Yukon University

SOP 401

Procedures: Human Research Ethics	SOP 401 Delegated 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, Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

2.0 SCOPE

This SOP pertains to YukonU Research Ethics Board (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.

The REB Co-Chairs or designee are responsible for determining if research is eligible for delegated review. In some circumstances, the REB Co-Chairs or designee may delegate this task to qualified REB Office Personnel; however, the responsibility for oversight remains with the REB Co-Chairs or designee.

The REB Co-Chairs or designee or qualified REB member(s) are responsible for conducting the delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

An expedited/delegated review procedure consists of a review of research involving human participants by the REB Co-Chairs or by one or more experienced reviewers designated by the Co-Chairs from among members of the REB.

The REB shall adopt a proportionate approach to research ethics review based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full review by an REB should be the default requirement for all research involving human participants unless the REB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research.

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels typically used by REBs are Full Board review or delegated review by one or more experienced REB members, as determined by the REB Co-Chairs or designee.

Research that may be reviewed by the REB through a delegated review procedure normally includes research activities that present no more than minimal risk to human subjects, and minor changes in approved research.

5.1 Definition of Minimal Risk

5.1.1 Minimal risk research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research;

5.1.2 Minor changes are changes that neither increase the risk, nor materially change the risk benefit ratio of the research study and do not substantially change the specific aims or design of the study;

5.2 Determination of Qualification for Delegated Review

5.2.1 Full Board review is the default for most new research projects submitted to the REB; however, some research may be eligible for delegated review;

5.2.2 Submissions that meet the following criteria may be eligible for delegated review:

- Research projects that involve no more than minimal risk,
- Minor or minimal risk changes to approved research,
- Continuing review of approved minimal risk research,
- Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB, and where the REB Co-Chairs have determined that delegated review is appropriate.
- The submission by the Researcher in response to the REB review as a condition of

approval, as authorized by the Board,

- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
- Reportable events, including adverse events. If the REB Co-Chairs or designee considers that action is needed to protect the safety of research participants, they may take such action immediately and/or request a review of the report at a convened REB meeting or by a designated sub-committee to determine what further action, if any, is required;

5.2.3 The REB Co-Chairs or designee may be authorized by the full Board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

5.2.4 When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the REB Co-Chairs or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

5.2.5 Examples of categories of research that may be delegated for research ethics review include:

- Research that is confidently expected to involve minimal risk;
- Minimal risk changes to approved research;
- Annual renewals of approved minimal risk research;
- Annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis.

5.3 Delegated Review Process

5.3.1 Qualified REB Office Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the REB may be forwarded for delegated review. For all other submissions, the REB Co-Chairs or designee will make the determination of whether the submission meets the criteria for delegated review;

5.3.2 For research that meets the criteria, delegated review may be conducted by the REB Co-Chairs, or by one or more qualified REB members as designated by the REB Co-Chairs or designee;

5.3.3 The REB Co-Chairs or designee reviewing research under delegated review must

not have a Conflict of Interest in the research;

5.3.4 In reviewing the research under delegated procedures, the REB Co-Chairs or designee may exercise all of the authorities of the REB, except that they may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;

5.3.5 REB member(s) conducting a delegated review will contact the REB Co-Chairs or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research;

5.3.6 If the REB Co-Chairs or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review;

5.3.7 The REB Co-Chairs or designee will record the decision regarding the designation of the research (i.e., either requiring FB or delegated review) and the outcome of the review. The Research Ethics Coordinator may issue the review or decision letter.

5.4 Notification of the REB

5.4.1 At its next Full Board meeting the REB will be informed of research that was reviewed and approved using delegated review procedures.

5.5 Documentation

5.5.1 The type of REB review conducted (i.e., Full Board or delegated) is documented in the REB records and noted in the decision letter issued to the Researcher, where appropriate;

5.5.2 The REB will be provided with a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous REB meeting was issued.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 401	July 2022	YukonU version adapted from N2/CAREB SOP 401.003 (October 8, 2019) and CAREB SOP401.001 (2021)

Yukon University

SOP 402

Procedures: Human Research Ethics	SOP 402: REB Review Decisions
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 decisions that the Research Ethics Board (REB) may make resulting from its review of proposed research for ethical acceptability.

2.0 SCOPE

This SOP pertains to the YukonU Research Ethics Board (REB) that reviews human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

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

The REB Co-Chairs or designee are/is responsible for ensuring that a decision is made for every submission that is reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly stated and agreed upon.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human subjects must be submitted for REB review according to the application format and processes of YukonU. This must include all the required elements. No research should begin with human participants, including recruitment, until the REB has reviewed and approved the research protocol, consent documentation, recruitment materials and any other relevant study documentation submitted for initial review.

As a result of its review, the REB has the authority to approve, disapprove, or to require modifications to submitted research. If there are questions that must be addressed prior to a determination, the REB may defer its decisions. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the REB members with voting rights who are present at a Full Board meeting at which there is a quorum. When a vote is used, dissenting opinions shall be documented (see SOP 302).

REB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the REB (if applicable), in accordance with the REB and organizations conflict of interest policies (see SOP 105A).

When the delegated review is used, the REB Co-Chairs and/or REB member(s) who are assigned to the review can decide to approve the research or to request revisions to the research; the decision to disapprove the research must be made by the Full Board.

Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.

5.1. REB Decisions

5.1.1. REB decisions are made either by consensus or, if a consensus cannot be reached, by a majority vote of the REB members with voting rights who are present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies.

5.1.2. **Full Board Reviews.** The REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

Approval (approve the application as submitted, including the consent form):

- When initial review criteria required for approval are satisfied, the research may be approved as submitted.
- The approval date is defined according to the date of Full Board REB meeting.
- For studies reviewed via delegated review, the approval date is defined as the date of issue of the Certificate of Approval
- The expiry date of the REB approval is one year from the approval date.

Approval with Modifications/Clarifications:

- When initial review criteria required for approval satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval, the REB may recommend "Approval with Modifications/Clarifications",
- When the REB recommends "Approval with Modifications/Clarifications", the REB

Co-Chairs or designee will ensure that the additional information, modifications, or clarifications required are identified (at the REB meeting for Full Board review or by designated reviewers for delegated review) and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:

  - The REB Co-Chairs or designee alone,
  - The REB Co-Chairs and one or more named REB members that were present at the REB meeting or who submitted written comments on the application,
  - A sub-group of the REB members designated by the REB Co-Chairs or designee or by the REB.
  - A designated REB member or members with sufficient knowledge and experience regarding the research and the regulations.

- In deciding the procedures to be followed, the REB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it.
- Where the information or modifications are administrative, it is acceptable to delegate the consideration of that material to the REB Co-Chairs or designee alone,
- Where the additional information/modification is technical (e.g., statistical clarifications), the REB Co-Chairs or designee should review the information with consideration given to involving other REB members, such as the lead reviewer(s) or relevant expert member(s),
- If the Researcher's response is deemed complete and satisfactory by the REB Co-Chairs, designee or REB (as determined above), approval can be issued,
- If the Researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the Researcher,
- The reviewers may decide upon reviewing the Researcher's response that the decision should be deferred and that the application and the Researcher's response materials should be reviewed at a subsequent Full Board meeting (see 'Deferral' process below),
- The approval date is the date of issue of the certificate of approval. The expiry date of the REB approval is one year from this date; however, the approval letter is not issued until all of the conditions for approval have been met.

Deferral (defer decision-making on the application and continue the deliberation of the application at a future Full Board meeting):

- The REB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met,
- The REB Co-Chairs or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting,
- The revised protocol and the Researcher's response materials shall be reviewed at

a Full Board meeting

- Upon consideration of the research along with the response from the Researcher, at the Full Board meeting, the REB will issue its final decision (approved, approved with modifications, deferral or disapproved),
- Researcher responses must be received and reviewed at a Full Board meeting. The approval date is the date of issue of the certificate of approval. The expiry date of the REB approval is one year from the approval date; however the approval letter is not issued until all the conditions for approval have been met.

Disapproval:

- The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination,
- Disapproval cannot be decided through the delegated review mechanism.
- If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a Full Board meeting,
- The REB Co-Chairs or designee should ensure that the reasons for the disapproval are identified at the Full Board meeting for communication to the Researcher,
- If the research is disapproved, the reasons for disapproval will be communicated to the Researcher and the Researcher will be given an opportunity to respond in person or in writing.

5.1.3. **Delegated Reviews**:

- When the research qualifies for delegated review, the reviewer(s) has the authority to make the final decision, i.e. approve the application, require modifications to any aspect of the application, or to request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting,
- When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Co-Chairs or designee as well as all other designated reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met,
- If the research cannot be approved through the delegated review mechanism, it must be reviewed at a Full Board meeting.

5.2. Reconsideration and Appeal of REB Decisions

5.2.1. A Researcher may appeal the decision of the REB if the disagreement between the Researcher/applicant and the REB cannot be resolved through a reconsideration process at a Full Board meeting at which the Researcher/ applicant shall have the right to be heard;

5.2.2. The Researcher must justify the grounds on which a reconsideration of the decision is

requested. An appeal may be launched only for procedural or substantive reasons, and a final decision after reconsideration must be issued by the REB prior to the initiation of an appeal process;

5.2.3. Appeals are conducted in accordance with the established YukonU policy. The organization at which the appeal will take place will be determined on a case-by-case basis by the REB in consultation with the Researcher (and their affiliated organization);

5.2.4. The appeal committee shall have the authority to review negative decisions made by the REB and in so doing it may approve, disapprove or request modifications to the research proposal. Its decision shall be final and shall be communicated to the Researcher and the REB in writing.

5.3. Documenting REB Decisions

5.3.1. The REB meetings minutes will satisfy the applicable requirements;

5.3.2. The REB shall notify the Researcher in writing of its decision to approve or disapprove the proposed research, or of modifications/clarifications required to secure approval of the research;

5.3.3. If the REB defers its decision, the letter to the Researcher should include the issues of concern and what further information is required;

5.3.4. The final approval letter should include standard conditions of approval to which the Researcher must adhere (e.g. requirement to submit amendments prior to implementing changes to the protocol);

5.3.5. When the decision to approve a submission is recorded on behalf of the Full Board, or when a delegated reviewer electronically signs off on a decision (under delegated review procedures), the notification or correspondence to the Researcher may be issued by the Research Ethics Office Personnel

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 402	March, 2022	YukonU version adapted from N2/CAREB SOP 402.003 October 8, 2019 and CAREB SOP402.001 (2021)

Yukon University

SOP 403

Procedures: Human Research Ethics	SOP 403 Initial Review – Criteria for REB Approval
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 minimum requirements that research proposals involving human participants must meet in order to be approved by the Research Ethics Board (REB), independent of the review pathway (i.e., Full Board or delegated review).

2.0 SCOPE

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

3.0 RESPONSIBILITIES

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

REB members are responsible for determining whether the research meets the criteria for approval.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human participants must meet certain criteria before REB approval may be granted. Initial REB approval of the research is based on assessment of a complete submission to the REB. The REB and/or REB Office Personnel may consult the Researcher for additional information as necessary. The criteria are based on the guiding ethical principles of the Tri-Council Policy Statement 2 and are specified in this SOP.

Following initial review of the research, the REB should be prepared to make a determination as to the approvability of the research. In addition to REB approval, the requirements of the organization where the research will be conducted must also be met before the research can begin (e.g., department approvals, adequate resources, etc.).

5.1 Minimal Criteria for Approval of Research

In order for the research to receive REB approval, the REB will take the following into consideration:

5.1.1 The application has been authorized by the Researcher and, if applicable, by a designated YukonU official, indicating that the Researcher has the authority and qualifications to conduct the research;

5.1.2 Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data;

5.1.3 The research will generate knowledge that could be generalized and lead to improvements in health or well-being of individuals or society;

5.1.4 The methodology is appropriate with respect to the discipline and capable of answering the research question;

5.1.5 The risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk;

5.1.6 The risks to participants (if any) are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;

5.1.7 The selection of participants is equitable. In making this assessment, the REB will take into account the purpose of the research and the research setting. The REB will consider vulnerability of participant populations with respect to ethical reasons for their inclusion, as appropriate;

5.1.8 There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research;

5.1.9 When some or all of the participants, may be in situations or circumstances that make them vulnerable in the context of the research, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants;

5.1.10 Recruitment methods which respect the privacy of individual participants must be followed

5.1.11 The amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts and schedule is provided to participants when applicable;

5.1.12 Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable regulations and guidelines;

5.1.13 The informed consent process will accurately explain the research and contain the required elements of consent;

5.1.14 The informed consent process will be appropriately documented in accordance with the relevant policy;

5.1.15 Any waiver or alteration of the informed consent process must be properly justified and documented.

5.1.16 There will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research.

5.1.17 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.1.18 There will be adequate provisions for the timely publication and dissemination of the research results, unless there is an ethically acceptable reason for withholding publication or dissemination (e.g. Indigenous community control);

5.1.19 The resources required for successful completion of the study are committed (e.g., funding, space, personnel, etc.);

5.1.20 If applicable, the research has been or will be registered via an internationally recognized clinical trial registry and a registration number has been/will be submitted to the REB. If the research is not yet registered, the researcher shall provide the REB with the registration number upon registration.

5.2 Additional Criteria

5.2.1 The REB may require verification of information submitted by the investigator. The need to verify any information will be determined by the REB at a convened

meeting. The purpose of the verification will be to provide necessary protection to participants when deemed appropriate by the REB. Sources of external verification are detailed in SOP 404 and criteria for considering external verification are detailed in SOP 405;

5.2.2 Studies proposing access to or collection of personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to;

5.2.3 Additional criteria for research involving Indigenous peoples in Canada, or research on materials related to human reproduction, or genetic research, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with policies and/or Regulations.

5.3 Length of Approval Period

5.3.1 The REB shall review research at periods appropriate to the degree of risk and at least annually;

5.3.2 The REB may require review more often than annually when there is a high degree of risk to participants relative to the population;

5.3.3 The REB may consider reviewing the research more often than annually as required by the continuing review procedure.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 403	July 2022	YukonU version adapted from N2/CAREB SOP 403.003 (October 8, 2019) and CAREB SOP 403.001 (2021)

Yukon University

SOP 404

Procedures: Human Research Ethics	SOP 404 Ongoing REB Review Activities
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 procedures for REB review ongoing research activities that occur after the initial Research Ethics Board (REB) approval of a research project and prior to the formally scheduled continuing review of the research project.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

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

The Researcher is responsible for reporting to the REB any unanticipated issues or events that may arise or proposed changes that are needed through the course of the research that might affect the rights, safety and well-being of research participants.

When action is taken to ensure the protection of the rights, safety, and well-being of participants (e.g., for an unanticipated problem involving risks to participants or others) the REB is responsible for reporting to the Researcher and the Organizational Official(s) and has the authority to notify the sponsor and/or the appropriate regulatory authorities of any events that meet the reporting criteria. The REB may delegate regulatory authority reporting (as applicable) to the organization.

The REB Co-Chairs or designee is responsible for reviewing all reportable events submitted to the REB as well as any proposed amendments to the research, and for determining the type of review (i.e., delegated or Full Board) or action required.

The REB members are responsible for reviewing any new information, reportable events or proposed amendments that are assigned to them or that are assigned to a Full Board meeting, and for recommending the appropriate course of action.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Circumstances may arise during the course of research that may need to be reported to the REB and/or require that changes be made to the project. It may be that the real risk/benefit ratio can be evaluated only after the research has begun; therefore, in addition to the formally scheduled continuing review, the REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such information may include:

- Proposed amendments to the previously approved research,
- Reports of unanticipated problems involving risks to participants or others,
- Reports of any serious or continuing non-compliance,
- Deviations to the previously approved research,
- Adverse events that meet the reporting criteria,
- Reports of any privacy breaches,
- Any other new information that my affect adversely the safety of the research participants or the conduct of the research

Modifications to the approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the Researcher must notify the REB immediately.

5.1 Amendments to the Approved Research

5.1.1 The Researcher is responsible for submitting to the REB any changes to the approved research in the form of an amendment request. Changes to the approved research include modifications including (for example) modifications to the research, to the consent form,), changes in participant materials (e.g., recruitment materials), a change in the Researcher or research team, etc.;

5.1.2 When the amendment includes a change to the consent form, the Researcher must indicate their recommendation for the provision of the new information to current and/or past research participants;

5.1.3 Amendments must clearly explain the following:

- What aspects of the protocol, consent form, information sheet and/or recruitment materials are affected. The revised documents must be highlighted on an attached, revised document,
- The nature of the proposed change,
- The reason for the proposed change,
- Any increase in risk or discomfort for study participants, and why it is required,
- Any need for a change in the consent process,
- Whether previously or currently enrolled study participants need to be re-consented,
- Whether or not the amendment meets minimal risk criteria;

5.1.4 The Researcher must indicate the new level of risk the research poses by incorporating the changes. Supporting correspondence documentation and/or background information may be appended to the amendment submission;

5.1.5 The REB Co-Chairs or designee reviews the amendment to determine the appropriate level of REB review required (i.e., Full Board or delegated review);

5.1.6 The REB Co-Chairs or designee also may use delegated review procedures for review of amendments when the conditions are met (see SOP 401):

5.1.7 If the proposed change represents more than minimal risk, it must be reviewed by the REB at a Full Board meeting.

5.1.8 For amendments requiring Full Board review, the Research Ethics Coordinator assigns the amendment to the next available Full Board meeting. For amendments that meet the criteria for delegated review, the Research Ethics Coordinator will forward the amendment to the designated reviewer;

5.1.9 When an amendment involves a revised consent, the REB will consider the recommendations of the Researcher in determining if, how and when the new information should be provided to the research participants and whether re-consent is required;

5.1.10 The REB must find that the criteria for approval are still met in order to approve the amendment;

5.1.11 The amended research may not be implemented prior to the REB review and approval, except when necessary to eliminate immediate hazards to participants.

5.2 Unanticipated Issues

5.2.1 The Researcher is responsible for reporting any unanticipated issue or event that may increase the level of risk to participants or have other ethical implications for participants.

5.2.2 Any unanticipated issue that may increase the level of risk to participants or may impact participants' welfare should be reported immediately.

5.2.3 The researcher should indicate whether the unanticipated issue was directly related to the research and whether changes to the protocol are necessary to reduct the change of recurrence.

- The report submitted to the REB must include **all** of the following information:
  - The description of the serious and unexpected event(s),
  - All previous safety reports concerning similar adverse events,
  - An analysis of the significance of the current adverse event(s) in light of the previous reports, **and**
  - The proposed research changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the event(s),
- The individual AE reports or periodic safety updates or safety summary reports that meet the reporting criteria must be submitted to the REB in a timely manner;

5.2.4 If changes are necessary, an amendment request should be submitted in addition to the unanticipated event report.

5.3 Deviations to Previously Approved Research

5.3.1 The Deviations from the approved protocol that are necessary to eliminate an immediate risk(s) to the participants may be implemented immediately but must be reported to the REB at the earliest opportunity.

5.3.2 Deviations that occur through the course of research may impact the risk assessment of the research or have other ethical implications must be reported to the REB. If a permanent change is required, an amendment request should be submitted.

5.3.3 Minor deviations (e.g. typographical corrections of consent form, changes of wording on questionnaires) from the research that do not impact risk or have ethical implications may be summarized in annual status reports.

5.3.4 **Privacy Breaches**: The Researcher must report to the REB any unauthorized

collection, use, or disclosure of personal information (PI) including, but not limited to:

- The collection, use and disclosure of PI that is not in compliance with the jurisdictional legislation or its regulation,
- Circumstances where PI is stolen, lost or subject to unauthorized use or disclosure or where records of PI are subjected to unauthorized copying, modifications or disposal,
- In the Researcher context, any unauthorized collection, use or disclosure of PI that was not authorized under the research and approved in the plan that was submitted to the REB,

The breach must be reported to the REB and to the appropriate Organizational Official as soon as the Researcher becomes aware of the breach;

5.3.5 **Research Participant Complaint**: The Researcher must report to the REB, and to the University if required by the REB, a complaint from a participant when the participant reports concerns about their rights as a research participant or about ethical issues related to the research. Researchers are required to include the YukonU REB contact information on all consent forms given to participants.

5.4 Review of Unanticipated Event and Deviation Reports by the REB

5.4.1 The Research Ethics Coordinator will screen the adverse event forms submission for completeness.

5.4.2 Privacy breaches are reviewed by the REB Co-Chairs or designee, and any recommendations including remedial action are determined in consultation with the organization's privacy office. The privacy breach report is forwarded to the REB Co-Chairs or designee for review and final acknowledgement;

5.4.3 The Research Ethics Coordinator may route the submission back to the Researcher to request clarifications, missing documents or additional information;

5.4.4 The Research Ethics Coordinator will forward the submission to the designated REB reviewer(s);

5.4.5 The assigned REB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;

5.4.6 The assigned reviewer(s) may request further information from the Researcher;

5.4.7 When reviewing a reportable event, the REB should:

- Assess the appropriateness of any proposed corrective or preventative measures by the sponsor and/or Researcher,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or Researcher,
- Consider whether the affected research still satisfies the requirements for REB approval; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics approval of the research is warranted;

5.4.8 If the event does not raise concerns and does not appear to involve risks to research participants or others, the REB Co-Chairs or designee acknowledges the report, and no further action is required;

5.4.9 If the REB Co-Chairs or designee determines that the event meets the criteria for an unanticipated problem, and if immediate action is required to protect the safety of research participants, they may suspend ethics approval of the research pending review by the Full Board, providing the justification for such action is documented;

5.4.10 If the event raises concerns or involves risk to research participants such that REB action may be required, the item is added to the agenda of the next Full Board meeting;

5.4.11 For reports reviewed at a Full Board meeting, the REB determines whether further action is required. Possible actions that could be taken by the REB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,
- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency of continuing review,
- Observing the research or the consent process,

- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- Allegation of non-compliance or break of responsible conduct of research in accordance with YukonU policy and procedures
- If the REB determines that the event does not raise concerns about risks to research participants, the REB may decide that no further action needs to be taken;

5.4.12 When action is taken to ensure the protection of the rights, safety, and well- being of participants (e.g., for an unanticipated problem involving risks to participants or others) the REB Co-Chairs or designee is responsible for reporting to the Researcher and the University (as necessary) and has the authority to notify the sponsor and the appropriate regulatory authorities (as applicable).

5.5 Site Visits/Audits

5.5.1 The REBs have the authority to observe, or have a third party observe, the consent process of research it has approved, and to verify that the study is being conducted as required by the REB and within University and site-specific Policies and Procedures as appropriate. Under the direction of the Office of Research Ethics, including but not limited to third parties not affiliated with the institution, may perform site visits to verify information in the initial study application or in any continuing review submissions;

5.5.2 The REB will consider the following criteria to determine if a site visit is required:

- The research involves vulnerable populations or high-risk procedures,
- The Researcher has a history of serious or continuing non-compliance related to continuing review in the past three years,
- The REB has reason to doubt the veracity of the information provided by the Researcher,
- The information provided by the Researcher is inconsistent with other information known to the REB and the inconsistency cannot be resolved through communication with the Researcher,
- Any other reason where the REB believes verification should be required.

5.6 External Verification

5.6.1 YukonUs REB may utilize sources other than the Researcher to identify information that may affect projects currently under their oversight. Those sources include but are not limited to the University, including the Researcher's supervisor, media reports, participant complaints, research staff informants, site visit reports and the Internet;

5.6.2 The following avenues provide YukonUs REB with information that is supplemental to the information provided by the Researcher:

- YukonUs site visit/continuing review procedure,
- YukonU Office of Research Ethics is in direct contact with YukonU officials responsible for handling all allegations of research misconduct. Research Ethics Office is notified in the event that a Researcher has his or her privileges revoked, or has otherwise been disciplined or investigated by the Institution regarding the conduct of the research,
- YukonUs REB are often directly contacted by research sponsors who notify the Boards of relevant information when appropriate.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 404	August 2020	YukonU version adapted from N2/CAREB SOP 404.003 (October 8, 2019) and CAREB SOP 401.001 (2021)

Yukon University

SOP 405

Procedures: Human Research Ethics	SOP 405 Continuing 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, Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the continuing review of research that is overseen by the Research Ethics Board (REB), and the criteria for continued REB approval.

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.

The REB Co-Chairs or designee and REB members are responsible for reviewing the submitted materials and reviewing continuing review submissions and respective materials as appropriate for Full Board or delegated review. The REB members should review each research application in enough depth to be prepared to discuss the research meaningfully at a Full Board meeting.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The YukonU REB must conduct continuing review of approved research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. The YukonU REB make the determination concerning the the interval by which continuing review must occur at the time of the initial review and approval.

5.1 Continuing Review by the Full Board

5.1.1 The Researcher is required to submit an application for continuing review of research at a frequency to be determined by the REB and which will be defined at the time of the initial approval of the research, or as otherwise revised;

5.1.2 At a minimum, the REB requires that an application for continuing review be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the REB;

5.1.3 The REB requires continuing review progress reports on an annual basis unless they designate otherwise;

5.1.4 The REB may determine that the research requires continuing review more frequently than once per year by considering the following:

- The nature of any risks posed by the research,
- The degree of uncertainty regarding the risks involved,
- The vulnerability of the participant population,
- The projected rate of enrolment and estimated research closure date,
- The REB believes that more frequent review is required;

5.1.5 Continuing review applications are due by the deadline for the applicable REB meeting. Submissions must provide sufficient time to be reviewed and approved prior to the date of expiry of approval, regardless of the type of review they may undergo;

5.1.6 To assist the Researchers in submitting on time, a courtesy reminder(s) prior to the expiry date may be generated;

5.1.7 The Research Ethics Coordinator reviews the application for completeness, and requests any clarifications, missing documents or other information from the Researcher, as applicable;

5.1.8 The REB may request verification from sources other than the investigator that no material changes have occurred since previous REB review. For example:

- Based on the results of a previous audit or inspection (internal or external),
- Suspected non-compliance,
- Studies involving vulnerable populations,
- Studies involving a potentially high risk to participants,
- Suspected or reported protocol deviations,
- Participant or Research Staff complaints,

- Any other situation that the REB deems appropriate;

5.1.9 The Research Ethics Coordinator will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review;

5.1.10 A summary report of the continuing review applications assigned to the REB meeting may be attached to the REB meeting agenda;

5.1.11 For research that meets the criteria for Full Board review, the REB will discuss the research at a Full Board meeting and will make a decision regarding the continued approval of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

5.2 Continuing Review by Delegated Review Procedures

5.2.1 When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;

5.2.2 Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met (see SOP 401);

5.2.3 The Research Ethics Coordinator reviews the continuing review application for completeness, including verification of the currently approved informed consent form(s), and requests any clarifications, missing documents or other information as applicable;

5.2.4 The Research Ethics Coordinator will forward the application to the appropriate REB reviewer(s) if applicable;

5.2.5 The reviewer(s) may request additional information or clarification, as necessary, and will make a decision regarding the continued approval of the research and the continued conduct of the research;

5.2.6 Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

5.3 REB Determinations

5.3.1 To grant a continuation of the approval of the research the REB must determine that Criteria for REB Approval (as described in SOP 402) are still met including:

- There have been no material changes to the research or to the informed consent form that have not been previously submitted and approved,
- There is no new conflict of interest or new information that has emerged that

might adversely affect the safety or the well-being of research participants,
- Risks to research participants are minimized and reasonable in relation to the anticipated benefits,
- Selection of research participants is equitable,
- Informed consent processes continue to be appropriate and documented,
- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data,
- Any complaints from research participants have been followed-up appropriately;

5.3.2 The REB may also make additional determinations (as per SOP 402, REB Review Decisions), including:
- Request changes to the informed consent form(s),
- Request changes for the continuing review interval (based on risks),
- Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period),
- Require modifications to the research,
- Suspend or terminate REB approval.

5.3.3 YukonU REB has the authority to determine which research activities require verification from sources other than the Researcher. This may be during the conduct of the research project in the course of on-going review or at the time of annual renewal;

5.3.4 The criteria that the REB will use to determine if such third party verification is required shall include, but not be limited to:
- If information provided by the researcher is internally inconsistent or inconsistent with other information known to the REB, and the inconsistency cannot be satisfactorily resolved by communications with the investigator,
- If the REB has reasons to doubt the veracity of the information provided by the investigator,
- If the investigator has a history of serious or continuing non-compliance with continuing review requirements in the past two years, or
- If the REB has other reasons in which it believes that verification from sources other than the investigator that no material changes have occurred since prior REB review is required;

5.3.5 If the Board determines that external verification is required, it will direct REB staff to obtain verification from sources other than the investigator that no material changes have occurred since prior REB review and to report back at a future convened meeting.

5.4 Continuing Review Applications not Received by the Expiry Date

5.4.1 Approvals shall expire on the anniversary date of their original approval as stated on the letter of approval and certificate.

5.4.2 If an application for continuing review is not submitted with all the required information by the expiry date, a warning or suspension notice will be issued to the Researcher. When suspended, the Researcher must suspend all research activities as specified by the REB. The Research Ethics Coordinator will follow-up with the Researcher to ensure that the application for continuing review is submitted as soon as possible;

5.4.3 No research-related activities may occur after the approval expiration date unless the Principal Investigator contacts the REB and a determination is made that it is in the best interest of individuals to continue during the lapse in REB approval;

5.4.4 In the event of a lapse in REB approval and the Researcher wants to continue with the research, the REB may allow the Researcher to submit an application for continuing review after the expiry date. The Researcher should provide as much detail as possible about the proposed continued activities. The REB will review the request as quickly as possible and the Researcher may resume the suspended activities once approval of the research is issued. The lapse in approval will be documented.

5.4.5 The Researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses.

5.4.6 The REB may define a reasonable length of time for which a Researcher may submit an application for continuing review (renewal), beyond which the research is closed a renewal application will not be accepted. A new submission will be required.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 405	July 2022	YukonU version adapted from N2/CAREB SOP 405.003 (October 8, 2019) and CAREB SOP 405.001 (2021)

Yukon University

SOP 406

Procedures: Human Research Ethics	SOP 406 Research Completion
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 procedures for the completion of research with the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to 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.

The REB Co-Chairs or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The Completion of research is a change in activity that must be reported to the REB. Although research participants will no longer be "at risk" under the study, a final report/notice allows the REB to close its files in addition to providing the REB with information that may be used in the evaluation and approval of related studies.

5.1 Determining when Research is complete

5.1.1 The Researcher may submit a study closure report to the YukonU REB when there

is no further participant recruitment or involvement, all new data collection is complete, no further contact with participants is expected, and the research objectives have been met. Other criteria may be determined as per YukonU policy;

5.1.2 The Research Ethics Coordinator will review the study closure application and request any outstanding information, clarification or documentation from the Researcher, if needed;

5.1.3 The REB Co-Chairs or designee will review the submission and issue a letter of Acknowledgement to the Researcher that the protocol file is "*complete*";

5.1.4 Once a research project is "*Complete*" with the REB, no further ethics submissions for that research are required; however, the Researcher still may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB, (e.g. adverse event reports, changes to data management plan);

5.1.5 If the sponsor requests additional data following the closure of the research, a request for approval shall be made to the REB and the conditions of this request will be determined at the time of the review.

5.2 Content of Notification of Study Closure Report

5.2.1 The completion of study form should include

- Principal Investigator's affirmation that participant data collection is completed,
- Total number of research participants enrolled in the study
- Final disposition/storage of all research-related study documents,
- The final disposition of any electronic data,
- End of study summary report
- Any other information relevant to the REB

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 406	July 2022	YukonU version adapted from N2/CAREB SOP 406.003 (October 8, 2019) and CAREB SOP 406.001 (2021)

Yukon University

SOP 407

Procedures: Human Research Ethics	SOP 407 Suspension or Termination of REB Approval
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 procedures associated with the suspension or termination of the Research Ethics Board's (REB) approval of research.

2.0 SCOPE

This SOP pertains to all research submitted to the YukonU REB for the review of human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB approval for the research being considered.

The Researcher is responsible for notifying the REB and the organization of any suspensions or terminations of the research and for providing a detailed explanation for the action.

The REB Co-Chairs or designee are/is not authorized to terminate REB approval; however, the REB Co-Chairs or designee is authorized to suspend REB approval, which must be reported to the REB at its next Full Board meeting. The REB is authorized to terminate REB approval following its review at a Full Board meeting.

The REB Co-Chairs or designee shall notify the Researcher, and the appropriate YukonU Official(s), of any suspension or termination of REB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB approval if the risks to the research participants are determined to be unreasonably high; for example, cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Researcher is not conducting the research in compliance with applicable regulations and guidelines. The REB also has the authority to suspend new enrollment while additional information is requested.

A decision to suspend or to terminate the REB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

The REB has the authority to suspend or to terminate the REB's approval of the research. The REB Co-Chairs or designee have/has the authority to suspend ethics approval. Any requests to lift a suspension or to re-approve the research must be reviewed by the Full Board.

A Researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of REB approval.

5.1 Suspension or Terminations of Research by the Sponsor

5.1.1 Research may be suspended or terminated by the REB or by the researcher for a variety of reasons, e.g., following results of interim analyses, in response to safety or privacy concern, due to pre-planned stopping criteria, etc.;

5.1.2 The Researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action;

5.1.3 Reports of suspensions or terminations of the research by the sponsor will be forwarded to the REB Co-Chairs or designee for review;

5.1.4 If the REB Co-Chairs or designee decide(s) to suspend REB approval of the research, they must notify the REB at its next Full Board meeting;

5.1.5 If REB approval is suspended, a subsequent review must be conducted and the REB suspension must be lifted prior to resumption of the research following the sponsor's

lifting of a suspension.

5.2 Suspension or Termination of REB Approval

5.2.1 If any concerns are raised during the REB's oversight of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with the REB-approved protocol or REB requirements,
- The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications),
- Repeated or deliberate failure to properly obtain or document consent from research participants,
- Repeated or deliberate failure to comply with conditions placed on the research by the REB, by the sponsor, or by regulatory agencies,
- Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;
- In accordance with an ongoing allegation or finding of a breach of responsible conduct of research, as determined through the Organization's policy and procedures.
- Any other non-conformity which the REB or the University considers to have serious implications to the safety of the participants or the integrity of the study

5.2.2 The REB Co-Chairs or designee are authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, they must notify the REB at its next Full Board meeting;

5.2.3 If a Yukon University official suspends approval of research they must notify the REB as per applicable requirements;

5.2.4 If a YukonU official suspends approval of the research, the Principal Investigator shall be notified of the requirement to suspend the study, the reasons for the suspension and the requirement that the REB be notified immediately

5.2.5 The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;

5.2.6 Prior to suspending or terminating REB approval, the REB must consider:

- Risks to current participants,
- Actions to protect the safety, rights and well-being of currently enrolled participants,
- The appropriate care and monitoring of research participants,
- Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- Whether participants should be informed of the termination or suspension,
- Whether adverse events or outcomes should be reported to the REB,
- Identification of a time frame in which the corrective measures are to be implemented;

5.2.7 The REB Co-Chairs or designee will notify the Researcher of any suspensions or terminations of REB approval, and the reasons for the decision;

5.2.8 Unless otherwise stated by the REB, when the REB Co-Chairs or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;

5.2.9 If the research is suspended or terminated, the REB Co-Chairs or designee will issue a formal letter to the Researcher with the reason(s) for the REB action and will enter into a dialogue with the Researcher concerning corrective measures proposed by the REB;

5.2.10 If REB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the REB's satisfaction.

5.2.11 In the event of such a suspension or termination, the REB will take appropriate actions to protect the rights and welfare of the currently enrolled participants in suspended or terminated research.

5.3 Reporting Suspensions or Terminations

The REB Co-Chair or designee will report any suspension or termination of REB approval to the Associate Vice-President Research.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 407	July 2022	YukonU version adapted from N2/CAREB SOP 407.003 (October 8, 2019) and CAREB SOP407.001 (2021)

Yukon University

SOP 409

Procedures: Human Research Ethics	SOP 409: Reconsideration of REB Decisions and Appeal Process
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

The purpose of this standard operating procedure (SOP) is to describe the process by which a Researcher may seek reconsideration of a Research Ethics Board (REB) decision, and ultimately, appeal the REB decision to the Research Ethics Appeal Committee (REAC).

2.0 SCOPE AND AUTHORITY

These procedures apply to all research proposals involving human participants or human biological materials where the researcher does not receive ethics approval or conditional approval based on the ethical acceptability of the research proposal.

3.0 RESPONSIBILITIES

The AVPR, REB Co-Chairs, REB Coordinator and/or REB delegate are responsible for executing, overseeing the implementation, administration and interpretation of these procedures.

4.0 DEFINITIONS

See the Glossary of Terms

5.0 PROCEDURES

The YukonU REB is guided by the principles of natural justice in their decision-making. In fulfilling their mandate, the YukonU REB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. The REB encourages on-going collegial and collaborative discussions with the Researcher/PI, through the REB Co-Chairs and/or REB Coordinator relating to the submission of research proposals. In the

event of a disagreement between the PI and REB over a decision regarding research proposal that cannot be resolved through discussion, the PI is entitled to reconsideration by the REB (Article 6.18 TCPS2 2018). If the reconsideration does not resolve the disagreement, the PI may appeal the REB decision in accordance with these procedures (Article 6.19, TCPS2 2018).

5.1 Reconsideration

5.1.1 A Researcher/Principal Investigator (PI) may request, and the REB has an obligation to provide, prompt reconsideration of the REB's decision. Initial reconsideration may be by way of informal discussions between the Researcher and the Co-Chairs of the REB;

5.1.2 If the matter is resolved through this informal process, the resolution will be documented by the Research Ethics Office and will also be reflected in the ethics application and study materials as appropriate;

5.1.3 If informal discussions do not result in a resolution of the issues, the Researcher may request formal reconsideration. In order to receive formal reconsideration, the Researcher shall submit a written request to the REB;

5.1.4 Reconsideration will take place at the next regularly scheduled Full REB meeting;

5.1.5 The onus is on researchers to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by TCPS2 or University Policy;

5.1.6 The Researcher may provide additional information for the Board's consideration, and may also attend the Full Board Meeting in person; however, the Researcher shall not be present during the REB's deliberation;

5.1.7 The Researcher shall submit any additional information for consideration on or before the application deadline for the next available Full REB meeting;

5.1.8 The Researcher and the REB must have fully exhausted the formal reconsideration process and the REB must have issued its final decision before the Researcher may initiate an appeals.

5.2 Notice of Appeal

5.2.1 If, after the completion of the relevant REB's reconsideration, a Researcher is still not satisfied with the decision made by a REB, the Researcher may seek an appeal of

that decision by sending a written Notice of Appeal to the Research Ethics Coordinator who has been delegated authority by the Associate Vice President Research (AVPR) to receive and manage appeals as outlined in this SOP;

5.2.2 The written Notice of Appeal must be filed with the Research Ethics Coordinator within thirty (30) working days of the final decision being received by the Researcher;

5.2.3 The appeal process is NOT a forum to merely seek a second opinion of the REBs decision. Instead, the Notice of Appeal must clearly state the grounds on which the appeal is being made and should be accompanied by supporting documentation. Such supporting documentation may include (but is not limited to):

5.2.3.1 The original ethics application,
5.2.3.2 The original REB decision,
5.2.3.3 All subsequent written communications between the REB and the Researcher,
5.2.3.4 Documents and records, including a copy of the funding proposal (if appropriate),
5.2.3.5 Relevant references or copies of pertinent guidelines, internal and external policies, and legislation;

5.2.4 An appeal may be based on:

5.2.4.1 procedural grounds (e.g., alleged noncompliance with the REB's terms of reference or procedures). A procedural error that materially and adversely influenced the decision of the originating REB, including real or reasonably apprehended bias, or undeclared conflict of interest on the part of one or more members of the REB, or
5.2.4.2 substantive grounds (e.g., alleged noncompliance with a specific article of the TCPS2 or a relevant regulation or guideline);

5.2.5 The Research Ethics Coordinator will acknowledge receipt of the Notice of Appeal in writing and forward a copy of the written Notice of Appeal to the Vice-President Research and the Co-Chairs of the REB;

5.2.6 The Chair of the REB will within fifteen (15) working days from the date the REB Coordinator received the Notice of Appeal provide written acknowledgement of the Notice of Appeal and, if the Co-Chairs of the REB deems it necessary, a response and documentation clarifying the REB's decision;

5.2.7 The Co-Chairs of the REB will send the response and documentation to the Research Ethics Coordinator, who in turn will forward a copy to the AVPR, the Coordinator of Research Ethics, and the Researcher.

5.3 Composition of the Research Ethics Appeal Committee

5.3.1 Upon receipt of a Notice of Appeal, the Research Ethics Coordinator will contact the Aurora College Research Ethics Manager to request the review by their Research Ethics Committee who have agreed to serve as the Research Ethics Appeal Committee for the purpose of reviewing the appeal;

5.3.2 The composition of the Appeal Committee is that of the Aurora College Research Ethics Committee (REC) and reflects the required range of expertise and knowledge for an REB whose decision is being appealed, and must also meet the procedural requirements of the Tri-Council Policy Statement (TCPS2) and Yukon University policy;

5.3.3 Specifically, the Appeal Committee shall consist of at least five (5) members, of whom:

a) at least 2 members shall have broad expertise in the methods or in the areas of research that are covered by the relevant REB,
b) at least one member shall be knowledgeable in ethics, and
c) at least one member shall have no affiliation with the Institution, but shall be recruited from the community served by the institution;

5.3.4 The Appeal Committee may appoint ad hoc experts as required;

5.3.5 Members of the Appeal Committee must all be free of conflicts of interest in relation to the study under appeal. In addition, no member of the Appeal Committee may be a member of the REB whose decision is under appeal, or can have been a member of the REB when the decision being appealed was made;

5.4 The Appeal

5.4.1 The onus is on the Researcher who filed the Notice of Appeal to justify the grounds of the appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS2, relevant regulations or guidelines, or YukonU policy;

5.4.2 The Appeal Committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final;

5.4.3 The Research Ethics Coordinator will assemble and distribute the Notice of Appeal and supporting documentation (including the REB minutes pertaining to the submission) to the appeal Committee for review, with a copy to the REB Co-Chairs whose decision is under review and the Researcher;

5.4.4 A meeting of the Appeal Committee, with provision for presentations by both the Researcher and the REB Co-Chairs (or other representative of the REB as delegated by the Co-Chair), will be organized by the Office of Research Ethics and held within **sixty (60) days** of receipt of the Notice of Appeal by the Research Ethics Coordinator. Both parties may be accompanied by a colleague of their choice who will not participate in the meeting; Attendance of the YukonU REB Co-Chairs and Researcher will be done via remote methods.

5.4.5 Meetings of the Appeal Committee will be conducted in accordance with the principles of natural justice. Both the Researcher and the REB representative have the right to speak to issues raised in the Notice of Appeal and supporting documentation and the Appeal Committee may ask questions throughout the process. Neither party shall be present when the Appeal Committee deliberates and makes a decision;

5.4.6 The majority decision of the Appeal Committee will be final and binding and will normally be communicated within thirty (30) days of the meeting;

5.4.7 The Chair of the Appeal Committee will communicate the decision of the Appeal Committee in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Researcher, the Co-Chairs of the REB, the AVPR and Research Ethics Coordinator;

5.4.8 The Co-Chairs of the REB will be responsible for any implementation and follow up required through the REB.

6.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.13, 6.18, 6.19, 6.20

7.0 REFERENCES

See References.

8.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 409	July 2022	YukonU version adapted from University of British Columbia (UBC) SOP 409 and Ontario Tech University REB SOP 212

Yukon University

SOP 501

Procedures: Human Research Ethics	SOP 501: REB Review During Publicly Declared Emergencies
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 research ethics review procedures during a publicly declared emergency.

2.0 SCOPE

This SOP pertains to 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

A publicly declared emergency is an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official in accordance with legislation and/or public policy. Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters and humanitarian emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research initiated as a result of the emergency. Potential research participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so.

During publicly declared emergencies, the REB must have established procedures to continue to provide the necessary research ethics oversight. Research ethics review during publicly declared emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, REBs might not be able to meet in person, and delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to current ongoing research. The existence of an emergency does not override established procedures to protect the welfare of research participants. Any relaxation of the usual procedural requirements for review should be proportionate to the complexity and urgency of the emergency, as well as to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified.

5.1. Determining Scope of Emergency

5.1.1. Subsequent to an officially publicly declared emergency, the REB Co-Chairs or designee will assess the scope of the emergency with respect to:

- Potential and current participants as individuals and communities
- Researchers
- REB members
- Yukon University (YukonU) infrastructure, and
- Research ethics review procedures;

5.1.2. Determining the scope of the emergency may involve consultation with YukonU officials and other representatives, researchers, REB members and Research Ethics Coordinator;

5.1.3. Scope of the emergency may assist the REB Co-Chairs or designee in determining the level of impact;

5.2. Determining the Level of Impact

5.2.1. Subsequent to a publicly declared emergency, the REB Co-Chairs or designee will assess the level of impact on the research ethics review procedures. The assessment will consider factors including (but not limited to):

- Whether the publicly declared emergency affects some or all of the research reviewed by the REB, including:
  - The review of ongoing research that is unrelated to or not arising from the publicly declared emergency,
  - The review of new research that is unrelated to or not arising from the publicly declared emergency, and
  - The review of research that arises from or is related to the publicly declared emergency,
- The nature of the risks imposed by the publicly declared emergency on research participants, communities, the REB, REB Ethics Coordinator and YukonU,

- Potential impact on YukonU resources or infrastructure (e.g. online systems, electricity, access to buildings),
- What research is considered “essential” during the emergency, and
- The potential duration of any alterations in review procedures, if predictable.

5.2.2. There are three levels of impact that may influence how ethics review will be conducted during the publicly declared emergency:

- **Mild** – little or no impact,
- **Moderate** – some impact; decisions to proceed at the discretion of the Co-Chairs or designee, in consultation with the Researcher, as necessary,
- **Severe** – extremely debilitating to normal research ethics review procedures;

5.2.3. The REB Co-Chairs or designee will use the level of impact to guide the review of research submissions during the publicly declared emergency;

5.2.4. Pending the determination of the level of impact on the review of ongoing or new research, the currently established ethics review procedures should be followed.

5.3. Emergency Preparedness Procedures

5.3.1. Subsequent to an officially publicly declared emergency, the ability for standard ethics review procedures will be evaluated by the REB Co-Chairs or designee and Research Ethics Coordinator. Temporary ethics review processes may be instituted, if necessary;

5.3.2. When the impact on the ethics review processes is deemed to be severe and the scope to include members of the REB, teleconferences or videoconferences may be used to conduct REB meetings;

5.3.3. When the impact on the ethics review processes is deemed to be severe, the Research Ethics Coordinator may conduct their activities remotely, if it is possible to do so (via remote access to email, mobile phone and voice mail access), with minimal disruption of services;

5.3.4. If the impact is deemed severe, the scope includes members of the REB and teleconferencing, videoconferencing or online access are not available, an REB subcommittee may be established for the duration of the publicly declared emergency. The REB Co-Chairs or designee may suspend the currently established REB meeting quorum, in which case an REB subcommittee would be established for the duration of the publicly declared emergency;

5.3.5. The REB subcommittee composition should be in accordance with the standard REB membership requirements and should include at least five members drawn from the existing REB membership;

5.3.6. The current REB Co-Chairs or designee should serve as the Chair of the REB subcommittee;

5.3.7. At their discretion, the REB subcommittee Chair or designee may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available to the REB subcommittee; however, ad hoc advisors may not contribute directly to the subcommittee's decision and their presence shall not be used in establishing a quorum;

5.3.8. When the impact is deemed to be severe, the REB Co-Chairs or designee may refer the ethics review and research oversight of new and ongoing research to another REB, subject to the applicable regulations and agreements;

5.3.9. Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the REB Co-Chairs or subcommittee Chair or designee will use their judgment in determining the type of review required (delegated or Full Board), taking into account the severity of the impact of the emergency and the complexity and urgency of the submission;

5.3.10. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified;

5.3.11. The REB Co-Chairs or designee should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly;

5.3.12. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency will cease as soon as is feasible after the emergency has officially ended (i.e., as declared by an authorized public official). The REB Co-Chairs or designee will determine when to resume routine ethics review processes;

5.3.13. All delegated approvals of research following a publicly declared emergency must be assessed to determine if subsequent Full Board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency;

5.3.14. At the conclusion of the publicly declared emergency, the REB Co-Chairs or designee and the Research Ethics Coordinator should work with the REB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

5.4. Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency

5.4.1. When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the following will apply to the review of ongoing research:

- The REB Co-Chairs or designee will determine if the scope of the emergency may include the research participants as individuals or as part of a community
- The REB Co-Chairs or designee will determine if the research needs to continue, or if it can be postponed until after the emergency is over,
- The research may continue at the discretion of the REB Co-Chairs or designee in consultation with the Researcher, as necessary,
- Researcher's response to REB reviews, major amendments, and adverse events will be prioritized for review,
- Continuing reviews will receive the next priority for review, followed by research completion reports,
- Other submissions will be reviewed as time allows;

5.4.2. When the impact of the publicly declared emergency on ethics review is determined to be severe, the following will apply to the review of ongoing research:

- Research activities not involving, or no longer involving, recruitment or direct contact with participants may continue,
- Research activities involving recruitment or direct contact with participants may only continue if ceasing such activity might pose significant risks to participant safety,
- Major amendments and adverse events related to these studies will be reviewed by the REB subcommittee or the REB subcommittee Chair or designee, as appropriate;

5.4.3. At the REB Co-Chairs or designee's discretion, and subject to applicable regulations, review procedures may be delayed or temporarily suspended depending upon volume. In such cases, research shall be deemed to have continuing approval until such time that the REB is able to conduct its review.

5.5. Review of New Research NOT Related to or Arising from the Publicly Declared Emergency

5.5.1. When the scope of the emergency is contained and impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the REB Co-Chairs or designee will determine whether review of any new research not related to the publicly declared emergency may proceed or will be postponed until after the emergency is over;

5.5.2. When the scope of the emergency is large or uncontained and the impact of the publicly declared emergency on ethics review processes is determined to be severe, any new research not related to the publicly declared emergency will not be reviewed until the emergency is declared to be over.

5.6. Review of Research RELATED to or Arising from the Publicly Declared Emergency

5.6.1. Researchers whose research focuses on publicly declared emergencies are encouraged to submit general protocols for conditional approval prior to emergencies to facilitate time-imperative REB approval;

5.6.2. If a request to review research related to a publicly declared emergency is received, it will be directed to the REB Co-Chairs or REB subcommittee Chair or designee, as applicable;

5.6.3. The REB Co-Chairs or designee will assess the risks associated with the proposed research, as well as aspects of the research that might require enhanced scrutiny or diligence, taking into account the severity of the impact of the emergency on ethics review procedures;

5.6.4. When the impact of the publicly declared emergency on ethics reviews is determined to be mild to moderate, research related to the publicly declared emergency has priority for review;

5.6.5. When the impact of the publicly declared emergency on ethics review is determined to be severe, time-sensitive review processes may be followed, such as delegated review as appropriate, review by an REB subcommittee, and/or meetings conducted via teleconference or videoconference. These alterations may be limited to the review of the research related to the publicly declared emergency;

5.6.6. The REB may implement any/all of the emergency preparedness procedures as deemed appropriate to the research/emergency.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 501	July 2022	YukonU version adapted from N2/CAREB SOP 501.003 October 8, 2019 and CAREB SOP 501.001 (2021)