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 Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.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)