a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

SOP 406

TITLE	**406: Research Completion**
SCOPE	All research submitted to the University of British Columbia's Research Ethics Boards
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Office of Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	August 2013, May 2011, April 2009; July 2003

1.0 PURPOSE

This purpose of this standard operating procedure (SOP) is to describe the procedure for the closure of a research project with the Research Ethics Board (REB).

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

4.0 PROCEDURE

The Completion of research is a change in activity and must be reported to the REB[1]. Although participants will no longer be "at risk" under the study, a final report/notice to the REB allows it to close its files as well as providing information that may be used by the REB in the evaluation and approval of related studies.

4.1 Determining when Research can be Closed

4.1.1 Studies may be considered completed, and an REB Completion of Clinical/Behavioural Study Form should be submitted, if the following applies:

- Subject to U.S. regulatory requirements, for studies that involve direct human participation, no further participant contact is contemplated and all data collection procedures as per the approved protocol have been completed,
- Subject to U.S. regulatory requirements, for studies that do not involve direct human participation (i.e., secondary use of data), the acquisition of data is complete (i.e., no new cases are being added to the study dataset),
- For studies that analyze human tissue, no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group,
- For an industry sponsored study there has been an official "close-out letter" from the sponsor,
- For a study monitored by the NCIC CTG to be considered complete the Principal Investigator must have been notified by the NCIC CTG;

4.1.2 The responsible REB Office Personnel will review the research closure application and request any outstanding information, clarification or documentation from the Researcher, if needed;

4.1.3 The REB Chair or designee will review the submission and issue a letter of Acknowledgement to the Researcher. The research state will change to "Terminated" and will show on the Researcher's "Inactive" tab in the RISe system;

4.1.4 Once a research project is "Terminated" with the REB, no further submissions for that research will be permitted; however, if required, the Researcher still may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB;

4.1.5 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;

4.1.6 **U.S. Federally Funded Research:** Studies that are funded or supported by the U.S. Federal Government are considered open and subject to annual review until a research

project no longer involves human subjects, as defined by the Office of Human Research Protections (OHRP). OHRP only considers a research project to no longer involve human subjects when investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects which includes **using, studying, or analyzing identifiable private information (including identifiable tissue).**

4.2 Content of Notification of Study Closure Report

4.2.1 Clinical Trials:

The Completion of Clinical Study Form should include:

- The Principal Investigator's affirmation that participant data collection is completed,
- Total number of research participants enrolled at the UBC (local) site,
- Date of Study Monitor's final visit,
- The final disposition/storage of all research-related study documents,
- The final disposition of any electronic data,
- An end-of-study summary report, along with confirmation the results have been submitted to ClinicalTrials.gov, when applicable,
- Any other information relevant to the REB;

4.2.2 Study trial summary results are required to be submitted to ClinicalTrials.gov for all registered studies, along with confirmation of such provided to the REB;

4.2.3 Other studies enrolling participants:

The Completion of Clinical Study Form (submitted via the RISe system) should include:

- The Principal Investigator's affirmation that participant data collection is completed,
- Total number of research participants enrolled at the UBC (local) site,
- Date of Study Monitor's final visit,
- The final disposition/storage of all research-related study documents,
- The final disposition of any electronic data,
- An end-of-study summary report,
- Any other information relevant to the REB.

The Completion of Behavourial Study Form (submitted via the RISe system) should include a detailed description on data disposition methods.

5.0 REFERENCES

1. International Conference on Harmonization – Good Clinical Practice (ICH-GCP 4.13):

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/efficacy/guidance-document-good-clinical-practice-integrated-addendum-e6-r1-topic-e6-r2.html#a4.13

Office for Human Research Protections, Continuing Review Guidance:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html