



TITLE	203: Duties of REB Members
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; March 2010; April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the management and oversight of the REB to ensure continuity of membership and the expertise to meet guidelines, regulations and institutional mandates.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

Each REB member’s primary duty is the protection of the rights and welfare of the individual human beings that are serving as the participants of research. The reviewer must understand that he or she is not serving on the Board to expedite the approval of research, but to serve as a link between the investigator and the research participants. In order to fulfill his or her duties, REB members are expected to be knowledgeable of the guidelines and regulations governing human participants’ protection and research ethics, and the policies of the University of British

Columbia, germane to human participant protection. The REB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The REBs are appointed as University Committees. As such, the REB members serve the University of British Columbia as a whole, rather than a particular school, department or hospital. Therefore, members must not allow their own interests or that of their departments or schools to supersede their duty to protect the rights and welfare of research participants.

3.1 Attendance

3.1.1 Regular REB members are expected to attend the regularly scheduled REB meetings. REB Members may be asked to step down if they regularly miss scheduled REB meetings;

3.1.2 REB members must notify the REB office if they will be absent for an REB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place;

3.1.3 Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member;

3.1.4 REB members are expected to be available for the entire REB meeting, not just the segments when the studies for which they have been assigned as reviewers will be discussed.

3.2 Terms of Duty

3.2.1 REB members are expected to commit to a minimum 1 year term and during that time, fulfill certain duties. These duties will be described prior to appointment and each REB member will be aware of their responsibilities as an REB member prior to accepting appointment to the REB.

3.3 Duties

3.3.1 All members are expected to review the relevant materials submitted for each item under review or consideration by the REB, to be familiar with them, to submit comments in advance of the REB meeting via the RISE online database, and be prepared to discuss each agenda item and provide input at the convened REB meeting;

- 3.3.2** Each REB member is expected to fulfill specific duties based on the role as outlined below. More than one REB member may fulfill each role, though individuals who can fulfill more than one role should not act in a dual capacity during the discussion and review of an application while attending the convened REB meeting;
- 3.3.3 Scientific members:** Scientific members are expected to contribute to the evaluation of a study on its ethical, scientific, and statistical merits. These members should also be able to advise the Board if additional expertise in a scientific or non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants;
- 3.3.4 Non-scientific members:** Non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or provincial requirements regarding consent. Non-scientific members should advise the Board if additional expertise in a non-scientific area is required to assess if the protocol adequately, protects the rights and welfare of participants, and to comment on the comprehension of the consent document;
- 3.3.5 Community member(s):** Community members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective¹.
The role of community members on REBs during the ethics review process is unique and at arm's length from the institution. Their primary role is to reflect the perspective of the participant. This is particularly important when participants are vulnerable and/or risks to participants are high.
- 3.3.6 Member(s) knowledgeable in relevant law:** Members knowledgeable in relevant law are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB;
- 3.3.7 Member(s) knowledgeable in ethics:** Members knowledgeable in ethics are expected to guide the REB in identifying and addressing ethics issues related to the research under review;
- 3.3.8 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 REB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the REB meeting to lend his/her expertise to the discussions;
- 3.3.9 REB Chair:** The role of the REB Chair is to provide overall leadership for the REB:

- The REB Chair and the Director, Office of Research Ethics, may recommend to the Vice-President, Research & Innovation the appointment of one or more Co-Chairs to assist or act on behalf of the chairperson in particular REB matters and at REB meetings, either as a general procedure, or on a case-by-case basis. The REB Chair also may delegate any of his/her responsibilities, as appropriate, to other qualified individual(s),
- Any responsibilities that are designated by the REB Chair must be documented,
- The REB Chair facilitates the review process, based on UBC and its affiliated hospital's institutional policies and procedures and the TCPS2². The REB Chair should monitor the REB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to Researchers in writing in a timely fashion,
- The REB Chair or designee ensures that all REB members are free to participate in discussions during the REB meetings. The REB Chair or designee can ask an additional expert REB member to attend an REB meeting in order to draw his/her expertise in an area that may be relevant to the REB's review and deliberations of the research,
- The REB Chair, in consultation with REB Office Personnel, the Co-Chair, or other voting members of the REB, determines level of risk and the appropriateness of an application for REB Review for delegated or full REB review. The REB Chair may delegate this function to another REB member, or to REB Office Personnel as appropriate;
- The REB Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review,
- The REB Chair or designee signs off on all REB decisions with an electronic signature via the RISE online database,
- For REB approval of clinical trials approved by Health Canada, the REB approval letter is electronically signed by the REB Chair or designee via the RISE online database. The REB Certificate of Approval generated on RISE contains required elements for the REB attestation;
- The REB Chair is empowered to suspend the conduct of a research project or clinical trial deemed to place individuals at unacceptable risk pending discussion by the Full Board. The REB Chair is also empowered to suspend the conduct of a study if he/she determines that a Researcher is not following the REB's policies or procedures,
- The Director, Office of Research Ethics (ORE) will provide a collective report on the activities of the UBC-affiliated REBs to the Vice-President, Research & Innovation on an annual basis. The Manager of each individual REB will provide a summary of their respective REB's activities to the Director, ORE,
- The REB Chair, in conjunction with the Director, Office of Research Ethics, the Managers of the Research Ethics Boards, and such other institutional representatives as are appropriate, is responsible for ensuring that REB members are informed of all new legislation, regulations and guidelines which bear on REB review,

- The REB chair, in conjunction with the REB Office Personnel, shall assess the educational and training needs of the REB members and Office Personnel, and will address any gaps identified,
- The REB Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards,
- In addition to the above responsibilities (germane to the member's capacity), this person chairs meetings of the REB;

3.3.10 REB Co-Chair: The REB Co-Chair or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so:

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

3.4 Primary and Secondary Reviewers

3.4.1 Primary and Secondary Reviewers: In addition to the duties described in section 3.2.1, each regular (or alternate) member will be expected to act as a primary and/or secondary reviewer for assigned studies at convened meetings. The primary and secondary reviewers present their findings resulting from detailed review of all of the application materials and provide an assessment of the soundness and safety of the protocol and recommend specific actions to the Board. They may lead the discussion of the study by the convened REB. The primary and secondary reviewers are required to review the entire submission, be familiar with it, and be prepared to conduct an in-depth review of all materials;

3.4.2 Primary and secondary reviewers are provided with a protocol review checklist for their reference when reviewing all new studies assigned to Full Board. Reviewers are to post their comments, discussion points and provisos via the RISE online database. The elements within the checklist will be discussed during the Full Board meeting and posted to the study with the relevant minutes on the RISE online database. The primary and secondary reviewers are expected to contact the REB Chair or Manager in advance of the convened meeting if further clarification of the investigator is required prior to review of the submission.

3.5 Training and Education

3.5.1 REB members are expected to follow training and education procedures as outlined by each UBC-affiliated REB office.

3.6 Conflict of Interest

3.6.1 REB members are expected to follow conflict of interest procedures.

4.0 REFERENCES

1. *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
2. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 6.8:
<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1a>