Yukon University

SOP 601

Procedures: Human Research Ethics	SOP 601 Communication – Researcher
Associated Policy	Human Research Ethics Policy AR-03
Procedure Holder	Associate Vice President Research
Executive Lead	Research Services
Approval Authority	President
Original Date	Replaces AR-03 procedures (May 2009, Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

This standard operating procedure (SOP) describes routine communication procedures between the Research Ethics Board's (REB) and the Researcher and with their research team.

2.0 SCOPE

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

For effective human research participant protection, it is important for the REB, Research Ethics Coordinator, Researcher and research team to maintain open communication. This applies not only to communication related to a specific research project, but also to communication related to questions, concerns, ethical issues and REB processes, policies and procedures. Feedback from Researchers should be encouraged and should be considered as an opportunity to review and to improve the function of the REB and of the Research Ethics Office procedures.

In order to facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures. All REB decisions regarding specific research projects shall be documented in writing. Informal communications

between the Researcher or research team and REB Co-Chairs or Research Ethics Coordinator may occur through email, over the phone or in person. Documentation should be created to ensure accurate reflection of discussions for future reference. All Researchers participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.

5.1 Notification of REB Decisions

5.1.1 The REB will notify the Researcher and/or their research staff of the REB's decision within 2 weeks following the review (i.e., from the REB meeting or delegated review) date of new research, modifications, or amendments to currently approved research, applications for continuing review or unanticipated events;

5.1.2 The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);

5.1.3 If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Co-Chairs or designee will notify the Researcher of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow;

5.1.4 The REB Co-Chairs or designee will review the draft REB review letter, make revisions as necessary, and will indicate their approval;

5.1.5 The REB review letter will be sent to the Researcher(s);

5.1.6 The Researcher may be asked to include the REB number or title to the research in all subsequent correspondence with the REB;

5.1.7 Upon receipt of the Researcher response to the REB review letter, the REB or Research Ethics Coordinator will follow-up with the Researcher and/or their staff to request any additional clarifications as needed, or as requested by the REB Co-Chairs or designee, or the reviewers;

5.1.8 Once all of the REB conditions are satisfied, the REB will issue a Certificate of Approval. Included in the Certificate of Approval is the study title and REB number, name of Principal Investigator and any co-investigator(s), and team members, funding agency, study sites and a list of approved documents with version numbers if applicable.

5.2 Researcher Consultation

5.2.1 A Researcher and/or research team may request advice, guidance or clarification with the REB Co-Chairs, designee or Research Ethics Coordinator for current for future research projects. Such consultations may involve communications through email, phone or in person.

5.2.2 REB Co-Chairs, designee or Research Ethics Coordinator will document such consultations in writing, including date, who was present and a brief description of what the concerns were and how they were addressed. Such documentation should be kept by the Research Ethics Coordinator for future reference if needed.

5.2.3 A Researcher may request a reconsideration or appeal the decision of the REB and/or any of the revisions to the research requested by the REB;

5.2.4 Appeals are conducted in accordance with established YukonU procedures (SOP 409) and the agreements that are established with other REBs for appeals review;

5.2.5 Only the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

5.3 Communications Concerns Non-compliance

Researcher non-compliance may be the result of communication difficulties. The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized.

However, if it appears that a Researcher is intentionally non-compliant with the protocol, SOPs, TCPS2, REB, and/or other applicable requirements, the REB, through the REB Co-Chairs or designee, will notify the Researcher in writing, detailing the alleged non-compliance, specifying corrective action, and stating the consequences. Such actions may be the result of an onsite audit conducted by the Research Ethics Office. When appropriate, copies of such correspondence shall also be sent to the Researcher's supervisor and/or Department Head, study Sponsor/Funding Agency and the Associate Vice-President Research.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 601	July 2022	YukonU version adapted from N2/CAREB SOP 601.003 (October 8, 2019) and CAREB 601.001 (2021)