Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Management of REB Membership
REB SOP # 005

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Purpose:
This standard operating procedure (SOP) describes the management of the membership of the Ontario Shores' 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:
REB membership (e.g., appointment, terms) must be adequately managed to continue to meet applicable regulatory and compositional requirements and to maintain the appropriate diversity, experience and expertise for the type and volume of research reviewed at Ontario Shores.

Appointments:

Regular Members and Alternates: REB members are appointed as per the organization's REB terms of reference; Community members (meeting membership requirements) are solicited from the greater local community; Each REB member selected is approved by the REB Chair or designee or as determined by the organizational REB terms of reference; Candidates selected to serve on the REB will be issued a letter of appointment by the REB Chair or designee. The members accepting the appointment will be asked to sign a Confidentiality of Information and Conflict of Interest Agreement.

REB Chair and Vice-Chair: The REB Chair is appointed as per the organization's REB terms of reference; The REB Vice-Chair is appointed as per the organization's REB terms of reference. The REB Chair and Vice-Chair will be asked to sign a Confidentiality of Information and Conflict of Interest Agreement.

Ad hoc Advisors: At his/her discretion, the REB Chair or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

Terms of Appointment: Each REB member will serve for a term specified by the organization – a 2 or 3 year term. Re-appointment of an REB member for (an) additional term(s) is allowed, by mutual agreement of the REB member and the REB Chair or designee; The REB Chair and Vice-Chair will serve for a term specified by the organization; Terms will be overlapping to preserve the level of experience, expertise, and continuity.

Qualifications and Training of REB Members: Each member of the REB will follow qualification and training procedures.

Resignations and Removals: An REB member may resign before the conclusion of his/her term upon provision of notice to the REB Chair or designee; An REB member may be asked to step down if they consistently miss a specified percentage of the scheduled Full Board meetings in their term; The REB Chair

or designee may otherwise remove an REB member at any time, if they are not fulfilling their designated REB duties in a timely, competent and ethical manner; An REB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest or any other relevant behavior that could be perceived as compromising his/her ethical judgment; Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve the level of experience and expertise and to ensure the continuity of the functions of the REB.

Compensation: Compensation and reimbursement of expenses for REB members will be according to organizational policies.

Liability and Coverage: All REB members are insured for their research ethics review-related work by the organization's insurance policy, subject to the terms and conditions of that policy.

Documentation: The REB Office Personnel will maintain an updated electronic REB membership list; The REB membership list is reviewed and updated as required, or with the initiation of new or conclusion/termination of existing terms; The current REB membership list and archived lists are maintained and available through the REB office.

CVs, other supporting documents related to education and expertise, signed members' letters of appointment and confidentiality agreements for all current and past REB members will be maintained in the REB office.

The REB office will maintain the REB membership roster which includes: name, degree(s), area(s) of expertise and organizational affiliation(s), role on the REB (e.g. scientific, nonscientific), sex, Canadian citizenship status, and indications of experience such as board certification, licenses, etc. sufficient to describe each member's chief anticipated contribution to REB deliberations (as applicable);

The REB office will maintain REB member contact information and additional information on areas of expertise for the purposes of communication and reviewer assignment. It will be kept confidential for access only by REB members and the REB Office Personnel;

When applicable, the REB Chair or designee will initiate and /or update the REB registration with the US Office for Human Research Protection (OHRP).

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 and the REB office are jointly responsible for overseeing and managing the REB membership and continuity of REB function.

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