fraserhealth	**RESEARCH ETHICS BOARD** **STANDARD OPERATING PROCEDURES**	
	SOP Number	406
	Research Completion	
	Date of Issue **Date of Revision**	2006 03 01 2010 08 23 2012 05 22 2018 03 30 2022 07 13

Purpose: This standard operating procedure (SOP) describes the procedures for the closure of research with the Research Ethics Board (REB).

Directive: Fraser Health Policy "The Ethical Conduct of Research and Other Studies Involving Human Participants"

Reference: 2019 10 08 CAREB SOP 406.003

Responsibility: 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.

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 research, a final report 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 and in addition, helps to ensure compliance with the Fraser Health research policies.

1.0 Determining When A Study Can Be Closed

1.1 Studies may be considered completed and an REB closure report 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- For Studies that analyze human tissue, no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group,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;

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;

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 "Completed";

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

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;

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).

2.0 Content of Notification of Study Closure Report

2.1 All study closure reports should include:
- The number of participants enrolled and/or participant records/samples collected,
- The final disposition/storage of all research-related study documents,
- The final disposition of any electronic data,
- The final disposition/storage of any bio-specimens,
- A description of the knowledge translation plans for the study results;

2.2 Clinical Trials: The closure report for a clinical trial should include:
- The Principal Investigator's affirmation that participant data collection is completed,
- Total number of research participants enrolled at the Fraser Health (local) site,
- Date of Study Monitor's final visit,

- The total number of local serious adverse events,
- 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.