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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 201

TITLE	**201: Composition of the Board**
SCOPE	The activities of the Research Ethics Boards operating under the direct authority of the University of British Columbia
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011, April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to state the requirements for the composition of the REBs responsible for reviewing research conducted under the auspices of the University of British Columbia.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

The membership of the REB will be sufficient to ensure the appropriate expertise, multi-discipline backgrounds, and independence required for competent research ethics review[1]. The membership of the UBC Research Ethics Boards will include individuals with varying backgrounds and appropriate professional competence to review the diverse types of protocols that are received[2]. The Board members will be qualified to ascertain the acceptability of the research in terms of institutional commitments and regulations, all applicable laws, and standards of professional conduct and practice 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. The membership will be diverse so selection will include consideration of race, sex, cultural backgrounds, research, healthcare or professional experience, organizational affiliation, and sensitivity to such issues as community attitudes to assess the research submitted for review.

3.1 Selection of REB Members

3.1.1 In selection of REB 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 REB 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 REB membership will not consist entirely of members of one profession;

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

3.2 Composition of the REB

Research Ethics Board members are nominated by the Deans or Departments Heads, or by the REB Chairs, REB Managers, or the Director, Office of Research Ethics. Members are approved by the REB Chair, Institutional Research leadership where applicable and appointed by the Vice-President, Research & Innovation.

3.2.1 The membership of the REB will be in compliance with the *Food and Drugs Act* and applicable *Regulations*, the Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans, 2 (2014), the International Conference on Harmonisation Good Clinical Practice Guidelines, Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013), and the U.S. Code of Federal Regulations;

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

3.2.3 As the size of the REB increases, every effort will be made to ensure that the number of community representatives will also increase.

3.2.4 The REBs shall consist of at least five (5) members, including both men and women[3]. The REB Members will be selected according to the following criteria:

- 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 is knowledgeable in ethics;
- at least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for all UBC-affiliated REBs; and
- at least one community member who has no affiliation with the institution or the sponsor, and who is not part of the immediate family of a person who is affiliated with the organization;

3.2.5 A member may not fulfill more than one representative capacity or discipline during the discussion and review of an application while attending the convened REB meeting;

3.2.6 Where applicable, the membership shall also include at least one member who has expertise in natural health products[4];

3.2.7 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;

3.2.8 Membership, when required, should include at least one member who has expertise in complementary or alternative care or pediatric health research;

3.2.9 At least one member, when possible, who is from an identifiable Aboriginal community or Native center, when the REB reviews research that recruits participants from that community;

3.2.10 Additional membership as required by applicable legislation or guidelines.

3.2.11 The REB Office Personnel updates the REB membership roster and OHRP registration, if applicable, to reflect changes to REB membership.

3.3 Regular REB Members

3.3.1 The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the REB[5]. The majority of regular members must be Canadian citizens or permanent residents under the Immigration and Refugee Protection Act;

3.3.2 Regular members shall serve an initial one year term, at which point the REB member may renew his or her appointment for a term of 3 years on the mutual agreement of the REB member, REB Chair, Director, Research Ethics and the Vice-President, Research. At the end of the 3 year term, an additional 3 year renewal period may be granted upon mutual agreement of the REB member, REB Chair, Director Research Ethics and the Vice-President, Research & Innovation[6];

3.3.3 Community member(s):
The community member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the Institution will draw its research participants. The community member(s) should not be vulnerable to intimidation by the professionals on the REB;

3.3.4 Scientific members:
The REB will include physicians and experts in physical, behavioural, social or biological science. When an REB encounters studies involving science beyond the expertise of the members, the REB may use ad hoc reviewers to assist in the review.

3.4 Alternate Members

Alternate members are qualified voting members who serve as designated alternates for regular members, but they are not expected to attend each meeting.

3.4.1 The REB Chair or his/her designate, or a designated member of the REB staff, may ask an alternate member to attend a meeting in order to draw on his/her expertise in an area that may be relevant to that meeting's deliberations and/or to establish a quorum for that meeting in the absence of the designated regular member;

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

3.4.3 For studies which are required to adhere to U.S. regulations, the minutes shall document when an alternate REB member replaces a primary REB member.

3.5 REB Chair

3.5.1 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;

3.5.2 The Chair of the REB will be appointed by the Vice-President, Research & Innovation and shall serve, initially, for a term of one year, renewable at the discretion of the Vice-President, Research & Innovation and with the agreement of the Chair, for an additional two years. At the expiry of the initial three year term, the appointment may be renewable for additional term(s) with the agreement of the Chair and at the discretion of the Vice-President, Research & Innovation[7].

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

3.6 Ad Hoc Advisors

3.6.1 At his/her 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 on the REB[8];

3.6.2 Consultation with an ad hoc advisor shall not alter the composition and representation of the REB as outlined in section 3.2 above;

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

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

3.6.5 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;

3.6.6 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 relevant REB files on the RISe online database.

3.7 Observers at REB Meetings

3.7.1 The REB may allow observers to attend its meetings;

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

3.7.3 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;

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

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

4.0 REFERENCES

1. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations* Part 46 (45 CFR 46.107): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.107

2. *U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations* Part 56 (21 CFR 56.107): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107

3. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 6.4: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.4
UBC Policy 89, Section 2.2.3:
https://www.universitycounsel.ubc.ca/files/2012/06/policy89.pdf

4. *Health Canada Natural and Non-prescription Health Products Directorate, Part 4:*
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/clinical-trials.html#a4.0

5. *Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects:*
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_documents-eng.php

6. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 6.6:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1a

7. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 6.6:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1a

8. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 6.5:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.5
ICH GCP International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Section 3.2.6:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php#a3.2