

Procedures: Human Research Ethics**SOP 301 Submission Requirements and Administrative 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 Research Ethics Board (REB) submission requirements and the document review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research, renewal applications for ongoing research and completion reports.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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

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

approval.

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

5.1 Submission Requirements for Initial Review

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

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

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

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

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

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

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

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

5.2 Submission Requirements for Continuing Review

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

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

5.3 Document Review Procedures

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

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

- 5.3.3** If the REB or Research Ethics Coordinator determines that the submitted documents are not complete (e.g. missing documents or information), investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No substantively incomplete submission will be reviewed by the REB.
- 5.3.4** The Research Ethics Coordinator will follow up with the Principal Investigator or Principal Applicant to request the required information for inclusion with the submission;
- 5.3.5** Upon receipt of a complete submission, the REB and Research Ethics Coordinator identifies any outstanding items that will be required to issue approval, as applicable;
- 5.3.6** For submissions requiring Full Board review, the Research Ethics Coordinator posts the submission to the agenda of the next Full Board meeting.
- 5.3.7** For submissions reviewed via delegated review procedures, the Research Ethics Coordinator puts out a call for reviewers. The REB Co-Chairs in consultation with the Research Ethics Coordinator then determines a reviewer(s) and provides them with the submission for their review.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 301	July 2022	YukonU version adapted from N2/CAREB SOP 301.003 (October 8, 2019) and CAREB SOP301.001 (2021)