



|                       |  |
|-----------------------|--|
| <b>SOP Title</b>      | Training and Education: NMREB Members and OHRE Staff |
| <b>Number.Version</b> | N102.003   |
| <b>Effective Date</b> | 08/10/2018   |

**Approvals**

| <b>Name and Title of Signatories</b>                          | <b>Signature</b>  | <b>Date<br/>mm/dd/yyyy</b> |
|---|---|----------------------------|
| Erika Basile<br>Director, Research Ethics                     |  | 2019-02-26                 |
| Dr. Randal Graham<br>Chair, Non-Medical Research Ethics Board |  | 2019-03-06                 |

**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 Non-Medical Research Ethics Board (NMREB) members and Office of Human Research Ethics (OHRE) staff.

**2. GENERAL POLICY STATEMENT**

NMREB 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 NMREB 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 NMREB Chair, Vice Chair(s), Director, NMREB members and OHRE staff.

The NMREB Chair and the Director or designee, are responsible for establishing the training and education requirements for NMREB 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 – NMREB Members**

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

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

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

- Regulatory and Guidance Documents (e.g. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans [TCPS]).
- 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, Best Practices for Protecting Privacy in Research, etc.);

5.1.3. As part of the orientation, new NMREB members will observe at least three REB meetings prior to commencing their NMREB member duties;

5.1.4. Conferences: NMREB 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 NMREB members. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);

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

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

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

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

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

5.1.10. New or revised policies and SOPs will be disseminated to the NMREB 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 NMREB including a general overview of the policies and procedures pertinent to their role in support of the NMREB;

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 NMREB 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 TCPS 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 NMREB meeting, as appropriate;
- 5.2.8. Other Educational Opportunities: The NMREB 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 NMREB 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 EO's.

### **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 NMREB 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 – NMREB Members, EO's and other OHRE Staff**

- 5.4.1. Ongoing ethics education in areas germane to NMREB members' responsibilities may be provided at the monthly NMREB meetings;
- 5.4.2. Conferences: NMREB 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 NMREB 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: NMREB members and OHRE staff are encouraged to attend (in person or via teleconference/webinars) other relevant local workshops and educational sessions;
- 5.4.4. NMREB members who have attended a workshop or conference may be asked to present the relevant conference/workshop information at an NMREB 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 NMREB Chair, Director or designee will distribute relevant articles and/or updated guidance documents as appropriate. NMREB members and OHRE staff are encouraged to submit relevant articles to the NMREB Chair, Director or OHRE staff for distribution;

5.4.6. NMREB 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 NMREB member, EO's and other office staff;

5.5.2. NMREB 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 TCPS certificate of completion;

5.5.3. NMREB EO's and office staff must record their relevant training and education in the training records in a timely fashion. A copy of the TCPS certificate of completion must be submitted to the NMREB 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. NMREB agendas and minutes will record the distribution of educational materials presented at the NMREB 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 (TCPS),;
- 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<br>mm/dd/yyyy |
|--------------------|--|------------------------------|
| N102.001           | Original   | 12/07/2015                   |
| N102.002           | Change ORE to OHRE                                 | 06/09/2016                   |
| N102.003           | Update to NMREB Chair & Administrative Corrections | 08/10/2018                   |