

**Procedures: Human Research Ethics****SOP 406 Research Completion****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 completion of research with the Research Ethics Board (REB).

**2.0 SCOPE**

This SOP pertains to 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 is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

**4.0 DEFINITIONS**

See Glossary of Terms.

**5.0 PROCEDURE**

The Completion of research is a change in activity that must be reported to the REB. Although research participants will no longer be “at risk” under the study, a final report/notice allows the REB to close its files in addition to providing the REB with information that may be used in the evaluation and approval of related studies.

**5.1 Determining when Research is complete**

**5.1.1** The Researcher may submit a study closure report to the YukonU REB when there

is no further participant recruitment or involvement, all new data collection is complete, no further contact with participants is expected, and the research objectives have been met. Other criteria may be determined as per YukonU policy;

- 5.1.2** The Research Ethics Coordinator will review the study closure application and request any outstanding information, clarification or documentation from the Researcher, if needed;
- 5.1.3** The REB Co-Chairs or designee will review the submission and issue a letter of Acknowledgement to the Researcher that the protocol file is “complete”;
- 5.1.4** Once a research project is “Complete” with the REB, no further ethics submissions for that research are required; however, the Researcher still may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB, (e.g. adverse event reports, changes to data management plan);
- 5.1.5** If the sponsor requests additional data following the closure of the research, a request for approval shall be made to the REB and the conditions of this request will be determined at the time of the review.

**5.2 Content of Notification of Study Closure Report**

- 5.2.1** The completion of study form should include
  - Principal Investigator’s affirmation that participant data collection is completed,
  - Total number of research participants enrolled in the study
  - Final disposition/storage of all research-related study documents,
  - The final disposition of any electronic data,
  - End of study summary report
  - Any other information relevant to the REB

**6.0 REFERENCES**

See References.

**7.0 REVISION HISTORY**

SOP Code	Effective Date	Summary of Changes
SOP 406	July 2022	YukonU version adapted from N2/CAREB SOP 406.003 (October 8, 2019) and CAREB SOP 406.001 (2021)