

SOP Title	UOIT REB Administration
Number.Version	REB SOP 104 Membership, Composition, Roles and Responsibilities
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1.0 PURPOSE

This standard operating procedure describes the membership, composition, roles, and responsibilities of the UOIT Research Ethics Board (REB).

2.0 GENERAL PROCEDURE STATEMENT

Research Ethics Board membership (e.g., appointment, terms) must be adequately managed to continue to meet the latest TCPS composition requirements and to maintain the appropriate diversity, experience, and expertise for the type and volume of research reviewed.

3.0 RESPONSIBILITY

This SOP applies to all UOIT REB members including the Chair, Vice-Chair, Research Ethics Coordinator, and all Administrative Personnel or designate(s).

The President, through the Office of Research Services and the REB Chair/Vice-Chair, is responsible for monitoring and managing the UOIT REB membership composition.

4.0 SPECIFIC PROCEDURES

4.1 Composition

The REB shall be comprised of at least ten members, including the following:

- a) Chair;
- b) Vice-Chair;
- c) At least two (2) members with broad expertise in relevant research disciplines covered by the REB;
- d) At least one (1) member who is knowledgeable in ethics;
- e) At least one (1) member who is knowledgeable in relevant law when biomedical research is being reviewed;
- f) At least one (1) community member who has no formal affiliation with the institution;
- g) Research Ethics Coordinator who will be an ex-officio non-voting member.

In addition, it is desirable (but not mandatory) to have 1 “member-at-large” who does not typically conduct research on human participants.

4.2 Definitions and Roles

- A. **Academic Members:** The backgrounds of the Academic members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the REB.
- B. **Community Member(s):** The community member(s), who can be either scientific or non-scientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective.
- C. **Ad Hoc Reviewers (Non-voting):** The chair may invite individuals with competence in special areas or knowledge to assist in the initial or continuing review of issues that require expertise beyond or in addition to that available on REB. These individuals are non-voting members and their presence or absence will not be used in establishing a quorum for an REB meeting.

5.0 APPOINTMENTS AND RE-APPOINTMENTS OF REB MEMBERS

5.1 Terms of Duty

Academic and Community members are expected to commit to 3-year terms, after which time they may be asked if they wish to renew. The Chair and Vice-Chair are expected to commit to 2-year terms, after which time their terms may be renewed. REB members will be well informed and aware of their responsibilities prior to accepting appointment to the REB.

Where research ethics administration staff have the requisite experience, expertise, and knowledge comparable to what is expected of REB members, institutions may appoint them (based on the written policies and procedures of the institution) to serve as non-voting members on the REB (TCPS2, Article 6.4).

5.2 Appointment of Members

The REB will appoint and re-appoint its members based on nominations from current members, the Office of Research Services, or from the broader community.

A community member or faculty member may self-nominate by sending a letter to the Chair or the Research Ethics Coordinator.

The Office of Research Services will approach a faculty member's Dean for endorsement of a nomination.

5.2.1

All nominations (whereby the nominee has expressed interest) and supporting documentation will be brought to the REB for discussion and vote. Potential members may choose to provide documentation of their experience (e.g., their resume). Nominees may not be present during the discussion or decision.

5.2.2

Once appointment/re-appointment is confirmed, the Office of Research Services will draft an appointment letter that will be forwarded to the President for review and approval.

5.2.3

Nominees appointed to serve on the REB will be asked to sign a letter of appointment.

5.2.4

Once an appointment letter is executed, copies will be sent to the Office of Research Services, the Member, and the Member's dean (if applicable).

5.3 Assignment of Roles

The REB will appoint the Chair and Vice-Chair from its current academic membership. A faculty member may self-nominate by sending a letter to the Chair or the Research Ethics Coordinator.

The Office of Research Services will approach a faculty member's Dean for endorsement of a nomination.

5.3.1

All nominations (whereby the nominee has expressed interest) and supporting documentation will be brought to the REB for discussion and vote. Nominees may not be present during the discussion or decision.

6.0 REB MEMBER ROLES AND RESPONSIBILITIES

6.1 Chair Responsibilities

The role of the REB Chair is to provide overall leadership for the REB and to facilitate the REB review process, based on institutional policies and procedures. The Chair should monitor the REB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible (TCPS2 Article 6.8).

The Chair shall act as a spokesperson for the REB and shall preside over Research Ethics Board meetings. In the absence of the Chair, the Vice-Chair will fulfill these functions. To this end, the Chair shall:

- a. Guide the REB through each successive agenda item;
- b. Ask REB members to put forward their ethical concerns for discussion;
- c. Moderate discussions at REB meetings and keep REB on task (in keeping with the TCPS and UOIT's REB Policy and Procedures). At the end of each review, the Chair will postulate the REB's position for vote based on the REB's recommendations. Possible decision outcomes are: Approved, Clarifications Required, Deferred (Major Clarifications, Re-submission), Rejected.
- d. Review, provide feedback, and approve clarification letters;
- e. Have the authority to sign all REB decision letters unless otherwise delegated;
- f. Be responsible for communicating directly with the applicant if an application is rejected;
- g. Review applicants' responses to ensure that they meet the requirements of the REB, and as applicable, are congruent with the latest TCPS and UOIT's REB Policy and procedures;
- h. Address, in a timely fashion, communications from applicants who do not understand, do not agree with, or cannot conform to the REB's decisions, policies, and procedures. The Chair may resolve these problems or refer them to the full REB as necessary;
- i. Investigate matters relating to non-compliance and take appropriate action as per UOIT Policy and procedures. The REB may also be consulted during this process.

- j. The Chair shall be responsible for assuming the duties of the Vice-Chair (Section 6.2), in circumstances where the Vice-Chair is unable to fulfill his or her duties. Some examples are situations involving conflict of interest, vacation, etc.
- k. Attend meetings representing the REB as required.

6.2 Vice-Chair Responsibilities

The role of the REB Vice-Chair is to provide leadership for the REB and to facilitate the REB review process, based on institutional policies and procedures.

- a. The Vice-Chair will be responsible for providing a summary of decisions, clarifications, and discussion items raised during the REB meeting.
- b. The Vice-Chair shall review all change requests and renewals, providing comments and clarifications as necessary for all previously approved applications. If the change request is significant, the Vice-Chair may suggest that the applicant fill out a new application for review.
- c. The Vice-Chair will be responsible for issuing approval of renewal requests and change requests, unless otherwise delegated. If an approval is not warranted, the matter will be brought forth to the Chair who will confer with the REB in determining a course of action.
- d. The Vice-Chair shall be responsible for assuming the duties of the Chair (Section 6.1), in circumstances where the Chair is unable to fulfill his or her duties. Some examples are situations involving conflict of interest, vacation, etc.
- e. Attend meetings representing the REB as required.

6.3 General Members (Including Chair, Vice-Chair, Academic Members, and Community Members)

The role of the REB members is to provide timely and effective review of REB applications that deal with human subjects ensuring that the rights and welfare of participants are protected.

- a. All Members of the REB are responsible for understanding ethical principles with respect to human research ethics at UOIT, and at the provincial and national levels (if applicable). Members are also responsible for educating themselves with other guidelines where appropriate. Each new member will be required to provide evidence of completion of the latest TCPS tutorial within one month of appointment.
- b. Members of the REB are expected to produce a thorough review in accordance with the latest TCPS and UOIT REB Policy and Procedures. Members may propose an alternative deadline if advance notice is given.
- c. Members may decline a review only due to conflict of interest (refer to Conflict of Interest SOP 106) or extenuating circumstances if advance notice is given.
- d. Members are expected to respond to the initial request for review within two (2) business days. Initial reviews should be completed within ten (10) business days, however, the Member has the right to request additional days to complete the review during peak submission periods.
- e. Members are expected to attend regularly scheduled meetings unless precluded by professional responsibilities, religious observances, personal emergencies or scheduled vacation. If members are unable to attend, they are expected to respond to meeting requests and to notify the Research Ethics Coordinator as soon as possible by email or voicemail.
- f. In exceptional cases, where advance notice is given, virtual attendance or communication from member(s) via the use of technology (e.g., phone, Skype) would be acceptable for members who cannot attend the meeting in person.

7.0 REMOVAL OF REB MEMBERS

REB members who consistently are unable to fulfill the above responsibilities may have their appointment reviewed according to the following procedure:

- a. The member will discuss his/her performance with Chair;
- b. The member will be given an opportunity to demonstrate satisfactory performance over the next three months;
- c. If the Chair determines that no improvement is seen, the Chair shall bring this forward to the full REB for discussion. The REB will be asked to decide if the member should remain on or if his/her appointment should be rescinded.
- d. If the member's appointment is rescinded and the member wishes to appeal this decision, the member may appeal to the REB Appeal Subcommittee (consisting of Vice-Chair and 2 randomly selected general members) for a full review of conduct. The member in question will be asked to leave during any deliberations.

REB members who have failed to comply with Standard Operating Procedure 106 - *Disclosure and Documentation of Conflicts of Interest* may have their appointments rescinded in keeping with this standard operating procedure.

8.0 LEAVE OF ABSENCE OF REB MEMBERS

Members who plan to go on a temporary leave of absence (e.g., sabbatical, medical leave or extended vacation), must inform the REB Chair or designate and Research Ethics Coordinator as soon as possible in writing. During a leave of absence, the member will be considered a continuing inactive member of the board until they return to the board or expiration of their term or they resign.

9.0 RESIGNATION OF REB MEMBERS

Members who plan to resign from must inform the REB Chair or designate and Research Ethics Coordinator as soon as possible in writing. Individuals listed in the appointment letter will be notified by the Research Ethics Coordinator. Faculty Members who resign from their faculty position are deemed to have resigned simultaneously from the REB.

10.0 EXPIRATION OF TERM

Upon the expiration of a term, a thank you letter will be sent to the member on behalf of the REB and the President.