RESEARCH COMPLETION
SOP 510

Procedures are a series of required steps to complete a task, activity or action

island health

Purpose:	To provide Island Health a standardized approach for the closing of a research project and the required notification of the Research Ethics Boards (REBs).
Context:	Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples. As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment. The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.

Scope:	• Affected Roles
	  ○ All REB Chairs
	  ○ All REB Members
	  ○ All REB Office Personnel
	• Environment
	  ○ Island Health Wide
	  ○ Research Environment

Outcomes:	• Procedures for the closure of research with the REBs.

1 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.

2 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.

2.1 Determining when Research can be Closed

2.1.1 Studies may be considered complete, and a REB Notification of Study Closure should be submitted as follows:

- 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 (e.g., secondary use of data), the acquisition of data is complete (e.g., no new cases are being added to the study dataset) and no further analysis of individually identifiable information is required.
- 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 the site has received an official "close-out letter" or documentation indicating the study can be closed from the Sponsor.
- For a study monitored by the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) to be considered complete the Principal Investigator must have been notified by the NCIC CTG;

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

2.1.3 The REB Chair or designee will review the submission and issue a letter of Acknowledgement to the Researcher. The research state will change to “Closed” or @Terminated@ in the appropriate online database system;

2.1.4 Once a research project is “Closed” 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;

2.1.5 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.

2.2 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 requirements until a research project no longer involves human subjects, as defined by the U.S. Office of Human Research Protextion (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).**

2.3 Content of Notification of Study Closure

2.3.1 Clinical Trials:

The Notification of Study Closure Form for a clinical trials should include:

- The Principal Investigator's affirmation that participant data collection is completed;
- Total number of research participants enrolled at the Island Health (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.

2.3.2 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.

2.3.3 Other studies enrolling participants:

The Notification of Study Closure Form for clinical studies (Submitting via the online database system) should include:

- The Principal Investigator's affirmation that participant data collection is completed;
- Total number of research participants enrolled at the Island Health (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.

2.3.4 The Notification of Study Closure Form for health (socio-behavioural) studies (submitted via the online database system) should include a detailed description on data disposition methods.

3 Training

3.1 Review of the SOP.

4 Compliance Monitoring

4.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with this SOP.

4.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.

4.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

5 Definitions

5.1 See Glossary – Research Ethics.

6 References

- University of British Columbia, SOP 406: Research Completion
- Network of Networks (N2), SOP 406.003: Research Completion
- ICH GCP International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R2); 4.13
- Office for Human Research Protections, Continuing Review Guidance (2010)

7 Summary of Changes

Version	Effective Date	Change Description
1.0	15 JUN 2013	New procedure
2.0	19 DEC 2022	Updated to current standards; Changed SOP title from Study Completion to Research Completion. Issuing Authority changed from Research & Capacity Building to Vice President, Quality, Research and Chief Nursing & Allied Health Officer