

SOP Title:	Composition of the Research Ethics Board		
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1.0 PURPOSE

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

2.0 POLICY STATEMENT

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 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 REB.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

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

The REB Chair or designee is responsible for ensuring that the composition of the REB meets the applicable regulatory requirements.

5.0 PROCEDURES

5.1 Selection of REB Members

- 5.1.1 In selection of REB members, equal consideration shall be given to qualified persons of all sexes. No appointment shall be made solely on the basis of sex or gender;
- 5.1.2 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;
- 5.1.3 The REB membership will not consist entirely of members of one profession;
- 5.1.4 REB members will be selected based on the needs of the REB as outlined below and per applicable regulations, guidelines and standards.

5.2 Composition of the REB

- 5.2.1 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, the International Conference on Harmonisation Good Clinical Practice Guidelines, the Ontario Personal Health Information Protection Act (PHIPA), Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013), the US Office for Human Research Protections (OHRP), and the US Code of Federal Regulations;
- 5.2.2 The REB Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions;
- 5.2.3 The REB 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 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 member who is knowledgeable in the relevant law. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research;
 - 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;
 - At least one member knowledgeable in considering privacy issues.
- 5.2.4 A member may not fulfill more than two representative capacities or disciplines.
- 5.2.5 Members will be of diverse genders, 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.
- 5.2.6 Membership, when required, should include at least one member who has expertise in complementary or alternative care or pediatric health research.
- 5.2.7 When the REB reviews research that recruits participants from Aboriginal or Native communities, at least one board member will identify as a member of that community, when possible.

- 5.2.8 Membership should consist of broad representation from across therapeutic areas and include physicians, nurses/health care professionals with clinical and/or research experience, community members, and members with expertise in research ethics, relevant law, privacy legislation and may consist of other related disciplines such as pharmacy, epidemiology, and biostatistics.
- 5.2.9 Additional membership as required by applicable legislation or guidelines.

5.3 Alternate Members

- 5.3.1 The REB Chair or designee may ask an alternate REB member to attend an REB 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 REB member;
- 5.3.2 Only alternate REB members of comparable qualifications may substitute for an REB member (a non-scientific member may not substitute for a scientific member);
- 5.3.3 The minutes shall document when an alternate REB member replaces a primary REB member.

5.4 REB Chair

- 5.4.1 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;
- 5.4.2 The REO Manager or designee updates the REB membership roster and OHRP registration, if applicable, to reflect this change.

5.5 Ad Hoc Advisors

- 5.5.1 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 on the REB;
- 5.5.2 The ad hoc advisor may be asked to participate in the REB meeting to lend their expertise to the discussions;
- 5.5.3 All ad hoc advisors shall sign a Confidentiality of Information and Conflict of Interest Agreement;
- 5.5.4 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;
- 5.5.5 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.

5.6 Observers at REB Meetings

- 5.6.1 The REB may allow observers to attend its meetings;
- 5.6.2 Observers will sign a Confidentiality of Information and Conflict of Interest Agreement agreeing to abide by the REB conflict of interest and confidentiality policies;
- 5.6.3 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;

- 5.6.4 Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application;
- 5.6.5 The minutes will reflect the presence of any observers as well as their expertise and contributions, when applicable.

6.0 REFERENCES

See References