

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)