Ρ		Ontinuing Review – Research Ethic Boards rocess For Expired Studies 5.5.509.2 Incedures are a series of required steps to complete a task, activity or action						
	Purpose:	To provide Island Health a standardized approach to outline the administrative Research Ethics Board (REB) process for research studies which have expired.						
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:	 Audience: All REB Office Personnel All REB Chairs and Members Environment: Research Environment Indications: Continuing Review – Research Ethic Boards Process For Expired Studiesapplies to all research submitted to the Island Health's REBs. Exceptions: None. 						
	Outcomes:	 Clearly document the administrative requirements for expired studies. 						

1.0 Responsibility

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

2.0 Procedure

- 2.1 REB Administrative Processes
 - 2.1.1 Online Database Systems Notifications
 - Research Services Portal:
 - The Principal Investigator and the Primary Contact for the study will be notified by an email notice from the ROMEO system of the requirement to submit an application for renewal for a study four to six weeks prior to the ethics approval expiry date.
 - RISe Notifications:
 - The Principal Investigator and the Primary Contact for the study will be notified by an automatically generated notice from the RISe system of the requirement to submit an application for renewal for a study four to six weeks prior to the ethics approval expiry date.

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice President Quality, Research & Chief Nursing & Allied Health Officer						
Version No.:	2.0	Last Revised:	2024-JAN-11	Last Reviewed:	2024-JAN-11	First Issued:	2013-SEP-01
							Page 1 of 3

This material has been prepared solely for use at Island Health. Island Health accepts no responsibility for use of this material by any person or organization not associated with Island Health. A printed copy of this document may not reflect the current, electronic version on the Island Health Intranet.



25.5.509.2

Continuing Review – Research Ethic Boards Process For Expired Studies



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

- The Principal Investigator and the Primary Contact for the study will be notified by a second automatically generated notice from the RISe system of the requirement to submit an application for renewal for a study two weeks prior to the ethics approval expiry date.
- The Principal Investigator and the Primary Contact for the study will be notified by a third automatically generated notice marked "URGENT, Expired Ethics Approval" on the date of the expiry of the approval certificate for the study. The notice of expiry will be copied to the Department Head who approved the study in the RISe system.
- The status of the study within the RISe system will change from "approved" to "expired". The study will
 move from the Principal Investigator's "Human Ethics" tab to the "My Inbox" tab on their homepage in the
 RISe system.
- **2.1.2** Studies that have been in an expired state for seven (7) days or longer may be suspended at the discretion of the REB Chair and/or their designee.
- **2.1.3** When a study is in a suspended state, no activities related to the study can be performed by anyone except REB Office Personnel. If the study is reactivated by the REB, it will revert to an expired state so that the Principal Investigator can submit an annual renewal application or a completion of study notice.
- **2.1.4** The REB Manager or their designate will review the expired studies report on a periodic and regular basis. The REB Manager or their designate shall personally contact the Principal Investigators for all expired studies on the report to ensure that a renewal or a notice of completion is submitted.

3.0 Training

3.1 Review Continuing Review – Research Ethic Boards Process For Expired Studies.

4.0 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.

5.0 Definitions

• **Continuing research ethics review** (also referred to as "continuing review"): any review of ongoing research conducted by a Research Ethics Board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.

6.0 Related Island Health Policy Documents

<u>Research Ethics - Continuing Review</u>

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice Pre	Vice President Quality, Research & Chief Nursing & Allied Health Officer					
Version No.:	2.0	Last Revised:	2024-JAN-11	Last Reviewed:	2024-JAN-11	First Issued:	2013-SEP-01
							Page 2 of 3

This material has been prepared solely for use at Island Health. Island Health accepts no responsibility for use of this material by any person or organization not associated with Island Health. A printed copy of this document may not reflect the current, electronic version on the Island Health Intranet.



Continuing Review – Research Ethic Boards Process For Expired Studies

25.5.509.2

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



7.0 Resources

- See Glossary of Terms Research Ethics
- University of British Columbia, SOP 405a REB Process for Expired Studies

8.0 Summary of Changes

Version	Effective Date	Change Description
2.0	12 JAN 2024	SOP 509.2 Continuing Review – REBs Process for Expired Studies is a new SOP that expands on content in SOP 509.1 Continuing Review (formerly known as 'SOP 509 Annual Renewals'. Changed Issuing Authority from Research & Capacity Building to Vice President Quality, Research & Chief Nursing & Allied Health Officer.

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice Pre	Vice President Quality, Research & Chief Nursing & Allied Health Officer					
Version No.:	2.0	Last Revised:	2024-JAN-11	Last Reviewed:	2024-JAN-11	First Issued:	2013-SEP-01
							Page 3 of 3

This material has been prepared solely for use at Island Health. Island Health accepts no responsibility for use of this material by any person or organization not associated with Island Health. A printed copy of this document may not reflect the current, electronic version on the Island Health Intranet.