

Procedures: Human Research Ethics**SOP 108 Standard Operating Procedures Maintenance****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 establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

2.0 SCOPE

This SOP pertains to the YukonU 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

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

5.1. Development, Review, Revision and Approval of Policies & Procedures

- 5.1.1. The Research Ethics Coordinator or designate will review the SOPs at least once every two years. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;
 - 5.1.2. SOPs may be revised for reasons including, but not limited to: changes to policies, regulations or guidelines, new policies, or changes to REB or administrative practices;
 - 5.1.3. The Research Ethics Coordinator or designee will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of “DRAFT version date” and removal of the previous “Final Version Date”;
 - 5.1.4. The revised SOP(s) will be circulated to the REB Office Personnel and REB Co-Chairs or designee, as well as REB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;
 - 5.1.5. Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the “Final Version Date”. The history of revisions will be recorded in the ‘SOP History’ section of each SOP;
 - 5.1.6. Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.
- 5.2. Distribution and Communication**
- 5.2.1. New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the ‘Responsibilities’ section of each SOP;
 - 5.2.2. The SOPs will be available to Researchers and research teams, YukonU personnel, sponsors and funders as required;
 - 5.2.3. Designated REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;
 - 5.2.4. Each new REB member must review the applicable policies and procedures prior to undertaking any responsibilities as an REB member;
 - 5.2.5. Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking any responsibilities with the REB office;

5.2.6. Evidence of training must be documented;

5.2.7. The REB office shall maintain all documentation of SOP training.

5.3. Forms, Memos and Guidance Documents

5.3.1. Forms ensure that policies and procedures are integrated into the daily operations of research and review throughout the YukonU system and enable the Research Ethics Office to manage review, tracking and notification functions consistently.

5.3.2. Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

5.3.3. Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

5.3.4. Memos and guidance documents will be made available to the Researchers and research teams as applicable;

5.3.5. Designated REB Office Personnel and/or REB Co-Chairs or designee will evaluate the need for new or revised forms, memos or guidance documents.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 108	February 2022	YukonU version adapted from N2/CAREB SOP 108.3 (October 8, 2019) and CAREB SOP 108.001 (2021)