

TITLE	201: Composition of the HREB
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 membership composition requirements of the Human Research Ethics Board (HREB).

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

Individual members of an HREB must be qualified through training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles, and applicable regulations, guidelines and standards pertaining to human participant protection.

To promote complete and adequate review of the type of research commonly reviewed by the HREB, the HREB must include appropriate diversity; therefore, selection of members must include a consideration of professional expertise (including both scientific and non-scientific) to assess the research submitted for review. Important considerations are also race, sex, cultural backgrounds, clinical and research experience, organizational affiliation, and sensitivity to such issues as broad representation from organizations served by the HREB.

3.1 Selection of HREB Members

- 3.1.1 In selection of HREB members, equal consideration shall be given to qualified persons of both sexes. No appointment shall be made solely on the basis of sex;
- 3.1.2 The HREB will make every effort to include cultural and ethnic minorities to represent the population from which research participants are recruited, within the scope of available expertise needed to conduct its functions;

- 3.1.3 The HREB membership will not consist entirely of members of one profession;
- 3.1.4 HREB members will be selected based on the needs of the HREB as outlined below and per applicable regulations, guidelines and standards.
- 3.2 Composition of the HREB
- 3.2.1 The membership of the HREB will be in compliance with the Food and Drugs Act and applicable Regulations, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;
- 3.2.2 The HREB Chair or designee monitors the HREB membership composition for appropriate membership in relation to the nature and volume of research submissions;
- 3.2.3 The HREB will include at least five members represented by the following categories:
- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the HREB (research involving human participants or the use of human tissue),
 - At least one member who is primarily experienced in non-scientific disciplines
 - At least one member who is knowledgeable in ethics,
 - At least one member who is knowledgeable in the relevant law, and
 - At least one community member who has no affiliation with the organization or the sponsor, and who is not part of the immediate family of a person who is affiliated with the organization;
- 3.2.4 A member may not fulfill more than two representative capacities or disciplines;
- 3.2.5 Members will include men and women, a majority of whom are Canadian citizens or permanent residents, and who collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed research;
- 3.2.6 Membership, when required, should include at least one member who has expertise in complementary or alternative care or pediatric health research;
- 3.2.7 At least one member, when possible, who is from an identifiable Aboriginal community or Native center, when the HREB reviews research that recruits participants from that community;
- 3.2.8 Additional membership as required by applicable legislation or guidelines.
- 3.3 Alternate Members
- 3.3.1 The HREB Chair or designee may ask an alternate HREB member to attend an HREB meeting to draw on his/her expertise in an area that may

be relevant to that meeting's deliberations, or to establish a quorum for that meeting in the absence of the regular HREB member;

3.3.2 Only alternate HREB members of comparable qualifications may substitute for an HREB member (a non-scientific member may not substitute for a scientific member);

3.3.3 The minutes shall document when an alternate HREB member replaces a primary HREB member.

3.4 HREB Chair

3.4.1 Whenever possible and practicable, the HREB Chair will be selected from experienced HREB members who have expressed interest in becoming the HREB Chair and who are familiar with the applicable regulations and guidance documents;

3.4.2 The HREB Office Personnel updates the HREB membership roster to reflect this change.

3.5 Ad Hoc Advisors

3.5.1 At his/her discretion, the HREB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the HREB;

3.5.2 The ad hoc advisor may be asked to participate in the HREB meeting to lend his/her expertise to the discussions;

3.5.3 All ad hoc advisors shall sign a *Confidentiality of Information and Conflict of Interest Agreement*;

3.5.4 The ad hoc advisor may not contribute directly to the HREB's decision and their presence or absence shall not be used in establishing a quorum;

3.5.5 Documentation of key information provided by the ad hoc advisor shall be summarized in the HREB minutes and if available, the written report shall be placed in the HREB files.

3.6 Observers at HREB Meetings

3.6.1 The HREB may allow observers to attend its meetings;

3.6.2 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the HREB conflict of interest and confidentiality policies;

3.6.3 Where the HREB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion;

3.6.4 Observers shall not participate when the HREB discusses its decision, reaches consensus or votes on the application;

3.6.5 The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

4.0 REFERENCES

See References.

5.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 201	November 14, 2019	Original version