

TITLE	203: Duties of HREB Members
SCOPE	The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of the members of the Human Research Ethics Board (HREB).

2.0 RESPONSIBILITIES

The HREB Chair or designee is responsible for clearly articulating all required duties associated with membership to the HREB to potential and current HREB members.

HREB members and alternates are responsible for fulfilling their duties as specified in this SOP.

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURE

Each HREB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, HREB members must be versed in regulations governing human participants' protection and biomedical research ethics, and policies germane to human research participant protection.

4.1 Attendance

- 4.1.1 Regular HREB members are expected to attend the regularly scheduled HREB meetings. HREB Members may be asked to step down if they consistently miss a specified percentage of the scheduled HREB meetings;
- 4.1.2 HREB members must notify the HREB office if they will be absent for an HREB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place;

- 4.1.3 Alternate HREB members are expected to attend the identified HREB meetings for which they have confirmed their availability to replace a regular HREB member, and/or a minimum of two HREB meetings per year;
- 4.1.4 HREB members are expected to be available for the entire HREB meeting, not just the sections for which they have been assigned as reviewers.
- 4.2 Terms of Duty
 - 4.2.1 All members of the HREB, including the HREB Chair and Vice-Chair, will be appointed for a term as specified by organizational policy.
- 4.3 Duties
 - 4.3.1 All HREB members attending an HREB meeting are expected to review the relevant materials submitted for each item under review or consideration by the HREB, to submit comments in advance of the HREB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;
 - 4.3.2 Each HREB member is expected to fulfill specific duties based on the role as outlined below. More than one HREB member may fulfill each role;
 - 4.3.3 Research specialist(s): are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. These members should advise the HREB if additional expertise in a specific research area is required to assess whether the research adequately protects the rights and welfare of human participants. These members should also comment on the comprehension of the consent document;
 - 4.3.4 Community member(s): are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective;
 - 4.3.5 Member(s) knowledgeable in relevant law: are expected to alert the HREB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the HREB;
 - 4.3.6 Member(s) knowledgeable in ethics: are expected to guide the HREB in identifying and addressing ethics issues related to the research under review;
 - 4.3.7 Ad hoc advisors: individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the HREB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the HREB meeting to lend his/her expertise to the discussions;

- 4.3.8 HREB Chair: The HREB Chair or designee provides overall leadership to the HREB:
- The HREB Chair can delegate any of his/her responsibilities, as appropriate to a Vice-Chair or other qualified individual(s),
 - Any responsibilities that are delegated by the HREB Chair must be documented,
 - The HREB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines. The HREB Chair or designee determines the level of risk of each research project. The HREB Chair or designee monitors the HREB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
 - The HREB Chair or designee ensures that all HREB members are free to participate in discussions during the HREB meetings. The HREB Chair or designee can ask a substitute HREB member to attend an HREB meeting in order to draw his/her expertise in an area that may be relevant to the HREB's review and deliberations of the research,
 - The HREB Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
 - The HREB Chair or designee performs or delegates authority to (an) HREB member(s) to perform a delegated review,
 - The HREB Chair or designee signs off on all HREB decisions in writing,
 - For HREB approval of clinical trials approved by Health Canada, the HREB approval letter which includes the HREB attestation, is signed by the HREB Chair or designee,
 - The HREB Chair or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the Full Board. The HREB Chair or designee can suspend the conduct of the research if he/she determines that a Researcher is not adhering to the HREB approved protocol or to the HREB's policies and procedures,
 - The HREB Chair or designee will report on the activities of the HREB to the organization on an annual basis,
 - The HREB Chair or designee, in conjunction with the HREB Office Personnel and other organizational representatives as applicable, ensures the HREB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall

advise the organization on policies and procedures related to research conduct,

- The HREB chair, in conjunction with the HREB Office Personnel, shall assess the educational and training needs of the HREB members and Office Personnel, and will address any gaps identified.
- The HREB Chair or designee reviews and approves HREB policies and procedures at set intervals, to ensure the HREB SOPs meet all current standards.

4.3.9 HREB Vice-Chair: The HREB Vice-Chair or equivalent is responsible for performing the responsibilities of the HREB Chair when the HREB Chair is unable to do so:

- The HREB Vice-Chair performs all responsibilities assigned by the HREB Chair,
- The HREB Vice-Chair assists with the overall operation of the HREB.

4.4 Primary and Secondary Reviewers

4.4.1 HREB members will act as primary and/or secondary reviewers for assigned research projects at Full Board meetings. The primary and secondary reviewers present their findings resulting from review of the HREB submission materials and provide an assessment of the soundness and safety of the research and recommends specific action to the HREB. They lead the discussion of the research project during the HREB meeting. The primary and secondary reviewers review additional material(s) as requested by the HREB for the purpose of approval of the research.

4.5 Training and Education

4.5.1 HREB members are expected to follow training and education procedures.

4.6 Conflict of Interest

4.6.1 HREB members are expected to follow conflict of interest procedures.

5.0 REFERENCES

See References.

6.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 203	November 14, 2019	Original version