	RESEARCH ETHICS BOARD **STANDARD OPERATING PROCEDURES**	
	SOP Number	201
	Composition of the REB	
	Date of Issue **Date of Revision**	2010 05 12 2017 06 09 2018 03 30 2022 07 13

Purpose: This standard operating procedure (SOP) describes the membership composition requirements of the Research Ethics Board (REB).

Directive: Fraser Health Policy "The Ethical Conduct of Research and Other Studies Involving Human Participants"

References: 2019 10 08 CAREB SOP 201.003, Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans

Responsibility: All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

Procedure

Individual members of an REB 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 REB, the REB 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 consideration 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 REB.

1.0 Selection of REB Members

1.1 In the selection of REB members, equal consideration shall be given to qualified persons of all sexes and genders. No appointment shall be made solely on the basis of sex or gender;

1.2 The REB will make every effort to include cultural and ethnic minorities to represent the population cared for by the Fraser Health Authority, within the scope of available expertise needed to conduct its functions;

1.3 The REB membership will not consist entirely of members of one profession;

1.4 REB members will be selected based on the needs of the REB as outlined below and per applicable regulations, guidelines and standards.

2.0 Composition of the FHREB

2.1 The membership of the REB will be in compliance with Health Canada (Division 5, Part C.05.001 of the Food and Drug Act) and applicable Regulations, Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans 2 (TCPS 2), The International Council on Harmonization Good Clinical Practices, Food and Drug Administration Code of Federal Regulations (US FDA CFR 56.107) and the US Office for Human Research Protections (OHRP) (46.107);

2.2 The REB Chairs or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research ethics submissions;

2.3 The REB will include at least five members represented by the following categories:

- at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body),
- at least one member who is primarily experienced in non-scientific disciplines,
- at least one member who is knowledgeable in ethics,
- at least one community member who has no direct affiliation to Fraser Health, and who is not part of the immediate family of a person who is affiliated with Fraser Health,
- at least one member who is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). Where possible, this role should be shared by two members on an alternating basis;

2.4 A member may not fulfill more than two representative capacities or disciplines;

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 expertise to review and evaluate the science, medical aspects and ethics of the proposed research;

2.6 A member knowledgeable in complementary or alternative health care shall be appointed to the REB on an ad hoc basis for the consideration of specific projects involving the investigation of natural health products alone and will not otherwise participate in the review of non-natural health product trials;

2.7 For pediatric health research studies, the REB may seek consultation with an external reviewer knowledgeable in pediatric health research, as applicable;

2.8 For the review of research on topics related to Indigenous peoples or affecting Indigenous communities, the REB may seek consultation with an external reviewer with relevant and competent knowledge and expertise in Indigenous cultures;

2.9 The composition of the REB also meets the regulatory requirements for research conducted in Canada that is sponsored by the US National Institutes of Health, Department of Health and Human Services or by other American government departments/agencies (e.g. US Army);

2.10 Additional membership as required by applicable legislation or guidelines.

3.0 Alternate Members

3.1 The REB Chair or designee may appoint an alternate REB member to attend REB meetings to draw on their expertise in an area that may be relevant to that meeting's deliberation, or establish quorum in the absence of the regular REB member;

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

3.3 The minutes shall document when an alternate REB member replaces a primary member.

4.0 REB Chair

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

4.2 The REB Office Personnel updates the REB membership roster and OHRP registration, if applicable, to reflect this change.

5.0 Ad Hoc Advisors

5.1 At their discretion, the REB 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 to the REB;

5.2 The ad hoc advisor may be asked to participate in the REB meeting to lend their expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available to the REB;

5.3 The ad hoc advisor may be asked to participate in the REB meeting to lend their expertise to the discussions;

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

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

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

6.0 Observers at REB Meetings

6.1 The REB may allow observers to attend its meetings;

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

6.3 Where the REB 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;

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

6.5 The minutes will reflect the presence of any observers as well as their expertise and contributions, when applicable.