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| **TITLE** | **201: Composition of the HREB** |
| **SCOPE** | The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA) |
| **APPROVAL AUTHORITY** | Ethics Director |
| **EFFECTIVE DATE** | April 2021 |

## 1.0 PURPOSE

This standard operating procedure (SOP) describes the membership composition requirements of the HREB.

## 2.0 DEFINITIONS

See the Glossary of Terms.

## 3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

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

## 4.0 PROCEDURE

Members of the HREB must be qualified through training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles, as well as applicable legislation, regulations, guidelines and standards pertaining to human participant protection. The membership of the HREB will be in compliance with the HREA Act, as well as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS2 (2018).

To promote complete and adequate review of the type of research commonly submitted to the HREB, the HREB membership must include appropriate diversity of disciplines, fields of research and methodologies. HREB membership will include applicable professional expertise (including both scientific and non-scientific), and consideration will be given to equality and diversity in the selection of members.

## 4.1 Selection of HREB Members

**4.1.1** The HREB will make every effort to have a diverse membership to represent the population from which research participants are recruited, within the scope of available expertise needed to conduct its functions.

**4.1.3** The HREB membership will draw upon a range of relevant disciplines and professions.

**4.1.4** HREB members will be selected based on the composition needs of the HREB as outlined below, and per applicable legislation, regulations, guidelines and standards.

## 4.2 Composition of the HREB

**4.2.1** The membership of the HREB will be in compliance with the HREA Act and the TCPS2 (2018).

**4.2.2** The HREB Chairperson or designee will monitor the HREB membership composition for appropriate membership in relation to the nature and volume of research submissions.

**4.2.3** As the size of the HREB increases, every effort will be made to ensure that the number of community representatives will also increase.

**4.2.4** The HREB shall consist of at least five (5) members. The HREB members will be selected according to the following criteria:

- at least two members have expertise in relevant research disciplines, fields and methodologies covered by the HREB (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 is knowledgeable in ethics;
- at least one member is knowledgeable in the relevant law. This is mandatory for biomedical research and is advisable but not mandatory for other areas of research; and
- at least one community member to represent the general public.

**4.2.5** Each member will be formally appointed to fulfill the requirements of only one of the categories listed in 4.2.4. Where the size of the HREB exceeds the minimum requirements (5 members), additional members may fulfill more than one category.

**4.2.6** Membership will collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed research.

**4.2.7** Membership will include a member with relevant and competent knowledge and expertise in Indigenous cultures when regularly reviewing research on topics related to Indigenous peoples or affecting Indigenous communities.

**4.2.8** Membership will include an ad hoc advisor with relevant and competent knowledge and expertise in Indigenous cultures when not regularly reviewing research on topics related to Indigenous peoples or affecting Indigenous communities.

**4.2.9** Additional members will be appointed as required by applicable legislation or guidelines.

**4.2.10** REO Personnel will update the HREB membership roster and Office for Membership Protections (OHRP) registration, if applicable, to reflect changes to HREB membership.

## 4.3 HREB Chairperson

**4.3.1** The HREA shall appoint one of the members of the research ethics board as the Chairperson who shall oversee the work of the board.

**4.3.2** The HREB Chairperson will be selected from experienced HREB members who have expressed interest in becoming the HREB Chairperson and who are familiar with the applicable legislation, regulations and guidance documents.

**4.3.2** REO Personnel will update the HREB membership roster and OHRP registration, if applicable, to reflect changes to the HREB Chairperson membership.

## 4.4 Ad Hoc Advisors

**4.4.1** The HREB Chairperson 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 HREB.

**4.4.2** Consultation with an ad hoc advisor shall not alter the composition and representation of the HREB as outlined in section 3.2 above.

**4.4.3** The ad hoc advisor will be asked to participate in the HREB meeting to lend specific expertise to the discussions

**4.4.4** All ad hoc advisors will sign a *Confidentiality of Information and Conflict of Interest Agreement.*

**4.4.5** The ad hoc advisor will not contribute directly to the HREB's decision and their presence or absence shall not be used in establishing a quorum.

**4.4.6** Documentation of key information provided by the ad hoc advisor will be summarized in the HREB minutes and if available, a written report shall be placed in the relevant HREB files.

## 4.5 Observers at HREB Meetings

**4.5.1** The HREB may allow observers to attend its meetings.

**4.5.2** Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the HREB conflict of interest and confidentiality policies.

**4.5.3** Where the HREB 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.

**4.5.4** Observers shall not participate when the HREB discusses its decision, reaches consensus or votes on the application.

**4.5.5** The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

## 5.0 REFERENCES

*Health Research Ethics Authority Act: An Act to Establish a Health Research Ethics Authority For The Province* (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

*The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 6: tcps2-2018-en-interactive-final.pdf (ethics.gc.ca)

U.S. Department of Health and Human Services*Title 21 Code of Federal Regulations Part 56 (21 CFR 56.107:* eCFR :: 21 CFR 56.107 -- IRB membership.