should include at least one member who has expertise in complementary or alternative care or pediatric health research
- At least one member, when possible, who is from an identifiable Aboriginal community or Native center, when the REB reviews research that recruits participants from that community
- Additional membership as required by applicable legislation or guidelines

Alternate Members: The REB Chair or designee may ask an alternate REB member to attend an REB meeting to draw on his/her expertise in an area that may be relevant to that meeting's deliberations, or to establish a quorum for that meeting in the absence of the regular REB member. Only alternate REB members of comparable qualifications may substitute for an REB member (a non-scientific member may not substitute for a scientific member). The minutes shall document when an alternate REB member replaces a primary REB member.

REB Chair: Whenever possible and practicable, the REB Chair will be selected from experienced REB members who have expressed interest in becoming the REB Chair and who are familiar with the applicable regulations and guidance documents. The REB Office Personnel updates the REB membership roster (and OHRP registration, if applicable), to reflect this change.

Ad Hoc Advisors: At his/her discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be asked to participate in the REB meeting to lend his/her expertise to the discussions. All ad hoc advisors shall sign a Confidentiality of Information and Conflict of Interest Agreement. The ad hoc advisor may not contribute directly to the REB's decision and their presence or absence shall not be used in establishing a quorum. Documentation of key information provided by the ad hoc advisor shall be summarized in the REB minutes and if available, the written report shall be placed in the REB files.

Observers at REB Meetings: The REB may allow observers to attend its meetings. Observers will sign a Confidentiality of Information and Conflict of Interest Agreement agreeing to abide by the REB conflict of interest and confidentiality policies. Where the REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion. Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application. The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

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 ensuring that the composition of the REB meets the applicable regulatory requirem**ents.**

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