Yukon University

SOP 101

Procedures: Human Research Ethics	**SOP 101 Authority and Purpose**
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:

1.1 State the organizational authority under which the Research Ethics Board (REB) is established and empowered;

1.2 Define the purpose of the REB;

1.3 State the principles governing the REB to assure that the rights and welfare of participants are protected;

1.4 State the authority of the REB.

2.0 SCOPE

This SOP pertains to Yukon University Research Ethics Board (REB) that reviews human participant research in compliance with applicable regulations and guidelines under the direct authority of Yukon University.

3.0 RESPONSIBILITIES

The Associate Vice-President Research (AVPR), all REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB receives its mandate from the highest level of Yukon University (YukonU) and fulfills this mandate by following all written policies, standards, and procedures consistent with federal and provincial regulations, good clinical practice, and ethics guidelines when reviewing proposed research.

5.1 Statement of Institutional Authority

5.1.1 Yukon University (YukonU) has authorized the REB to review the ethical acceptability of all research involving human participants conducted under the auspices of the University;

5.1.2 The REB is established and empowered under the authority of the University. The University requires that all research involving human participants be reviewed and approved by the REB prior to initiation of any research related activities.

5.2 Purpose of the REB

5.2.1 The REB's purpose is to protect the rights and welfare of human participants participating in research;

5.2.2 The YukonU REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection;

5.2.3 These include, but are not limited to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the US Federal Policy for the Protection of Human Subjects (Final Common Rule), YukonU Policy AR-03 and where applicable, US Federal Regulations.

5.3 Governing Principles

The REB is guided by the ethical principles regarding all research involving human participants including:

- Respect for Persons:
  - Recognize the intrinsic value of human beings and the respect and consideration they are due,
  - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
  - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
  - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
  - Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - Obligation to treat people fairly with equal respect and concern,
  - Vulnerable or marginalized people may need to be afforded special attention.

5.4 REB Authority

5.4.1 YukonU's REB is established to review all research involving human participants within its established jurisdiction;

5.4.2 The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.

5.4.3 Specifically, the REB has the authority to:

- establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,
- approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction,
- ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants,
- request, receive and share any information involving the research that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy,
- conduct continuing ethical review to protect the rights and welfare and privacy of research participants,
    - Review of regular progress reports;
    - Review of changes in the design or conduct of the study prior to implementation;
    - Review of unanticipated problems and serious adverse events;
    - Monitoring to determine that a study is being conducted as approved;
    - Observation of the informed consent process; and
    - Any other review procedure deemed to be necessary to protect the rights and welfare of human participants;
- suspend or terminate the ethics approval for the research,
- place restrictions on the research,
- take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB's jurisdiction.

5.5 Relationship of the REB to Institutional and other committees

5.5.1 Research that has been reviewed and approved by the REB may be subject review and disapproval by the officials or committees of the University. Those officials or committees may not approve research if it has been disapproved by the REB.

5.5.2 The REB functions independently of the University. They are however, accountable to the University for their research ethics review processes.

5.6 Authorization

The Yukon University President has authorized the YukonU REB to review research involving human participants conducted by faculty, staff and students under the auspices of YukonU.

5.7 Federally Funded Research

If the study is part of a funded grant by a sponsoring agency, the human protocol must be reviewed by the REB prior to expenditure of any grant funds.

6.0 RESEARCH SUBJECT TO US REGULATIONS

The REB shall apply the requirements of the applicable US and International regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.

7.0 USE OF POLICIES AND PROCEDURES

The REB will maintain and follow all written policies and procedures consistent with federal and territorial regulations, good clinical practice and ethics guidelines when reviewing proposed research.

8.0 REFERENCES

See References.

9.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 101	July, 2022	YukonU version adapted from the N2/CAREB SOP 101.003 (October 8, 2019)

Procedures: Human Research Ethics	SOP 102 Research Requiring REB Review
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, revised Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review and research activities that are exempt from review and activities that are not defined as research requiring review.

2.0 SCOPE

This SOP pertains to Yukon University (YukonU) REB that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human participants and all other activities which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by the YukonU REB. No intervention or interaction with human participants in research, including recruitment, may begin until the YukonU REB has reviewed and approved the research protocol, consent documents and recruitment materials. Specific determination as to the definition of “research” or “human participants” and their implications for the jurisdiction of the REB under Yukon University policy are determined by the REB. Determination of exemption from REB review must

be based on regulatory, guideline and institutional criteria.

5.1 Research that Requires REB Review

5.1.1 "Research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (including pilot studies, exploratory studies and course based assignments). TCPS2 Article 2.1. The following requires ethics review and approval by the REB before the research commences:

(a) All research involving living human participants,

(b) All research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

5.1.2 In addition, the YukonU REB review is required when the research is:

5.1.2.1 Conducted by members or associated members of the University acting in their University capacity, including but not limited to faculty, staff, sessional instructors, administrators, students, visiting or adjunct scholars, and any other person associated with research at the University;

5.1.2.2 Conducted with the authorization of the University using resources (including but not limited to space that is under the administration of the University) that has been provided by the University;

5.1.2.3 In need of research review by the University pursuant to the terms of an affiliation agreement with another agency.

5.2 Research Exempt from REB Review

5.2.1 Research that relies exclusively on publicly available information does not require REB review when:

5.2.1.1 The information is legally accessible to the public and appropriately protected by law,

5.2.1.2 The information is publicly accessible and there is no reasonable expectation of privacy;

5.2.2 REB review is not required for research involving the observation of people in public places where:

(a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,

(b) Individuals or groups targeted for observation have no reasonable expectation of privacy,

and

(c) Any dissemination of research results does not allow identification of specific individuals;

5.2.3 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;

5.2.4 The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations to a particular research project.

5.3 Activities Not Requiring REB Review

5.3.1 Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than the REB;

5.3.2 Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of REB review;

5.3.3 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

5.3.4 For research/scholarly work where the researcher is uncertain whether a review is required, they should consult with the research ethics office and/or REB to determine to determine if the research should be subject to an ethics review.

6.0 FAILURE TO SUBMIT PROJECT FOR REB REVIEW

The implications of engaging in activities that qualify as research that is subject to REB review without obtaining such review are significant. Results from such studies may not be published unless REB approval was obtained prior to collecting the data. In addition, conducting research without REB approval can constitute research misconduct in accordance with the provisions of YukonU Policy AR-02. It is also again policy to use that data to satisfy thesis or dissertation requirements.

If a researcher begins a project and later finds that the data gathered could contribute to generalizable knowledge and has changed in some fashion as to now require REB review, the

researcher should submit an application to the REB for review as soon as possible. The YukonU REB will not review or grant approval for research that has been conducted without approval. If the REB does not approve the research, data collected cannot be used as part of a study, thesis or dissertation nor may the results of the research be published.

7.0 REFERENCES

See References.

8.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP102	July 2022	YukonU version adapted from N2/CAREB SOP102.003 (October 8, 2019)

Procedures: Human Research Ethics	SOP 103 Training and Education
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 training and education requirements for Yukon Universities (YukonU) Research Ethics Board (REB) members and REB Office Personnel.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

The Associate Vice-President Research, REB Co-Chairs and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB members, Research Ethics Office Personnel and others charged with the responsibility for reviewing, approving, and overseeing human participant research should be well-versed in the regulations, guidelines, policies, and ethical principles applicable to human participant research. This training is fully supported by the management of the REB. Adequate training and education in these areas is critical for the REB to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner.

5.1 Training and Education – REB Members

5.1.1 Members of the REB who oversee research on human participants will receive initial and ongoing training regarding the responsible review and oversight of research and the policies and procedures that accompany such activities.

5.1.2 The Associate Vice President Research (AVPR), in consultation with the Research Ethics Office and the REB Co-Chairs, establish the educational and training requirements for REB members who review human participant research. Initial and ongoing training for REB members is provided and documented by the Research Ethics Coordinator;

5.1.3 The REB Co-Chairs will receive additional training in areas relevant to their responsibilities;

5.1.4 The REB Coordinator with the Co-Chairs will provide new REB members with a general overview of the policies and procedures pertinent to REB meeting functions and REB member expectations, as well as an orientation to the principles and guidelines for research ethics;

5.1.5 New REB members will receive an orientation before beginning their formal duties. REB members are required to complete the TCPS online tutorial and are expected to participate in the orientation process which may include, but is not limited to:

- Background on the REB (e.g., Terms of Reference, governance structure, annual reports, process flowchart),
- Policies and Procedures (e.g., relevant SOPs and associated forms, consent form template, consent form checklist),
- Member information (e.g., meeting schedule, membership list, information and guidelines for members, reviewer guide),
- Regulatory and guidance documents,
- Other member-specific information (e.g., copy of signed confidentiality and conflict of interest agreement, membership appointment letter),
- Resource information (e.g., list of training and education references, relevant articles, etc.);

5.1.6 As part of their orientation, new REB members will be offered the opportunity to observe at least one REB meeting prior to commencing their REB member duties;

5.1.7 REB members are encouraged to attend conferences and other educational sessions pertaining to human participant research protection, such as the Canadian Association of Research Ethics Board (CAREB) annual general meeting and CAREB regional meetings. These may be in person or virtual. The REB office will support such activities to the extent possible and as appropriate to the responsibilities of REB members. Attendance is based on availability of funding and other practical considerations (e.g., timing,

conference location);

5.1.8 Ongoing ethics education in areas germane to the REB members' responsibilities may be provided at REB meetings or as special meetings;

5.1.9 New or revised policies and SOPs will be disseminated to the new REB members;

5.1.10 REB members are encouraged to engage in self-directed learning in research ethics and in the conduct of research to enhance their ability to fulfill their responsibilities.

5.2 Training and Education – REB Office Personnel

5.2.1 The REB Coordinator, in consultation with the AVPR and REB Co-Chairs, establish educational and training requirements for REB Office Personnel and others who perform related administrative duties. Initial and ongoing training for REB Office Personnel is provided and documented by the AVPR.

5.2.2 The REB Co-Chairs or designee will provide new REB Office Personnel with an overall orientation to the REB including a general overview of the policies and procedures pertinent to their role in support of the REB;

5.2.3 REB Office Personnel who are overseeing research on human participants will receive ongoing training regarding the responsible overview and oversight of research ethics and the policies and procedures pertinent to their role in support of the REB;

5.2.4 New REB Office Personnel will receive an orientation package and training regarding the responsible overview of research and the policies and procedures that accompany such activities. Before commencing their official duties in the REB office, REB Office Personnel are expected to read and become familiar with the information;

5.2.5 New REB Office Personnel will receive training on the REB SOPs and will be expected to be knowledgeable and compliant with the SOPs;

5.2.6 New REB Office Personnel are required to complete the TCPS online tutorial, and are encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of research;

5.2.7 REB Office Personnel are encouraged to participate in local, regional and national educational opportunities pertaining to human participant research protection, such as the CAREB annual general meeting and CAREB regional meetings. These may be in person or virtually. The REB office will support such activities to the extent possible and as appropriate to the responsibilities of REB Office Personnel. Attendance is based on availability of funding and other practical considerations (e.g., workload, staffing,

conference location);

5.2.8 New or revised policies and SOPs will be disseminated to the REB Office Personnel;

5.2.9 REB Office Personnel are encouraged to engage in self-directed learning in research ethics and in the conduct of research to enhance their ability to fulfill their responsibilities.

5.3 Documentation of Training and Education

5.3.1 The REB office will retain copies of the CVs of all REB members and REB Office Personnel;

5.3.2 REB members and REB Office Personnel will record their relevant training and education and provide copies of their certificates of completion. Training records will be kept on file in the REB office;

5.3.3 REB members and REB Office Personnel are encouraged to retain copies of agendas of relevant workshops, seminars and conferences attended;

5.3.4 REB agendas and minutes will record the distribution of any educational materials presented at the REB meetings.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP103	July 2022	YukonU version adapted from N2/CAREB SOP103.003 (October 8, 2019) and CAREB SOP101.001 (January 2021)

Yukon University

SOP 104

Procedures: Human Research Ethics	SOP 104 Management of REB Office Personnel
Associated Policy	Human Research Ethics Policy AR-03
Procedure Holder	Associate Vice President Research (AVPR)
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 overall management of the Yukon University Research Ethics Board (REB) Office Personnel.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

The Associate Vice-President Research (AVPR), REB Co-Chairs or designee and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met. Yukon University is responsible for providing sufficient resources to adequately support the functions of the REB.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB Office Personnel provide consistency, expertise and administrative support to the REB, and serve as a daily link between the REB and the research community. The REB Office Personnel are the most vital component in the effective operation and enforcement of the Yukon University human participants protection program. This ensures the efficient and effective administration and enforcement of REB decisions, thus the highest level of professionalism and integrity on the part of the REB Office Personnel is expected.

5.1 Job Descriptions

5.1.1 Job descriptions will be developed to establish the role requirements for the REB Office Personnel, in accordance with organizational policies and procedures;

5.1.2 REB Office Personnel will be provided with a copy of their job description and details of responsibilities expected in their position, as well as access to all applicable organizational policies and procedures. The performance of REB Office Personnel will be reviewed according to current University guidelines.

5.2 Responsibilities

5.2.1 REB Office Personnel responsibilities may include:

- screening and pre-review of submissions and requests to the REB,
- quality management activities,
- management of administrative issues involving REB research ethics oversight as described by applicable REB policies,
- the implementation of REB directives, and
- the provision of advice and information to the REB and researchers
- serving as a non-voting REB member (as per SOP 204)

5.3 Hiring and Terminating REB Office Personnel

5.3.1 The human resources policies of Yukon University will determine procedures for the recruitment, hiring, and termination of REB Office Personnel, in accordance with YukonU policies and procedures.

5.4 Delegation of Authority or Responsibility

5.4.1 Appropriate tasks or responsibilities may be delegated to the REB Office Personnel in accordance with Yukon University/REB policy, if the individual has the expertise to carry out the task(s), the task is compliant with the REB SOPs and the task delegation has been agreed to by both the REB Office Personnel and the University.

5.5 Performance Evaluations and Documentation

5.5.1 Performance feedback will be provided on an ongoing basis;

5.5.2 The human resource policies of Yukon University will determine responsibility for conducting formal performance evaluations in accordance with organizational policies and procedures;

5.5.3 The AVPR will determine responsibility for identifying, documenting and retaining formal REB Office Personnel interactions.

5.6 Periodic Evaluation of REB Office Human Resource Needs

5.6.1 A periodic evaluation of the adequacy of the REB resources will be conducted;

5.6.2 The evaluation will assess whether the REB Office Personnel, equipment, finances and space are adequate to carry out its function in support of the REB;

5.6.3 The assessment takes into consideration the volume, complexity and types of research projects administered by the REB Office Personnel and whether activities in support of the REB can be completed in a timely manner;

5.6.4 The need for additional resources will be discussed with the AVPRO and Research Ethics Office as appropriate.

5.6.5 Staffing levels and function allocation will be determined according to University policy, management assessment of support requirements, and budget constraints.

6.0 REFERENCES

- HR-21.0 Performance Conditions for Ongoing Employment
- HR-24.0 Recruitment of Permanent and Term Employees
- HR-28.0 Staff Development and Training

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 104	July 2022	YukonU version adapted from the N2/CAREB SOP 104.003 (October 8, 2019)

Procedures: Human Research Ethics	SOP 105A Conflicts of Interest – REB Members and REB Office Personnel
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 potential Conflicts of Interest (COI) for Research Ethics Board (REB) members, REB Chairs, ad hoc advisors and REB Office Personnel. This extends to consultants who are not REB members but may be asked to review a project because of their expertise. It describes the requirements and procedures for disclosure and management of COI.

2.0 SCOPE

This SOP pertains to the Yukon University 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 disclosing any real, potential or perceived COI and for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

COI (real, potential or perceived) arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence their professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the

conflict.

The YukonU REB should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.

The YukonU REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or non-professional sources.

The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual's actions or decisions could be influenced by factors other than the rights, welfare and safety of the participants.

5.1 REB Reviewer Assignment

5.1.1 The REB Co-Chairs or designee reviews the agenda prior to the REB meeting to identify potential COI;

5.1.2 When the agenda is distributed, REB members are expected to disclose as soon as possible, any conflicting interest(s) for any of the projects on the agenda;

5.1.3 If a member is unclear as to whether a COI exists, they must contact the REB Co-Chairs or designee to seek clarification. The REB Chairs or designee will determine whether the circumstances should be defined as a COI and the member shall follow the REB's decision regarding any actions required to mitigate their real or perceived COI;

5.1.4 If a COI is identified in the reviewer assignments, the project is assigned to another REB member.

5.2 Full Board Meeting

5.2.1 At the beginning of the meeting, REB members are reminded of their obligation to verbally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the REB meeting minutes;

5.2.2 Any REB member who is named as part of a research team on a study application being reviewed by the REB will be blocked from having access to reviewer comments. If an REB member is not named on a study but is in COI in relation to the study, they must declare their conflict. The procedures for recusal of REB members, including the Chair from deliberating/voting on any protocols for which there is a potential or actual COI are detailed in the REB minutes.

5.2.3 If a COI is declared and determined as such, the REB member may be asked to provide information about the research, but must be recused for the deliberation and decision;

5.2.4 The REB member's recusal will be recorded in the minutes and the REB member will not be counted towards quorum for the specific protocol for which they are in conflict. In the event that a member's COI and necessary withdrawal from the meeting will threaten the maintenance of quorum, the REB can ensure that a substitute member be in attendance to maintain quorum;

5.2.5 If recused, the REB member should abstain from voting on/approving the minutes of that meeting.

5.3 Delegated Review

5.3.1 The REB Co-Chairs or designee will assess projects undergoing the delegated review process to determine potential COI;

5.3.2 REB members involved in the delegated review process are expected to disclose any conflicting interests;

5.3.3 If a COI is identified, the project is assigned to another REB member.

5.4 REB Chair

5.4.1 In the event that the an REB Chair declares a COI, the Co-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific project(s).

5.5 REB Office Personnel

5.5.1 All REB Office Personnel are expected to disclose any conflicts that arise and any REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves when such research is reviewed;

5.5.2 Any disclosure of a COI by REB Office Personnel should be referred to the REB Co-Chairs or designee for the development of a management plan;

5.5.3 If REB Office Personnel are unclear as to whether a COI exists, they must contact the REB Co-Chairs or designee to seek clarification. The REB Co-Chairs or designee will determine whether the circumstances should be defined as a COI.

5.5.4 REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves from any meeting at which such a protocol is reviewed.

5.6 External Ad Hoc Advisors

5.6.1 At their, 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;

5.6.2 All ad hoc advisors must sign a *Confidentiality of Information and Conflict of Interest Agreement* prior to commencement of their consultation, and disclose any COI to the REB Co-Chairs.

5.6.3 Any disclosure of a COI by an ad hoc advisor should be referred to the REB Co-Chairs or designee for the development of a management plan, as applicable.

5.6.4 If ad hoc advisors are unclear as to whether a COI exists, they must contact the REB Co-Chairs or designee to seek clarification. The REB Co-Chairs or designee will determine whether the circumstances should be defined as a COI.

5.7 Documentation

5.7.1 All REB members, guests and ad hoc advisors must sign a *Confidentiality of Information and Conflict of Interest Agreement* and agree to abide by the REB COI and confidentiality policies;

5.7.2 REB members sign a *Confidentiality of Information and Conflict of Interest Agreement* annually, or as determined by the organization;

5.7.3 The signed *Confidentiality of Information and Conflict of Interest Agreement* is filed in the REB office;

5.7.4 The REB minutes will record any COI that are declared on any of the projects under review at the REB meeting, and the decision on the management of the conflict;

5.7.5 The REB minutes will also record the recusal of an REB member;

5.7.6 At the time of hire, all REB Office Personnel sign a *Confidentiality of Information and Conflict of Interest Agreement* as a condition of their employment with the organization agreeing to abide by the COI and confidentiality policies of the organization. REB Office Personnel must also comply with REB COI SOPs;

5.7.7 The signed *Confidentiality of Information and Conflict of Interest Agreement* will be retained;

5.7.8 The REB management plan for Research COI declarations will be documented in the appropriate research files. Any discussion at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes.

5.8 Education and Training in Conflicts of Interest

5.8.1 REB members and REB Office Personnel are encouraged to participate in education and training activities related to COI issues where available.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP105A	July 2022	YukonU version adapted from N2/CAREB SOP 105A.003 (October 8, 2019) and CAREB SOP 105A.001 (January 2021)

Procedures: Human Research Ethics	SOP 105B Conflicts of Interest – Researcher
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 potential Conflicts of Interest (COI) for Researchers and research staff engaged in human participant research, and the requirements and procedures for disclosure and managing COI.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REBs) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

Researchers are responsible for disclosing any real, potential or perceived COI to the REB.

The REB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

COI (real, potential or perceived) arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her

professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict.

Researchers and research staff should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict.

This SOP is not intended to prohibit Researcher relationships with companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI.

The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or nonprofessional sources.

The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual's actions or decisions are based on factors other than the rights, welfare and safety of research participants.

5.1 Researcher Disclosure of Conflicts of Interest

5.1.1 Researchers submitting research applications to the REB are required to declare any COI including those of their sub/co-Researcher(s), research staff, and their immediate families (which includes spouse, domestic partners and dependent child), and close relationships;

5.1.2 Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict;

5.1.3 The Researcher shall disclose any conflicts to the REB at the following times:

- With the initial REB application,
- At each continuing review of the project,
- Whenever a COI arises, such as changes in responsibilities or financial circumstances;

5.1.4 The Researcher shall cooperate with the REB and with other Yukon University (YukonU) officials involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the REB and with YukonU COI policies to eliminate and/or to manage the conflict;

5.1.5 The Researcher shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

5.2 REB Review of Researcher Conflict of Interest

5.2.1 The REB will review each application for disclosure of COI;

5.2.2 If the Researcher indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research;

5.2.3 The REB review shall focus on those aspects of the COI that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks;

5.2.4 In determining the appropriate action, the REB may take into consideration information presented by the Researcher such as:

- The nature of the research,
- The magnitude of the interest or the degree to which the conflict is related to the research,
- The extent to which the interest could affect the research,
- Whether a specific individual is unique in his/her clinical or scientific qualifications to conduct the research,
- The degree of risk to the human participants involved in the research that is inherent in the research, and/or
- The management plan for the COI already developed by the Researcher;

5.2.5 The REB may approve the research and may require a management plan, which may include changes at the Researcher's or sponsor's expense, to eliminate or to mitigate the conflict. The researcher may be required to provide a management plan for review by the REB. Required actions may include, but are not limited to:

- Divestiture or termination of relevant economic interests,
- Mandating Researcher recusal from research,
- Modifying or limiting the participation of the Researcher in all or in a portion of the research,
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data)),
- Independent clinical review of appropriateness of clinical care given to research participants, if applicable,
- Monitoring the consent process, and/or
- Disclosure of the conflict to organizational committees, research participants, and journals;

5.2.6 The REB has the final authority to determine whether a COI has been eliminated or

managed appropriately;

5.2.7 Any COI management plan will be documented in the final project files. Any discussions at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes;

5.2.8 After review by the REB and input by the appropriate Organizational Official, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 105B	July 2022	YukonU version adapted from the N2/CAREB SOP105B.003 (October 8, 2019) and CAREB SOP105B.001 (2021)

Procedures: Human Research Ethics	SOP 105C Conflicts of Interest – Organization
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 purpose of this standard operating procedure (SOP) is to outline potential Conflicts of Interest (COI) in the relationship between the organization (Yukon University) establishing the Research Ethics Board (REB) and the REB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.

2.0 SCOPE

The SOP pertains to Yukon University REB that reviews human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

The Yukon University Associate Vice President Research (AVPR), the REB members, REB Co-Chairs, and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Organizational policies should address the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing COI relevant to research, including disclosure to REBs. Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by the organization.

The REB must be fair and impartial, immune from pressure by the sponsor, the parent organization and the Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the REB must act independently from its parent organization, and avoid or manage real or apparent COI. The organization must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether YukonU actions or decisions could be based on factors other than the rights, welfare, and safety of the research participants.

5.1 Disclosure of Conflict of Interest

5.1.1 All organizational employees must be familiar with the Conflict of Interest Policy and must complete a Disclosure of Conflict of Interest Form(s) (if applicable) at the time of hire and annually thereafter, or as per organizational policy;

5.1.2 Prior to engaging in any of the professional activities listed in the Conflict of Interest Policy, employees must seek the approval of the appropriate Organizational Official to ensure that no conflict exists in doing so;

5.1.3 REB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the REB and the organization. The actions of the REB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;

5.1.4 REB meetings are closed to employees of the organization unless they are REB members, REB Office Personnel, permitted as observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place;

5.1.5 Organizational senior administrators shall not serve as REB members nor observe REB meetings when their presence may influence REB deliberations.

5.2 Management of Conflicts of Interest

5.2.1 The REB Co-Chairs or designee must be notified if an organizational COI relating to the REB is declared or discovered;

5.2.2 The REB Co-Chairs or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment;

5.2.3 The REB Co-Chairs or designee will review the available information to determine if a

conflict exists, and to determine those aspects of the COI that might reasonably affect human participant protection;

5.2.4 The REB Co-Chairs or designee may require a management plan, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:

- Divestiture or termination of relevant economic interest,
- Recusal of REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB,
- If YukonU staff members are involved, inform the appropriate responsible management personnel to develop and implement a management plan for remediation;

5.2.5 If the REB Co-Chairs or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the REB, the REB Co-Chairs or designee will bring this to the appropriate Organizational Officials for determination of the appropriate course of action;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP105C	July 2022	YukonU version adapted from N2/CAREB SOP 105C.003 (October 8, 2019) and CAREB SOP 105C.001 (2021)

Yukon University

SOP 106

Procedures: Human Research Ethics	**SOP 106 Signatory Authority**
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 purpose of this standard operating procedure (SOP) is to describe who has the authority to sign documents on behalf of the Research Ethics Board (REB) and describes the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

All REB members, the REB Co-Chairs and 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 Co-Chairs or designee is authorized to sign any and all documents related to REB review and approval of research projects involving human participants, which have been reviewed and approved pursuant to REB policies and procedures, and upon decision of the REB. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Co-Chairs. Implementation shall be the responsibility of the REB Co-Chairs and the Research Ethics Coordinator.

REBs are accountable for their activities and decisions, and appropriate controls must be applied to ensure that documentation related to REB review and approval of research are signed by a person or persons having the appropriate authority to do so. Documentation includes both hard copy and electronic formats. Signing may be done with ink, e-signature or scanned signature, as per REB and YukonU policies and procedures.

5.1 Delegation of Signing Authority

5.1.1 Authorization to sign documents not described in this procedure may be made by the REB Co-Chairs

5.1.2 The REB Co-Chairs or designee may delegate signing authority for documents related to REB review and approval;

5.1.3 The REB Co-Chairs or designee may only delegate signing authority to REB members or REB Office Personnel with the skill and knowledge necessary for the effective exercise of the authority;

5.1.4 The REB Co-Chairs or designee may not delegate their signing authority to ad hoc advisors or to independent contractors;

5.1.5 The REB Co-Chairs or designee should clearly define the parameters of the delegated authority;

5.1.6 The REB Co-Chairs or designee may delegate signing authority indefinitely or for defined periods of time (e.g., for absences);

5.1.7 Delegation of signing authority must be documented and retained.

5.2 REB Reviews, Decisions and Other Correspondence with the Researcher

5.2.1 For each submission reviewed at a Full Board meeting, the responsible REB Office Personnel records the decision made by the Full Board;

5.2.2 Communication of the REB decision made at a Full Board meeting must be reviewed and authorized by the REB Co-Chairs or designee or as otherwise delegated by the REB Co-Chairs or designee;

5.2.3 For each submission that undergoes delegated review, the reviewer's decision is documented;

5.2.4 Once a final decision is documented by the REB Co-Chairs or designee, the Research Ethics Coordinator may issue the decision or letter;

5.2.5 Certificates of approval are issued by the Research Ethics Coordinator, subsequent to approval being signed by the REB Co-Chairs or designate.

5.2.6 All activities are documented in the research file, which may be physical or electronic;

5.2.7 Any letters, memos, or emails between the REB and Researchers that provide information concerning the review of research (e.g., requests for consent form changes, requests for additional information) and that do not imply or appear to imply approval of the research, may be issued as per delegated signing authority;

5.2.8 All reviews, actions, decisions and signatures (where applicable) are filed within the research file;

5.2.9 All correspondence and communication between the REB and Principal Investigator is coordinated through the Research Ethics Office and is retained in the research file.

5.3 Correspondence with External Agencies

5.3.1 The responsible Organizational Official or the REB Co-Chairs or designee signs all correspondence with agencies of the federal government (Health Canada, OHRP, FDA) and with all funding agencies and/or sponsors.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 106	July 2022	YukonU version adapted from the N2/CAREB SOP 106.003 (October 8, 2019) and CAREB SOP 106.001 (2021)

Yukon University

SOP 107

Procedures: Human Research Ethics	SOP 107 Use and Disclosure of Personal Information (PI)
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 duties of the Research Ethics Board (REB) and the REB office in the protection of the Personal Information (PI) of research participants.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

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

The Researcher is responsible for submitting information to the REB and to the participant regarding the nature of the PI (including personal health information (PHI)) that will be collected for the research, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected.

The REB Co-Chairs, REB members and the Research Ethics Coordinator are responsible for ensuring that the plan to protect confidentiality of participants' of PI is appropriate, while ensuring that any PI received or assessed by the REB office, whether in the process of ethics review, inadvertently, or for other purposes is protected.

The YukonU **privacy office** is responsible for providing Researchers and research staff with guidance on privacy policies and regulations.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Privacy is a fundamental value that is essential for the protection and promotion of human dignity. Breaches in privacy and confidentiality may cause harm to individuals or groups of individuals. Hence, PI must be collected, used and disclosed in a manner that respects a research participant's right to privacy, and in accordance with applicable federal and territorial privacy regulations.

PI may be obtained directly from research participants or through data stewards or custodians.

Privacy regulations permit the use and the limited disclosure of PI for research purposes as long as certain requirements are met. One of the key ethical challenges for the research community is in protecting appropriately the privacy and confidentiality of PI used for research purposes. The REB plays an important role in balancing the need for research against the risk of the infringement of privacy and in minimizing invasions of privacy for research participants. Individuals should be protected from any harm that may be caused by the unauthorized use of their PI and they should expect that their rights to privacy and confidentiality are respected.

5.1. REB Review of Privacy Concerns

5.1.1. The REB shall review the research submitted to determine if the Researcher has access to and/or is using PI and whether appropriate privacy legislation is adhered to;

5.1.2. In reviewing the research, the REB will include such privacy considerations as:

- The type of PI to be collected,
- The research objectives and justification for the requested personal data needed to fulfill these objectives,
- The purpose for which the personal data will be used,
- How the personal data will be controlled, accessed, disclosed, and de-identified,
- Limits on the use, disclosure and retention of the personal data,
- Any anticipated secondary uses of identifiable data from the research,
- Any anticipated linkage of personal data gathered in the research with other data about research participants, whether those data are contained in public or in personal records,
- Whether consent for access to, or the collection of personal data from participants is required,
- How consent is managed and documented,
- If and how prospective research participants will be informed of the research,
- How prospective research participants will be recruited,
- The administrative, technical and physical safeguards and practices in place to protect the personal data including de-identification strategies and managed

linkages to identifiable data,
- How accountability and transparency in the management of personal data will be ensured;

5.1.3. The REB must find that there are adequate provisions to protect the privacy interests of participants before approving the research.

5.2. Receipt, Use and Disclosure of PI

5.2.1. The REB Co-Chairs, REB members and the Research Ethics Coordinator are bound by confidentiality agreements signed prior to commencement of their duties;

5.2.2. The REB does not intentionally collect PI;

5.2.3. Subject to consent, as applicable, the REB is permitted to access PI for the purposes of the review, the approval, the ongoing monitoring, and/or the auditing or other Quality Assurance activities of the conduct of the research;

5.2.4. The YukonU Research Ethics Office

5.2.4.1. Shall treat all information received from investigators as confidential and shall use or disclose such information only as necessary for the purpose of REB operations;

5.2.4.2. Must adopt reasonable safeguards and ensure that there is training for Research Ethics office Personnel to protect PI from unauthorized access;

5.2.4.3. Shall maintain and properly secure research files and other records related to REB operations, to ensure competent record-keeping and to avoid unintentional disclosures.

5.2.4.4. Arrange for copies of REB minutes and approved attachments to be distributed to authorized persons only

5.2.4.5. Shall ensure the confidential disposal/destruction of all confidential records related to the review of research studies and other REB operations.

5.2.5. Training on the policies and procedures set forth in this document will be provided for the Research Ethics Coordinator, the REB Co-Chairs and the REB members to the extent applicable for their respective positions.

5.2.6. REB members or Research Ethics Coordinator may consult with the REB Co-Chairs or designee if they are uncertain about the appropriate use or disclosure of PI;

5.2.7. The REB Co-Chairs will ensure that reports to researchers on REB decisions do not contain any personal identifiers of individual reviewers;

5.2.8. In the event that a Principal Investigator is invited to attend an REB meeting to address questions about his/her research application, ensure the Principal Investigator attends only that portion of the meeting necessary to address questions or concerns. A Principal Investigator cannot attend the reviewer's presentations, the vote or discussion of any study including their own;

5.2.9. The REB Co-Chairs, in collaboration with the Research Ethics Coordinator, the Privacy Officer of the institution, and any other applicable Institutional Officer, shall manage all requests for release of documents that are under the custody and/or control of the REB;

5.2.10. If any PI is received inadvertently in the REB office (e.g. disclosed by a Researcher), appropriate notification must take place and any corrective action that is required including, if applicable, notification to the appropriate University Official. The facts surrounding the breach, the appropriate steps taken to manage the breach, remedial activities to address the breach and the outcome will be documented. The PI will be destroyed in a secure manner as per Yukon University policies and procedures;

5.2.11. If there is an internal breach involving the use or dissemination of PI, the REB Co-Chairs or designee will be notified, and if applicable, notification of the appropriate University Official, and a determination will be made in a timely manner regarding a corrective action plan. This process may include notification, containment, investigation and remediation, and strategies for prevention. The facts surrounding the breach, the appropriate steps taken to manage the breach and the outcome will be documented. The PI will be destroyed in a secure manner as per the organizational policies and procedures;

5.2.12. At the discretion of the REB Co-Chairs or designee, in consultation with the organization, the territorial privacy office (or equivalent) may be notified.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 107	July 2022	YukonU version adapted from the N2/CAREB SOP 107.003 (October 8, 2019) and CAREB SOP 107.001 (2021)

Yukon University

SOP 108

Procedures: Human Research Ethics	SOP 108 Standard Operating Procedures Maintenance
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 processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

2.0 SCOPE

This SOP pertains to the YukonU Research Ethics Boards (REB) that review 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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

5.1. Development, Review, Revision and Approval of Policies & Procedures

5.1.1. The Research Ethics Coordinator or designate will review the SOPs at least once every two years. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;

5.1.2. SOPs may be revised for reasons including, but not limited to: changes to policies, regulations or guidelines, new policies, or changes to REB or administrative practices;

5.1.3. The Research Ethics Coordinator or designee will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of "DRAFT version date" and removal of the previous "Final Version Date";

5.1.4. The revised SOP(s) will be circulated to the REB Office Personnel and REB Co-Chairs or designee, as well as REB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;

5.1.5. Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the "Final Version Date". The history of revisions will be recorded in the 'SOP History' section of each SOP;

5.1.6. Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

5.2. Distribution and Communication

5.2.1. New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the 'Responsibilities' section of each SOP;

5.2.2. The SOPs will be available to Researchers and research teams, YukonU personnel, sponsors and funders as required;

5.2.3. Designated REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;

5.2.4. Each new REB member must review the applicable policies and procedures prior to undertaking any responsibilities as an REB member;

5.2.5. Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking any responsibilities with the REB office;

5.2.6. Evidence of training must be documented;

5.2.7. The REB office shall maintain all documentation of SOP training.

5.3. Forms, Memos and Guidance Documents

5.3.1. Forms ensure that policies and procedures are integrated into the daily operations of research and review throughout the YukonU system and enable the Research Ethics Office to manage review, tracking and notification functions consistently.

5.3.2. Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

5.3.3. Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

5.3.4. Memos and guidance documents will be made available to the Researchers and research teams as applicable;

5.3.5. Designated REB Office Personnel and/or REB Co-Chairs or designee will evaluate the need for new or revised forms, memos or guidance documents.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 108	February 2022	YukonU version adapted from N2/CAREB SOP 108.3 (October 8, 2019) and CAREB SOP 108.001 (2021)