
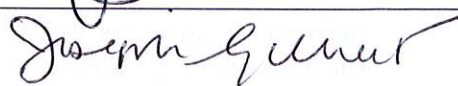


SOP Title	Training and Education: REB Members and REO Staff
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		05/11/2016
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1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the training and education requirements for the University of Western Ontario's Health Sciences Research Ethics Board (UWO HSREB) members and Office of Human Research Ethics (OHRE) staff.

2. GENERAL POLICY STATEMENT

HSREB members and OHRE staff charged with the responsibility of reviewing, approving and overseeing human research and the associated administrative functions should be well-versed in the regulations, guidelines, policies and ethical principles applicable to human research. Education and training in these areas is important for the HSREB to fulfill its mandate of protecting the rights and welfare of human research participants and human materials in a consistent manner.

3. RESPONSIBILITY

This SOP applies to the HSREB Chair, Vice Chair(s), Director, HSREB members and OHRE staff.

The HSREB Chair and the Director or designee, are responsible for establishing the training and education requirements for HSREB members and OHRE staff. The Director, or designee, will ensure that initial and ongoing training is provided and documented in accordance with such requirements.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Training and Education – HSREB Members

5.1.1. The HSREB Chair or the Director will provide new members with a general overview of the policies and SOPs pertinent to HSREB meeting functions and HSREB member expectations, as well as an orientation to the principals and guidelines for research ethics;

5.1.2. New HSREB members will receive an orientation package for review. The orientation package will include items such as but not limited to:

- Background on the HSREB (e.g., Terms of Reference, relevant Standard Operating Procedures, and newsletters, etc.),
- HSREB member information (e.g., OHRE Contact Information, REB Meeting Schedule, HSREB Membership List),

- Regulatory and Guidance Documents (e.g. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans [TCPS]; ICH Good Clinical Practice Guidelines).
- Other member-specific information (e.g., Confidentiality and Conflict of Interest Agreement),
- 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 the orientation, new HSREB members will observe at least one REB meeting prior to commencing their HSREB member duties;

5.1.4. Conferences: HSREB members (including the Chair & vice Chair) are encouraged to attend conferences pertaining to human participant research protection. Participation will be supported to the extent possible and as appropriate to the responsibilities of HSREB members. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);

5.1.5. Workshops and Seminars: HSREB members are encouraged to attend (in person or via teleconference/webinars) other relevant local workshops and educational sessions;

5.1.6. HSREB members who have attended a workshop or conference may be asked to present the relevant conference/workshop information at an HSREB meeting;

5.1.7. Other Educational Opportunities: The HSREB Chair, Director or designee will distribute relevant articles and/or updated guidance documents as appropriate. HSREB members are encouraged to submit relevant articles to the HSREB Chair, Director or designee for distribution;

5.1.8. HSREB members are expected to engage in self-directed learning in research ethics to enhance their ability to fulfill their responsibilities;

5.1.9. HSREB members should complete the online TCPS introductory or equivalent tutorial;

5.1.10. New or revised policies and SOPs will be disseminated to the HSREB members.

5.2. Training and Education – Ethics Officers

5.2.1. The Director or designee will provide new Ethics Officers (EO's) with an overall orientation to the HSREB including a general overview of the policies and procedures pertinent to their role in support of the HSREB;

5.2.2. New EO's will receive an orientation package. Before commencing their official duties, EO's are expected to read and become familiar with the information;

5.2.3. New EO's will receive training on the HSREB SOP's and will be expected to be knowledgeable and compliant with the SOPs;

5.2.4. The EO's are required to complete the TCPS2 online tutorial, and are encouraged to complete additional and ongoing relevant education and training in research ethics;

5.2.5. Conferences: EO's are encouraged to attend conferences pertaining to human participant research protection. Participation will be supported to the extent possible and as appropriate to the responsibilities the EO's. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);

- 5.2.6. Workshops and Seminars: EO's are encouraged to attend (in person or via teleconference/webinars) other relevant local workshops and educational sessions;
- 5.2.7. EO's who have attended a workshop or conference may be asked to present relevant conference/workshop information to their colleagues at a team and/or HSREB meeting, as appropriate;
- 5.2.8. Other Educational Opportunities: The HSREB Chair, Director or designee will distribute relevant articles and/or updated guidance documents as appropriate. EO's are encouraged to submit relevant articles to the HSREB Chair, Director or OHRE staff for distribution;
- 5.2.9. EO's are expected to engage in self-directed learning in research ethics to enhance their ability to fulfill their responsibilities;
- 5.2.10. EO's are required to complete the online TCPS introductory or equivalent tutorial;
- 5.2.11. New or revised policies and SOPs will be disseminated to the HSREB members.

5.3. Training and Education – Other Office Staff

- 5.3.1. The Director or designee will provide new Office staff with an orientation to their role;
- 5.3.2. New Office staff are expected to read and become familiar with the SOPs and related policies;
- 5.3.3. New Office staff will receive training on the relevant HSREB SOP's in addition to other training related to their position;
- 5.3.4. Office staff are required to complete the online TCPS introductory or equivalent tutorial;
- 5.3.5. Conferences: Office staff are encouraged to attend conferences relevant to their roles and responsibilities. Participation will be supported to the extent possible and as appropriate to the responsibilities the office staff. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);
- 5.3.6. Office staff who have attended a workshop or conference may be asked to present relevant conference/workshop information to their colleagues at a team meeting;
- 5.3.7. Relevant new or revised policies and SOP's will be disseminated to all office staff;
- 5.3.8. Office staff are expected to engage in self-directed learning in research ethics to enhance their ability to fulfill their responsibilities.

5.4. Continuing Education – HSREB Members, EO's and other OHRE Staff

- 5.4.1. Ongoing ethics education in areas germane to HSREB members' responsibilities may be provided at the bi-monthly HSREB meetings;
- 5.4.2. Conferences: HSREB members (including the Chair & Vice Chair(s)), EO's and other OHRE staff are encouraged to attend conferences pertaining to human participant research protection. Participation will be supported to the extent possible and as appropriate to the responsibilities of HSREB members and OHRE staff. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);
- 5.4.3. Workshops and Seminars: HSREB members and OHRE staff are encouraged to attend (in person or via teleconference/webinars) other relevant local workshops and educational sessions;

- 5.4.4. HSREB members who have attended a workshop or conference may be asked to present the relevant conference/workshop information at an HSREB meeting. OHRE staff will be asked to present relevant conference/workshop information to their colleagues at a team and/or REB meeting, as appropriate;
- 5.4.5. Other Educational Opportunities: The HSREB Chair, Director or designee will distribute relevant articles and/or updated guidance documents as appropriate. HSREB members and OHRE staff are encouraged to submit relevant articles to the HSREB Chair, Director or OHRE staff for distribution;
- 5.4.6. HSREB members are expected to engage in self-directed learning in research ethics to enhance their ability to fulfill their responsibilities.

5.5. Documentation of Training and Education - REB Members and OHRE Staff

- 5.5.1. The OHRE retains copies of the CV's of all HSREB member, EO's and other office staff;
- 5.5.2. HSREB members (including the Chair and Vice-Chair(s)) will be asked to provide the OHRE with details of relevant training and education and to provide a copy of the TCPS2 certificate of completion;
- 5.5.3. HSREB EO's and office staff 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 HSREB Director or designee;
- 5.5.4. Training records will be kept on file in the OHRE office;
- 5.5.5. OHRE staff are encouraged to retain copies of agendas for relevant workshops, seminars and conferences attended as evidence of continuing education;
- 5.5.6. HSREB agendas and minutes will record the distribution of educational materials presented at the HSREB meetings.

6. REFERENCES

- 6.1. 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),;
- 6.2. Health Canada Therapeutic Products Directorate Food and Drug Regulations, Part C, Division 5;
- 6.3. Personal Health Information Protection Act (PHIPA), S.O. 2004;
- 6.4. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.107;
- 6.5. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Part 56.107;
- 6.6. National Institutes of Health (NIH) NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>;
- 6.7. Office for Human Research Protections (OHRP) IRB Guidebook;

7. SOP HISTORY

SOP Number. Version	Key Changes	Effective Date mm/dd/yyyy
103.001	Original	05/22/2014
103.002	Minor Administrative Changes	05/10/2016