

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) |
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Procedures: Human Research Ethics

**SOP 202 Management of REB
Membership**

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|---------------------------|---|
| 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

This standard operating procedure (SOP) describes the management and oversight of the REB to ensure continuity of membership and expertise to meet guidelines, regulations and institutional requirements.

2.0 SCOPE

This SOP pertains to the 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 monitoring and managing the REB membership.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB membership (e.g., appointment, terms) and oversight of member appointments, REB related activities, communications, and other administrative requirements are the responsibility of the Research Ethics Coordinator. This must be adequately managed to continue to meet applicable regulatory composition requirements and to maintain the appropriate diversity, experience and expertise for the type and volume of research reviewed.

5.1 Appointments – Regular Members and Alternates

5.1.1 The Associate Vice-President Research (AVPR), REB Co-Chairs, Research Ethics Coordinator and REB shall recommend members for appointment to the REB.

Appointments to the REB are made by the University President. This process is outlined in

the YukonU REB terms of reference and kept on file in the Research Ethics Office. Members will be sought from the University and the Yukon.

5.1.2 Community members (meeting membership requirements) are solicited from the greater local community (Yukon);

5.1.3 Each REB member selected is approved by the REB Co-Chairs or designee or as determined by the YukonU REB terms of reference;

5.1.4 Candidates selected to serve on the REB will be provided a letter of appointment by the President and a *Confidentiality of Information and Conflict of Interest Agreement*.

5.1.5 REB members will be required to complete the TCPS2 CORE Tutorial within 6 months of appointment.

5.2 Appointments – REB Co-Chairs

5.2.1 The REB Co-Chairs are appointed as per YukonU's REB terms of reference;

5.2.2 The REB Co-Chairs will be asked to sign a *Confidentiality of Information and Conflict of Interest Agreement*.

5.3 Ad hoc Advisors

5.3.1 At their discretion, the REB Co-Chairs or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

5.4 Terms of Appointment

5.4.1 Each REB member will serve for a term of 2 years;

5.4.2 Renewal of an REB member may occur for 3 additional terms by mutual agreement of the REB member, the AVPR, REB Co-Chairs and Research Ethics Coordinator. Every effort will be made to ensure continuity and a core of knowledgeable and experienced members;

5.4.3 The Co-Chairs of the REB will be appointed by the REB members and shall serve, initially, for a term of one year, renewable at the discretion of the REB members with the agreement of the Chair, for an additional two years. At the expiry of the initial two year term, the appointment may be renewable for additional term(s) with the agreement of the Chair and REB;

5.4.4 Terms will be overlapping to preserve the experience level, expertise, and continuity of the REB.

5.5 Qualifications and Training of REB Members

5.5.1 Each member of the REB will follow qualification and training.

5.6 Resignations and Removals

5.6.1 An REB member may resign before the conclusion of their term upon provision of notice to the REB Co-Chairs or designee. The vacancy will be filled as quickly as possible;

5.6.2 An REB member may be asked to step down if they regularly miss scheduled Full Board meetings in their term;

5.6.3 The REB Co-Chairs or AVPR may otherwise remove an REB member at any time, if they are not fulfilling their designated REB duties in a timely, competent and ethical manner;

5.6.4 An REB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest or any other relevant behavior that could be perceived as compromising their ethical judgment;

5.6.5 Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve the level of experience and expertise and to ensure the continuity of the functions of the REB.

5.7 Compensation

5.7.1 Compensation and reimbursement of expenses for REB members will be according to YukonU policies.

5.7.2 Participation by University faculty or staff as an REB member is considered a component of their job responsibilities as established by their supervisors. Community members shall receive reimbursement for miscellaneous expenses upon request.

5.8 Liability and Coverage

5.8.1 All REB members are insured for their research ethics review-related work by the organization's insurance policy, subject to the terms and conditions of that policy.

5.8.2 Members are indemnified by the University as part of their REB membership in their capacity as agents of the University.

5.9 Documentation

- 5.9.1** The Research Ethics Office Personnel will maintain an updated electronic REB membership list;
- 5.9.2** The REB membership list is reviewed and updated as required, or with the initiation of new or conclusion/termination of existing terms;
- 5.9.3** The current REB membership list is available on the YukonU REB’s website. Archived REB membership lists are kept on file and available through the Research Ethics Office;
- 5.9.4** CVs, other supporting documents related to education and expertise, signed members’ letters of appointment and confidentiality agreements for all current and past REB members will be maintained in the Research Ethics office;
- 5.9.5** The REB Co-Chairs or designee will maintain the REB membership roster which includes:
 - Names of REB members
 - Earned degree(s),
 - Area(s) of expertise and organizational affiliation(s),
 - Role on the REB (e.g. faculty or staff member, community member, etc.), and indications of experience sufficient to describe each member’s chief anticipated contribution to REB deliberations (as applicable);
- 5.9.6** A detailed membership list will be kept in the Research Ethics office. This list will contain REB member contact information and additional information on areas of expertise for the purposes of communication and reviewer assignment. It will be kept confidential for access only by REB members and the Research Ethics Office Personnel;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|----------|----------------|--|
| SOP 202 | July 2022 | YukonU version adapted from N2/CAREB SOP 202.003 (October 8, 2019) and CAREB SOP202.001 (2021) |
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Procedures: Human Research Ethics**SOP 203 Duties of REB Members****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

This standard operating procedure (SOP) describes the duties of the members of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to the 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 are responsible for clearly articulating all required duties associated with membership to the REB to potential and current REB members.

REB members and alternates are responsible for fulfilling their duties as specified in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Each REB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill their duties, REB members are expected to be knowledgeable of the regulations and guidelines governing human participants' protection and research ethics, and policies of Yukon University germane to human research participant protection.

The REB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The REB is appointed as a University Committee. The REB members serve Yukon University as a whole, rather than a particular school or department. Therefore, members must not allow their own interests or that of their departments or schools to supersede their duty to protect the rights and welfare of research participants.

5.1 Attendance

- 5.1.1 Regular REB members are expected to attend the regularly scheduled REB meetings. REB Members may be asked to step down if they consistently miss a specified percentage of the scheduled REB meetings;
- 5.1.2 REB members must notify the Research Ethics office and/or REB Co-Chairs if they will be absent for an REB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in their place;
- 5.1.3 Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member, and/or a minimum of two REB meetings per year;
- 5.1.4 REB members are expected to be available for the entire REB meeting, not just the sections for which they may have been assigned as reviewers.

5.2 Terms of Duty

- 5.2.1 All members of the REB, including the REB Co-Chairs, will be appointed for a term as specified by Organizational policy.

5.3 Duties

- 5.3.1 All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, to be familiar with them, to submit comments in advance of the REB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;
- 5.3.2 Each REB member is expected to fulfill specific duties based on the role as outlined below. More than one REB member may fulfill each role;
- 5.3.3 **Members with relevant expertise in research disciplines, fields and methodologies:** are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits and standards of practice. These members should also advise

the REB if additional expertise is required to assess whether the research adequately protects the rights and welfare of human participants;

- 5.3.4 Community member(s)** are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective. The role of community members on REBs during the ethics review process is unique and at arm's length from the institution. Their primary role is to reflect the perspective of the participant. This is particularly important when participants are vulnerable and/or risks to participants are high.
- 5.3.5 Member(s) knowledgeable in relevant law** are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB;
- 5.3.6 Member(s) knowledgeable in ethics:** are expected to guide the REB in identifying and addressing ethics issues related to the research under review;
- 5.3.7 Ad hoc advisors** are individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the REB meeting to lend their expertise to the discussions;
- 5.3.8 REB Co-Chairs:** The REB Co-Chairs provides overall leadership to the REB:
- The REB Co-Chairs can delegate any of their responsibilities, as appropriate to other qualified individual(s),
 - Any responsibilities that are delegated by the REB Co-Chairs must be documented,
 - The REB Co-Chairs or designee facilitates the review process based on YukonU policies and procedures, SOPs, TCPS2 and other applicable regulations and guidelines. The REB Co-Chairs or designee determines the level of risk of each research project. The REB Co-Chairs or designee monitors the REB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
 - The REB Co-Chairs or designee ensures that all REB members are free to participate in discussions during the REB meetings. The REB Co-Chairs or designee can ask a substitute REB member to attend an REB meeting in order to draw their expertise in an area that may be relevant to the REB's review and deliberations of the research,
 - The REB Co-Chairs in consultation with Research Ethics Office, or other voting members of the REB, determines level of risk and the appropriateness of an application for REB Review for delegated or full review. The REB Co-Chairs may delegate this function to another REB member, or to the Research Ethics Coordinator as appropriate; or designee determines the appropriateness of a Full Board or delegated review of the research,

- The REB Co-Chairs or designee performs or delegates authority to (an) REB member(s) to perform a delegated review,
- The REB Co-Chairs or designee authorizes approval on all REB decisions confirmed through signature, electronic signature or official letter,
- The REB Co-Chairs or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the Full Board. The REB Co-Chairs or designee can suspend the conduct of the research if they determines that a Researcher is not adhering to the REB approved protocol or to the REB's policies and procedures,
- The Research Ethics Coordinator in consultation with the REB Co-Chairs will report on the activities of the REB to the YukonU President and AVPR organization on an annual basis,
- The REB Co-Chairs, in conjunction with the REB Office Coordinator and other organizational representatives as applicable, is responsible for ensuring that REB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the organization on policies and procedures related to research conduct and ethical requirements,
- The REB Co-Chairs, in conjunction with the Research Ethics Coordinator I, shall assess the educational and training needs of the REB members and Office Personnel, and will address any gaps identified.
- The REB Co-Chairs reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards.
- In addition to the above responsibilities (germane to the member's capacity), these individuals chair the meetings of the REB;

5.4 Primary and Secondary Reviewers

- 5.4.1** The REB may assign reviewers for studies reviewed at a full boarding or for delegated reviews.
- 5.4.2** For delegated review: assigned reviewers present their findings resulting from review of the REB submission materials and provide an assessment of these materials, recommending specific action to the REB Co-Chairs or designee.
- 5.4.3** For full board review: If reviewers are assigned to conduct in-depth reviews of their assigned submissions they may submit comments prior to the REB meeting. Reviewers may lead the discussion of the research project during the REB meeting.

5.5 Training and Education

- 5.5.1** REB members are expected to follow training and education procedures.

5.6 Conflict of Interest

- 5.6.1** REB members are expected to follow conflict of interest procedures.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|----------|----------------|---|
| SOP 203 | July 2022 | YukonU version adapted from N2/CAREB SOP 203.003 (October 8, 2019) and CAREB SOP 203.001 (2021) |
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Procedures: Human Research Ethics

**SOP 204 REB Office Personnel
Serving as REB Members**

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|---------------------------|---|
| 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

This standard operating procedure (SOP) describes the duties of REB Office Personnel serving as members of the Research Ethics Board (REB).

2.0 SCOPE

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

3.0 RESPONSIBILITIES

The REB Co-Chairs, the REB Office Personnel and Organizational officials are responsible for ensuring that the requirements of this SOP are met.

The REB Co-Chairs or designee are responsible for ensuring that the Research Ethics Office Personnel serving as members have the requirements for fulfilling this role and clearly articulating all required duties associated with their duties as members of the REB.

REB Office Personnel are responsible for understanding and fulfilling their roles as REB members and as REB staff and managing real, potential or perceived conflict of interest appropriately.

The Organizational Official(s) is responsible for ensuring that the REB Office Personnel serving as members of the REB understand and execute their functions appropriately.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Each REB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, REB members must be dedicated to meeting the REB's responsibilities to its research community and must be knowledgeable in the policies germane to human research participant protection. REB Office Personnel who serve as REB members must meet the same standard as other REB members (as per SOP 203).

5.1 Duties

- 5.1.1 REB Office Personnel who are designated as Board members may attend convened meetings and participate in discussions, but they shall not be counted in determining a quorum and they shall not participate in any votes;
- 5.1.2 REB Office Personnel that have been appointed to serve as REB members may perform delegated review in accordance with the delegated review procedure;
- 5.1.3 The assignment of these tasks to REB Office Personnel will be documented.

5.2 Appointment Criteria

- 5.2.1 REB Office Personnel serving as REB members shall have knowledge, experience, and training comparable to what is expected of REB members. The REB shall ensure that Office Personnel can fulfill their responsibilities as REB members independently.
- 5.2.2 To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

5.3 Training and Education

- 5.3.1 REB Office Personnel serving as REB members are expected to additionally follow training and education procedures for REB members in addition to any professional training requirements for organizational personnel.

5.4 Conflict of Interest

- 5.4.1 REB Office Personnel serving as REB members are additionally expected to follow conflict of interest procedures for REB members in addition to conflict of interest procedures for organizational personnel.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|----------|----------------|--|
| SOP 204 | July 2022 | YukonU version adapted from N2/CAREB SOP 204.003 (October 8, 2019) and CAREB SOP204.001 (2021) |
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Procedures: Human Research Ethics**SOP 301 Submission Requirements and Administrative Review**

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|---------------------------|---|
| 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

This standard operating procedure (SOP) describes the Research Ethics Board (REB) submission requirements and the document review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research, renewal applications for ongoing research and completion reports.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

The Research Ethics Coordinator is responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB members must rely on the documentation provided by investigators, or other parties for initial and continuing review. Therefore, the materials submitted must provide sufficient information about a study to conduct the review and to make the required determinations.

The REB is supported by administrative procedures that ensure that REB members not only have adequate time for the assessment of the proposed research, but that the materials they receive allow them to adequately assess whether the research submission meets the criteria for REB

approval.

The requirements for REB submissions are made available to all Researchers. The Research Ethics Coordinator is responsible for maintaining and disseminating this information to Researchers.

5.1 Submission Requirements for Initial Review

5.1.1 Submission requirements for initial review are outlined on the YukonU research ethics webpage. The required documents, checklists, format and submission procedures are outlined on the REB's website and on the appropriate REB submission forms and checklists such as, but not limited to:

- REB application form
 - Researcher application
 - Student application
 - Instructor application (course)
- Annual Renewal (Continuing Review) form,
- Course-based Project Renewal or Closure Form
- Final Reporting – Study Closure Form (Research Completion Form)
- Study Modification (Amendment) form,
- Adverse Event/Unexpected Problems form,
- Request to Release Funds Form
- Application for Exemption from REB review

5.1.2 All sections of the application form, including all required accompanying documentation, deemed necessary to the ethics review or for research ethics oversight must be completed.

5.1.3 The REB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight;

5.1.4 Investigators may be invited to an REB meeting during the discussion portion of their application to answer questions or explain details of the study. This will be arranged through the Research Ethics Coordinator

5.1.5 **Research Requirements:** The research question and methodology is written in sufficient detail to permit evaluation of the merit of the project. The research should include all of the required elements applicable to the research such as, but not limited to:

- Research rationale and objectives,
- Design and detailed description of methodology,

- Eligibility criteria, description of the population to be studied,
- Recruitment and consent process,
- Research interventions,
- Treatment allocation (if applicable),
- Primary and secondary outcome measures,
- Assessment of safety,
- Sample size justification,
- Data analysis,
- Data monitoring.

5.2 Submission Requirements for Continuing Review

During the term of the approval and the conduct of the research study, investigators must submit documentation to inform the REB about changes in the status of the study. Submission requirements are outlined in the Study Modification (Amendment) form. Revisions to documents such as consent forms must be tracked using track changes, highlighted, underlined or in bold text. The original application should also be updated and submitted to the REB with all changes highlighted on the form.

- 5.2.1** In some instances, investigators need to provide certain study related details including the submission of unanticipated adverse events or problems or notification that a study is on hold, closed or other necessary information. This includes any new information that might adversely affect the safety or well-being of the study participants or investigators.
- 5.2.2** During or after the review process, the REB may require additional information from the investigator. Investigators are required to complete a response to a request for information.
- 5.2.3** Annual Reports/Renewals - Prior to relevant REB approval expiration date, investigators requesting renewal of approve research project must submit a completed Annual Renewal Form or Final Reporting Form. Investigators are responsible for ensuring that they complete these requirements in a timely manner.

5.3 Document Review Procedures

- 5.3.1** Application deadlines will be 2 weeks prior to an REB meeting. Timelines are provided on the YukonU Research Ethics webpage.
- 5.3.2** A unique number is assigned to each submission at the time of the receipt of the

application. The Research Ethics Coordinator screens the submission for overall completeness;

- 5.3.3** If the REB or Research Ethics Coordinator determines that the submitted documents are not complete (e.g. missing documents or information), investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No substantively incomplete submission will be reviewed by the REB.

- 5.3.4** The Research Ethics Coordinator will follow up with the Principal Investigator or Principal Applicant to request the required information for inclusion with the submission;

- 5.3.5** Upon receipt of a complete submission, the REB and Research Ethics Coordinator identifies any outstanding items that will be required to issue approval, as applicable;

- 5.3.6** For submissions requiring Full Board review, the Research Ethics Coordinator posts the submission to the agenda of the next Full Board meeting.

- 5.3.7** For submissions reviewed via delegated review procedures, the Research Ethics Coordinator puts out a call for reviewers. The REB Co-Chairs in consultation with the Research Ethics Coordinator then determines a reviewer(s) and provides them with the submission for their review.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|----------|----------------|--|
| SOP 301 | July 2022 | YukonU version adapted from N2/CAREB SOP 301.003 (October 8, 2019) and CAREB SOP301.001 (2021) |
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Procedures: Human Research Ethics**SOP 302 REB Meeting Administration****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

This standard operating procedure (SOP) describes the required activities for the preparation, management and documentation of Full Board meetings of the Research Ethics Board (REB).

2.0 SCOPE

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

3.0 RESPONSIBILITIES

The REB Co-Chairs and the Research Ethics Coordinator are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Except when a delegated review procedure is used, the REB must review proposed research at Full Board meetings at which quorum is present and maintained.

The REB meeting agenda provides structure and order for meeting. Agenda items normally include review and approval of minutes from the previous meeting, declarations of conflict of interest, an overview of all items that have been reviewed and approved through the delegated review procedure, new information pertinent to REB review such as new policies or guidelines, a list of items that are pending review by the Full Board, and assigned reviewer(s) for each of those items (if required).

Information documented in the REB meeting agenda provides the foundation for the REB meeting minutes.

The REB meeting minutes document the actions that occur during an REB meeting. The minutes

should enable a reader who was not present at the REB meeting to determine how and with what justification the REB arrived at its decisions. They should also provide the REB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

5.1 Agenda Preparation

- 5.1.1 Following a document review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the Research Ethics Coordinator and the determination of the review type by the REB Co-Chairs or designee, the Research Ethics Coordinator adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;
- 5.1.2 For submissions that were reviewed and approved via delegated review procedures, the list of approvals is appended to the next Full Board meeting agenda;
- 5.1.3 The Research Ethics Coordinator attaches to the agenda any previous REB meeting minutes for Full Board review and approval, and adds any other items for information or discussion at the REB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);
- 5.1.4 The Research Ethics Coordinator, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns reviewers if required;
- 5.1.5 The REB Co-Chairs or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;
- 5.1.6 The agenda (and reviewer assignment if required) is issued in a timely manner prior to the REB meeting date. The REB members attending the REB meeting will receive a copy of the REB meeting agenda;
- 5.1.7 Ad hoc advisors will receive copies of relevant submissions;
- 5.1.8 Any changes to the agenda are communicated to all REB members and the Research Ethics Coordinator. The Research Ethics Coordinator or designee also may issue an updated agenda notice depending on the nature of the changes.

5.2 Primary and Secondary Reviewers

- 5.2.1 Prior to the meeting, the Research Ethics Coordinator, in consultation with the REB Co-Chairs or designee as necessary, may assign a primary and one or more secondary reviewers for each new research project as required, and one or more reviewers for each amendment;

- 5.2.2 No REB member will be assigned as a reviewer on a submission in which they are a Researcher or Supervisor or in which there is a declared conflict of interest;
- 5.2.3 The Research Ethics Coordinator will issue the reviewer assignment if applicable. The assigned reviewers will receive notification with a copy of the meeting agenda;
- 5.2.4 If any of the assigned reviewers declares a conflict, the submission is reassigned to another reviewer.

5.3 Prior to the REB Meeting

- 5.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the REB meeting. The primary reviewer should be prepared to lead the discussion at the Full Board meeting;
- 5.3.2 All REB members are expected to conduct a review of each agenda item prior to the Full Board meeting, including previous REB meeting minutes on the agenda and any attachments to the agenda for review or discussion;
- 5.3.3 REB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to the meeting;
- 5.3.4 All REB members should be prepared to present their comments and participate in the discussion at the Full Board meeting.

5.4 During the REB Meeting

- 5.4.1 A quorum must be present to proceed with a Full Board meeting;
- 5.4.2 Should quorum fail during a Full Board meeting (e.g., through recusal of REB members with conflicts of interest or early departures), the REB may not make further decisions unless quorum can be restored;
- 5.4.3 An alternate REB member may attend in the place of a regular REB member to meet quorum requirements. When a REB member and their alternate both attend the REB meeting, only one is allowed to participate in the deliberations and final decisions regarding approval;
- 5.4.4 Should a REB member not be physically present during a Full Board meeting,

they may participate via videoconference or teleconference. REB members participating by videoconference or teleconference count towards quorum;

- 5.4.5 Ad hoc advisors will not be used to establish a quorum;
- 5.4.6 REB members recusing themselves due to a conflict of interest are not counted toward quorum;
- 5.4.7 REB Office Personnel serving as REB members are not counted toward quorum.
- 5.4.8 Under unusual circumstances (e.g., public health alerts and quarantines) the REB Co-Chairs or designee may, at their discretion, conduct an REB meeting with all REB members attending via simultaneous videoconference or teleconference, provided everyone has access to the review materials and quorum is met;
- 5.4.9 Only those REB members present (i.e., in person, or via videoconference or teleconference) at the Full Board meeting may participate in the deliberation and final decision regarding approval;
- 5.4.10 Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and execution of a *Confidentiality Agreement*. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the REB meeting;
- 5.4.11 If requested, Researchers may (in person or via videoconference or teleconference) attend the REB meeting to present their research and respond directly to any comments or questions raised by the REB, subject to the agreement of the REB;
- 5.4.12 Any individual not listed on the official REB membership roster may not participate in the decisions of the REB.

5.5 Meeting Minute Preparation

- 5.5.1 The Research Ethics Coordinator will draft the REB meeting minutes including key discussions, decisions and votes;
- 5.5.2 The key REB discussions and decisions for submissions are recorded;
- 5.5.3 The REB's concerns, clarifications and recommendations to the Researcher as discussed at the REB meeting are included in the REB review letter that is sent to

the Researcher. The information documented is included in the REB meeting minutes;

- 5.5.4 The meeting may be audio recorded (on an encrypted device or secure platform) for reference purposes for the generation of the final draft of the minutes;
- 5.5.5 The minutes are intended to reflect what the REB discussed, how it resolved controverted issues, and the decisions made;
- 5.5.6 The draft minutes should be completed prior to the next REB meeting.

5.6 Meeting Minute Approval

- 5.6.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval;
- 5.6.2 The REB motion and votes on the previous REB meeting minutes are recorded in the current REB meeting minutes;
- 5.6.3 If the previous REB meeting minutes are approved pending revisions, the Research Ethics Coordinator makes the required changes, and unless the REB requests further review of the minutes prior to approval, the Research Ethics Coordinator records the minutes as “approved by the REB”.

5.7 Documentation

- 5.7.1 The REB meeting minutes include the following items:
 - Date, place, and time the REB meeting commenced and adjourned,
 - Names of REB members in attendance (present, teleconference, videoconference),
 - Names of REB members absent,
 - Name of the Research Ethics Coordinator present at the meeting,
 - Presence of observers,
 - Use of ad hoc advisors and their specialty,
 - List of declared conflicts of interest, a summary of any discussions, and the decision taken by the REB to address them (as applicable) or a note that none were declared,
 - A summary of key discussions and controverted issues and their resolution for each submission, as applicable,
 - The decisions taken by the REB regarding approval for each submission, as applicable,
 - The basis for requiring changes or for disapproving submissions,

- Number of REB members in attendance for the review of each submission requiring a decision,
- REB member(s) recused related to conflicts of interest for each submission requiring a decision,
- Number(s) voting for, against or abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda;

5.7.2 All REB meeting agendas and minutes are retained in the REB records;

5.7.3 The agendas, REB meeting minutes and review documents are confidential and will not be released or made available unless required for inspection or auditing purposes.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---|
| SOP 302 | July 2022 | YukonU version adapted from N2/CAREB SOP 302.003 (October 8, 2019) and CAREB 2021 updates |
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Procedures: Human Research Ethics

SOP 303 Document Management

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| 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

This standard operating procedure (SOP) describes the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the Research Ethics Board (REB) for initial or for continuing review, as well as to all REB administrative documents.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

All REB members and the Research Ethics Coordinator are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB office must retain all relevant records (e.g., documents reviewed and approved or disapproved, REB meeting minutes, correspondence with Researchers, written SOPs, REB membership rosters) to provide a complete history of all actions related to the REB review and approval of submitted research. Such records must be retained for the length of time required by applicable regulations and guidelines.

Relevant records must be made accessible to authorized organization personnel, Researchers and funding agencies within a reasonable time upon request.

5.1 Research-Related Documents

5.1.1 The REB office retains the submission materials for all research that have been submitted for REB review and have been either approved, acknowledged or disapproved;

5.1.2 Research-related documents include, but are not limited to, the following (as applicable):

- REB initial application form and all associated attachments;
- Correspondence between the REB and the Researcher, including REB approval letters, requests for modifications, etc.;
- Records of ongoing review activities such as,
 - Reportable event submissions, including reports of significant new findings, Data and Safety Monitoring Board (DSMB) reports, interim analysis reports, local adverse events and non-local (external) adverse events, research deviations, privacy breaches, any investigations into allegations of serious or continuing non-compliance, and reports of inspections and audits by regulatory agencies or others,
 - Modifications to the application including amendments to the research and/or any changes to the consent(s), participant materials or Investigator Brochures;
- Continuing review applications;
- Copies of correspondence between the REB and regulatory agencies;
- Reports of any complaints received by the REB and their resolution.

5.2 REB Administrative Documents

5.2.1 The REB office retains all administrative records related to the REB review activities;

5.2.2 REB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all REB meetings;
- Submitted REB member reviews;
- REB member records:
 - Current and obsolete REB membership rosters, including alternate REB members,
 - CVs and training/qualification documentation of current and past REB members;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete SOPs;
- Current and obsolete documentation of the REB Co-Chairs or designee's

- delegation of authority, responsibilities, or specific functions;
- Records of registration of the REB with the US Office of Human Research Protection, if applicable, and REB membership updates.

5.3 Document Access, Storage and Archiving

- 5.3.1 Access to individual research projects and related documents is role-based to ensure that users only have access to documents and activities that are required by their role;
- 5.3.2 The REB records are housed securely with back-up, disaster and recovery systems in place.

5.4 Confidentiality and Document Destruction

- 5.4.1 All submissions received by the REB are considered confidential and are accessible only to REB members (including the REB Co-Chair(s)), and the Research Ethics Coordinator;
- 5.4.2 Relevant research projects and associated documents may be made accessible to organizational officials, representatives, if the Researcher or their research team submits a request for access to the research;
- 5.4.3 Relevant research projects and associated documents may be made accessible to members of regulatory agencies, or representatives of the sponsor or Researcher for review. Access is limited to the applicable research and research-related submissions;
- 5.4.4 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) for a minimum of 3 years after completion/termination of the study, or for the maximum amount of time stipulated in any applicable requirement;
- 5.4.5 Any confidential materials in paper format in excess of the required documentation will be shredded.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|----------|----------------|---|
| SOP 303 | July 2022 | YukonU version adapted from N2/CAREB SOP 302.003 (October 8, 2019) and CAREB 2021 updates |
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