

Procedures: Human Research Ethics**SOP 201 Composition of the REB****Associated Policy**

Human Research Ethics Policy AR-03

Procedure Holder

Associate Vice President Research

Executive Lead

Research Services

Approval Authority

President

Original Date

Replaces AR-03 procedures (May 2009, Oct. 2014)

Effective Date

July 2022

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the membership composition requirements of the Research Ethics Board (REB) responsible for reviewing research conducted under the auspices of Yukon University.

2.0 SCOPE

This SOP pertains to YukonU REB that reviews human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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 research participant protection.

To ensure thoughtful and proportional review it is important that the REB is composed of

members with expertise in the disciplines and methods that match with the research submitted to them. Representatives of the communities from which research participants are recruited must also sit on the REB as members.

5.1 Selection of REB Members

- 5.1.1** In selection of REB members, consideration shall be given to qualified persons all gender identifies. No appointment shall be made solely on the basis of gender identity;
- 5.1.2** The REB will make every effort to foster diversity as it reflects the population from which research participants are recruited, within the scope of available expertise needed to conduct its functions;
- 5.1.3** 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;
- 5.2.2** The REB Co-Chairs or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions;
- 5.2.3** As the size of the REB increases, every effort will be made to ensure that the number of community representatives will also increase.
- 5.2.4** 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 (,
 - 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, and
 - At least one community member who has no affiliation with the organization, and who is not part of the immediate family of a person who is affiliated with the organization;
- 5.2.5** Membership, should include a First Nations member with relevant and competent

knowledge and expertise in Indigenous cultures for the review of research on topics related to Indigenous peoples or affecting Indigenous communities. This may also include inclusion of additional indigenous representatives through membership as hoc advisors for specific reviews.

- 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 Additional membership as required by applicable legislation or guidelines.

5.3 Regular REB Members

- 5.3.1 The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the REB.
- 5.3.2 Regular members shall serve an initial two year term, and this may be renewed for 3 additional two year terms to a maximum of 8 years. At the end of the initial 2 year term, the renewal may be granted upon mutual agreement of the REB member, REB Co-Chairs, Research Ethics Coordinator and the Associate-Vice President Research.
- 5.3.3 The community member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the Institution will draw its research participants.
- 5.3.4 Scientific members on the REB will include experts in physical, behavioural, social or biological science. When the REB encounters studies involving science beyond the expertise of the members, the REB may use ad hoc reviewers to assist in the review

5.4 Alternate Members

Alternate members are qualified voting members who serve as designated alternates for regular members, but they are not expected to attend each meeting.

- 5.4.1 The REB Co-Chairs or designee may ask an alternate REB member to attend an REB meeting to draw on their 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;

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

5.4.3 The minutes shall document when an alternate REB member replaces a primary REB member.

5.5 REB Co-Chairs

5.5.1 Whenever possible and practicable, the REB Co-Chairs 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;

5.5.2 The REB Co-Chairs are appointed for a 1 year term by the REB members and can be renewed for additional terms.

5.5.3 The REB Office Personnel updates the REB membership roster to reflect this change.

5.6 Ad Hoc Advisors

5.6.1 At their discretion, the REB Co-Chairs 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;

5.6.2 The ad hoc advisor may be asked to participate in the REB meeting to lend their expertise to the discussions;

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

5.6.4 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;

5.6.5 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.

5.7 Observers at REB Meetings

5.7.1 The REB may allow observers to attend its meetings;

5.7.2 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement*

agreeing to abide by the REB conflict of interest and confidentiality policies;

- 5.7.3** 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;
- 5.7.4** Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application;
- 5.7.5** 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 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP201	July 2022	YukonU version adapted from N2/CAREB SOP 201.003 (October 8, 2019) and CAREB SOP 201.001 (Jan. 2021)