



Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Training and Education
REB SOP # 006

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Purpose:

This standard operating procedure (SOP) describes the training and education requirements for Research Ethics Board (REB) members and REB Office Personnel.

Scope:

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

Description:

REB members, REB Office Personnel and others charged with the responsibility for reviewing, approving, and overseeing human participant research should be well-versed in the regulations, guidelines, policies, and ethical principles applicable to human participant research. Adequate training and education in these areas is critical for the REB to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner.

Training and Education – REB Members

The REB Chair or designee will provide new REB members with a general overview of the policies and procedures pertinent to REB meeting functions and REB member expectations, as well as an orientation to the principles and guidelines for research ethics; New REB members will receive an orientation before beginning their formal duties. REB members are required to complete the TCPS online tutorial and are expected to participate in the orientation process which may include, but is not limited to:

- Background on the REB (e.g., Terms of Reference, governance structure, annual reports, process flowchart etc.)
- Policies and Procedures (e.g., relevant SOPs and associated forms, consent form template, consent form checklist etc.)
- Member information (e.g., meeting schedule, membership list, information and guidelines for members, reviewer guide etc.)
- Regulatory and guidance documents
- Other member-specific information (e.g., copy of signed confidentiality and conflict of interest agreement, membership appointment letter etc.)
- Resource information (e.g., list of training and education references, relevant articles, etc.)
- New REB members may be offered the opportunity to observe at least one REB meeting prior to commencing their REB member duties
- Ongoing ethics education in areas germane to the REB members' responsibilities may be provided at REB meetings by the Chair and/or his/her designee

REB members are encouraged to engage in self-directed learning in research ethics and in the conduct of research to enhance their ability to fulfill their responsibilities. New or revised policies and SOPs shall be disseminated to all REB members.

Training and Education - REB Office Personnel

The REB Chair or designee will provide new REB Office Personnel with an overall orientation to the REB including a general overview of the policies and procedures pertinent to their role in support of the REB;

- New REB Office Personnel will receive an orientation package. Before commencing their official duties in the REB office, REB Office Personnel are expected to read and become familiar with the information;
- New REB Office Personnel will receive training on the REB SOPs and will be expected to be knowledgeable and compliant with the SOPs;
- New REB Office Personnel are required to complete the TCPS online tutorial, and are encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of research;

REB Office Personnel are encouraged to engage in self-directed learning to enhance their ability to fulfill their responsibilities. New or revised policies and SOPs shall be disseminated to all REB office personnel.

Conferences

REB members/REB office personnel are encouraged to attend conferences and other educational sessions pertaining to human participant research protection, such as the Canadian Association of Research Ethics Board (CAREB) annual general meeting and CAREB regional meetings. The organization and REB office will support such activities to the extent possible and as appropriate to the responsibilities of REB members and REB Office Personnel. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location etc.).

Documentation of Training and Education

The REB office will retain copies of the CVs of all REB members and REB Office Personnel;

REB members and REB Office Personnel will record their relevant training and education and provide copies of their certificates of completion. Training records will be kept on file in the REB office;

REB members and REB Office Personnel are encouraged to retain copies of agendas of relevant workshops, seminars and conferences attended;

REB agendas and minutes will record the distribution of any educational materials presented at the REB meetings.

Responsibility:

All REB members including the Chair and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met. REB alternate members must also ensure to meet the requirements of 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>