Title	Training and Education
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Approvals

Name and Title of Signatories	Signature	Date yyyy/mm/dd
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1.0 PURPOSE

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

2.0 GENERAL POLICY STATEMENT

REB members, REB office staff and others charged with the responsibility for reviewing, approving, and overseeing human research should be well-versed in the regulations, guidelines, policies, and ethical principles applicable to human 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 subjects in a consistent manner.

3.0 DEFINITIONS

See glossary of terms.

4.0 RESPONSIBILITY

This SOP applies to all OCREB members including the Chair and Vice-Chair and to all OCREB office personnel including the Executive Director.

The Chair and the Executive Director, or designee are responsible for establishing the training and education requirements for the OCREB members and OCREB office personnel.

The Executive Director will ensure that initial and ongoing training is provided and documented in accordance with such requirements.

5.0 SPECIFIC POLICIES AND PROCEDURES

5.1 Training and Education – REB Members

5.1.1 The Chair, or the Executive Director, or designee will provide new members with a general overview of the policies and procedures pertinent to OCREB meeting functions and OCREB member expectations, as well as an orientation to the principles and guidelines for research ethics;

5.1.2 New OCREB members will receive an orientation package, usually during a formal orientation session(s). Before beginning their formal duties on OCREB, members are required to complete the TCPS2 online tutorial and are expected to read and become familiar with the information in the orientation package. The orientation package will include, but is not limited to:

- Background on OCREB (e.g., Terms of Reference, governance structure, annual reports, newsletters, process flowchart),
- Policies and Procedures (e.g., relevant SOPs and associated forms, list of institutions using OCREB, Board of Record Study Agreement, consent form template, consent form checklist),
- OCREB member information (e.g., meeting schedule, membership list, information and guidelines for members, OCREB reviewer guide),
- Regulatory and guidance documents,
- Other member-specific information (e.g., copy of signed confidentiality and conflict of interest agreement, membership appointment letter),
- Resource information (e.g., list of training and education references, relevant articles, Belmont Report, CIHR Best Practices for Protecting Privacy in Health Research, etc.,);

5.1.3 As part of their orientation, new OCREB members will be offered the opportunity to observe at least one OCREB meeting prior to commencing their OCREB member duties;

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

5.1.5 Ongoing ethics education in areas germane to OCREB members' responsibilities may be provided at the monthly OCREB meetings;

5.1.6 OCREB members are encouraged to attend (in person or via teleconference or webinar) other relevant workshops and educational sessions such as, the University of Toronto Joint Centre for Bioethics seminars; Centre for Addiction and Mental Health Brown Bag Ethics Discussion Groups; St. Michael's Hospital REB Issues in Research Ethics speakers' series;

5.1.7 OCREB members who have received funding from the OCREB office to attend a workshop or conference may be asked to present the relevant conference/workshop information at a subsequent OCREB meeting, time permitting;

5.1.8 The OCREB Chair, Executive Director or designee will distribute articles related to human subject protections, trends in oncology research or updated guidance documents as appropriate. OCREB members are encouraged to contribute relevant articles for distribution;

5.1.9 New or revised policies and SOPs will be disseminated to the OCREB members;

5.1.10 OCREB members are expected to engage in self-directed learning in research ethics and in the conduct of clinical trials to enhance their ability to fulfill their responsibilities.

5.2 Training and Education – Research Ethics Coordinators

5.2.1 The Executive Director or designee will provide new Research Ethics Coordinators (RECs) with an overall orientation to OCREB including a general overview of the policies and procedures pertinent to their role in support of OCREB;

5.2.2 New RECs will receive an orientation package. Before commencing their official duties in the OCREB office, RECs are expected to read and become familiar with the information;

5.2.3 New RECs will receive training on the OCREB SOPs and will be expected to be knowledgeable and compliant with the SOPs;

5.2.4 New RECs will be expected to attend the next available OICR orientation session;

5.2.5 The RECs are required to complete the TCPS2 online tutorial, and are encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of clinical trials;

5.2.6 The RECs are required to attend the monthly teleconferences with the Ontario centres and are encouraged to submit education topics for the sessions and to lead occasional education sessions or discussions at the teleconferences;

5.2.7 The RECs are encouraged to attend conferences pertaining to human participant research protection, such as the CAREB annual general meeting and CAREB regional meetings. The OCREB office will support such activities to the extent possible and as appropriate to the responsibilities of members and staff. Conference attendance is based on availability of funding and other practical considerations (e.g., workload, staffing, conference location);

5.2.8 The RECs are encouraged to attend (in person or via teleconference or webinars) other relevant workshops and educational sessions such as the University of Toronto Joint Centre for Bioethics seminars; Centre for Addiction and Mental Health Brown Bag Ethics Discussion Groups; St. Michael's Hospital REB Issues in Research Ethics speakers' series. Attendance at these sessions is based on availability of funding and other practical considerations (e.g., workload, staffing);

5.2.9 The RECs may be asked to present relevant conference/workshop information to their colleagues at a subsequent team meeting and/or at one of the monthly teleconferences with the Ontario centres, as appropriate;

5.2.10 The Chair, the Executive Director or designee will distribute articles related to human subject protections, trends in oncology research or updated guidance documents. The RECs are encouraged to contribute relevant articles for distribution;

5.2.11 New or revised policies and SOPs will be disseminated to the RECs;

5.2.12 The RECs are expected to engage in self-directed learning to enhance their ability to fulfill their responsibilities.

5.3 Training and Education – Other OCREB Office Personnel

5.3.1 The Executive Director or designee will provide new OCREB office personnel with an overall orientation to OCREB including a general overview of the policies and procedures pertinent to their role in support of OCREB;

5.3.2 New office personnel will be expected to attend the next available OICR orientation session;

5.3.3 New office personnel will receive training on the relevant OCREB SOPs in addition to other training related to their position;

5.3.4 New office personnel are required to complete the TCPS2 online tutorial;

5.3.5 All office personnel are encouraged to attend conferences and workshops relevant to their roles and responsibilities. The OCREB office will support such activities to the extent possible and as appropriate to the responsibilities of members and staff. Conference attendance is based on availability of funding and other practical considerations (e.g., workload, staffing, conference location);

5.3.6 Office personnel may be asked to present relevant conference/workshop information to their colleagues at a subsequent team meeting;

5.3.7 Relevant new or revised policies and SOPs will be disseminated to all office personnel;

5.3.8 Office personnel are expected to engage in self-directed learning to enhance their ability to fulfill their responsibilities.

5.4 Documentation of Training and Education

5.4.1 The OCREB office will retain copies of the CVs of all OCREB members, RECs and other office personnel;

5.4.2 OCREB members will be asked to provide the OCREB office with details of relevant training and education and to provide a copy of the TCPS2 certificate of completion;

5.4.3 OCREB RECs and office personnel must record their relevant training and education in the training records in a timely fashion. A copy of the TCPS2 certificate of completion must be submitted to the OCREB Executive Director or designee;

5.4.4 Training records will be kept on file in the OCREB office.

5.4.5 OCREB members, RECs and office personnel are encouraged to retain copies of agendas of relevant workshops, seminars and conferences attended;

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

6.0 REFERENCES

1. 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 (TCPS2);
2. Health Canada Therapeutic Products Directorate Food and Drug Regulations, Part C, Division 5;
3. Personal Health Information Protection Act (PHIPA), S.O. 2004;
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Part 56.107;
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.107;
6. National Institutes of Health NOTICE: Required Education in the Protection of Human Research Participants: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html;
7. Office for Human Research Protections (OHRP) IRB Guidebook;
8. Amdur, Robert and Bankert, Elizabeth. Institutional Review Board Member Handbook;
9. OCREB List of Training and Education References.

7.0 SOP HISTORY

SOP Number	Version	Key Changes
103	001	Original
103	002	• Approvals section – signatory was changed to the curent OCREB Chair; • Section 3 – definitions are provided in a separate glossary of terms; • Section 5 - the initial and ongoing training procedures were consolidated into the same section and minor modifications were made to the procedures. The OCREB Office Personnel section was divided into separate sections for RECs and other office personnel; • Section 6.0 – references to the TCPS2 and to PHIPA were added.