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1 PURPOSE

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

2 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All designated REB staff 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.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

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.¹

To promote complete and adequate review of the type of research commonly reviewed by the REB, the REB must include appropriate diversity²; 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 sex, cultural background, clinical and research experience, organizational affiliation, and sensitivity to such issues as broad representation from organizations served by the REB.

5.1 Selection of REB Members

- 5.1.1 REB members will be selected based on the needs of the REB as outlined below and as per applicable regulations, guidelines and standards;
- 5.1.2 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;
- 5.1.3 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;

¹ *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "Modèle", s. 6.1; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.2.1.*

² *Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 4.*

5.1.4 The REB membership will not consist entirely of members of one profession.

5.2 Composition of the REB

5.2.1 The membership of the REB will be in compliance with applicable laws, regulations, and guidelines;

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 members³ 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 is a physician, dentist, or pharmacist and who is in good standing with the Council of Physicians, Dentists and Pharmacists (CPDP)⁴),
- At least one member who is primarily experienced in non-scientific disciplines,⁵
- At least one member who is knowledgeable in ethics,⁶
- At least one member with legal expertise, knowledgeable in laws relevant to the types of research being reviewed,⁷
- At least one community member or representative of an organization interested in the areas of research being reviewed who has no affiliation with the institution or the sponsor,⁸ and who is not part of the immediate family of a person who is affiliated with the institution;

5.2.4 A member may fulfill more than one representative capacity or discipline;

5.2.5 Members will include men and women,⁹ a majority of whom are Canadian citizens or permanent residents under the *Immigration and Refugee Protection Act*¹⁰;

³ *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec, Part I, vol. 35, 1998, hereafter "Avis", p. 1039; Food and Drug Regulations, C.R.C., c. 870, art. C.05.001, definition of Research Ethics Board; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, hereafter "PAM", p. 21; ICH GCP, s. 3.2.1 (a); Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 6.4.*

⁴ *Avis, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (i); PAM, p. 21; Modèle, s. 6.1; TCPS2, art. 6.4 (a).*

⁵ *Food and Drug Regulations, art. C.05.001 (b) (iv); ICH GCP, s. 3.2.1 (b); Modèle, s. 6.1.*

⁶ *Avis, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (ii); PAM, p. 21; Modèle, s. 6.1; TCPS2, art. 6.4 (b).*

⁷ *Avis, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (iii); PAM, p. 21; Modèle, s. 6.1; TCPS2, art. 6.4 (c).*

⁸ *Avis, p. 1039; Food and Drug Regulations, art. C.05.001 (b) (v); Modèle, s. 6.1; ICH GCP, s. 3.2.1 (c); TCPS2, art. 6.4 (d) and p. 74. N.B.: According to PAM, this person must use the services of the institution, p. 21.*

⁹ *Food and Drug Regulations, art. C.05.001 (b); Modèle, s. 6.1; TCPS2, art. 6.4.*

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

At least one member, when relevant, should be from an identifiable Indigenous community or center, when the REB reviews research that recruits participants from that community;

- 5.2.7 REB Support Staff will update the list of potential REB members as well as the U.S. Office for Human Research Protections (OHRP) register, if applicable, to reflect any change to the composition of the REB.

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 a meeting. The REB Chair or designee may also ask an alternate REB member to attend an REB meeting in the absence of the regular REB member;

- 5.3.2 Only alternate REB members of comparable knowledge, qualifications, and training may substitute for an REB member (a non-scientific member may not substitute for a scientific member).¹¹

5.4 REB Chair

- 5.4.1 Whenever possible, the REB Chair is an experienced REB member who is familiar with the applicable regulations and guidance documents;

- 5.4.2 To exercise his mandate, the REB Chair must first be appointed as an REB member.

5.5 Ad Hoc Advisors

- 5.5.1 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 REB¹²;

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

- 5.5.3 The ad hoc advisor shall not participate in REB deliberations and their presence or absence shall not be used in establishing a quorum;

- 5.5.4 The minutes will document the presence of ad hoc advisors, as well as their expertise and contributions, when applicable.

¹⁰ *Food and Drug Regulations*, art. C.05.001 (b).

¹¹ TCPS2, p. 82.

¹² *Avis*, p. 1039; ICH GCP, s. 3.2.6; PAM, p. 22; TDR, s. 4.6; *Modèle*, s. 6.8.

5.6 Observers at REB Meetings

- 5.6.1 The REB may allow observers to attend its meetings;
- 5.6.2 Administrators of the institution may not serve as observers at meetings where their presence might influence REB deliberations;
- 5.6.3 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the REB conflict of interest and confidentiality policies;
- 5.6.4 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;
- 5.6.5 Observers shall not participate in REB deliberations, consensus, or voting on the application;
- 5.6.6 The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|----------------|--------------------|
| REB-SOP 201.001 | 2020-03-20 | Original version |
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8 APPENDICES