
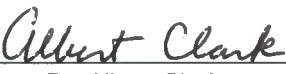



Section 200:	HSREB Organization
Title:	Composition of the HSREB
SOP Code:	201.001
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015 May 22
	Name: Jennifer Couture	Date
Approval Authority:		
Chair, HSREB		May 22, 2015
	Name: Dr. Albert Clark	Date
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015
	Name: Dr. Andrew Winterborn	Date

1.0 PURPOSE

This SOP describes the membership composition requirements of the Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

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

The HSREB Chair and the Director of Research Ethics Compliance are responsible for ensuring that the composition of the HSREB meets the applicable regulatory requirements.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Individual members of the HSREB 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 HSREB, the HSREB 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, institutional affiliation, and sensitivity to such issues as broad representation from the institutions served by the HSREB.

5.1 Selection of HSREB Members

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

5.2 Composition of the HSREB

- 5.2.1 The membership of the HSREB will be in compliance with the Food and Drugs Act and applicable Regulations, the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 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 US Code of Federal Regulations;
- 5.2.2 The HSREB Chair and the Director of Research Ethics Compliance monitor the HSREB membership composition for appropriate membership in relation to the nature and volume of research submissions;
- 5.2.3 The HSREB 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 HSREB (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,
- At least one community member who has no affiliation with Queen's University and affiliated teaching hospitals, and who is not part of the immediate family of a person who is affiliated with Queen's University or affiliated teaching hospitals,
- At least one member knowledgeable in considering privacy issues;

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

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

5.2.6 A member may not fulfill more than two representative capacities or disciplines;

5.2.7 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;

5.2.8 Queen's University or affiliated teaching hospital Senior Administrators may not serve as HSREB members;

5.2.9 Additional membership as required by applicable legislation or guidelines.

5.3 Alternate Members

5.3.1 The HSREB Chair or designee may ask alternate HSREB member(s) to attend HSREB meetings to draw on his/her expertise in an area that may be relevant to meeting's deliberations, or to establish a quorum for meeting(s) in the absence of regular HSREB member(s);

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

- 5.3.3 The minutes shall document when an alternate HSREB member replaces a primary HSREB member;
- 5.3.4 All alternative members shall sign a Confidentiality Agreement and Conflict of Interest Disclosure form.

5.4 HSREB Chair/Vice Chair

- 5.4.1 Whenever possible and practicable, the HSREB Chair and Vice Chair will be selected from experienced HSREB members who have expressed interest in becoming the HSREB Chair or Vice Chair and who are familiar with the applicable regulations and guidelines;
- 5.4.2 The HSREB Ethics Coordinator or designee updates the HSREB membership roster and OHRP registration, if applicable, to reflect this change.

5.5 Ad Hoc Advisors

- 5.5.1 At his/her discretion, the HSREB 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 HSREB;
- 5.5.2 The ad hoc advisor may be asked to participate in the HSREB meeting to lend his/her expertise to the discussions;
- 5.5.3 All ad hoc advisors shall sign a Confidentiality Agreement and Conflict of Interest Disclosure form;
- 5.5.4 The ad hoc advisor may not contribute directly to the HSREB'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 HSREB minutes and if available, the written report shall be placed in the HSREB files.

5.6 Observers at HSREB Meetings

- 5.6.1 The HSREB may allow observers to attend its meetings;
- 5.6.2 Observers will sign a Confidentiality Agreement and Conflict of Interest Disclosure form agreeing to abide by the HSREB conflict of interest and confidentiality policies;
- 5.6.3 Where the HSREB 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 HSREB 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 his/her expertise and contributions, when applicable.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Composition of the HSREB	v.201.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

