

**Purpose:**

To describe the responsibilities of the Island Health Research Ethics Boards (REBs) and REB Office to protect the privacy of personal information, as defined by the British Columbia Freedom of Information and Protection of Privacy Act as recorded information about an identifiable individual other than business contact information.

The Standard Operating Procedure (SOP) provides guidance for the protection of information that:

- Is disclosed to the REB for the purposes of ethical review
- Arises during the review and approval processes, or
- Is related to the operation of the REB itself.

Scope:

- Affected Roles
 - Research Privacy Specialist
 - REB Office Personnel; REB Chairs, and members
 - Manager, Research Ethics & Compliance
 - All Island Health Researchers
- Environment
 - Research Environment

Outcomes:

- For affected roles to increase their understanding of the REB's use and protection of personal information.

1 RESPONSIBILITY

- 1.1 All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met;
- 1.2 The Researcher is responsible for submitting information to the REB and to the participant regarding the nature of the personal information (including personal health information (PHI)) that will be collected for the research, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected.
- 1.3 The REB Chair(s), REB members, and the REB Office Personnel are responsible for maintaining the confidentiality of any personal information received by the REB office during the course of the research.
- 1.4 Island Health's Information Stewardship, Access & Privacy (ISAP) office delegated through the Research Privacy Specialist role is responsible for providing Researchers and research staff with guidance on privacy policies and regulations. The Research Privacy Specialist acts as the liason between ISAP and the REBs and REB Office Personnel.

2 PROCEDURE

It is the policy of the Research Ethics & Compliance office at Island Health that personal information will be used and disclosed in a manner that respects individuals' rights to privacy, and in compliance with applicable federal and provincial privacy law and regulations, other applicable laws, and Island Health policies.

The Researcher is responsible for submitting information to the REB and to the participant regarding the nature of the Personal Information (including PHI) that will be collected for the research.

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice-President, Knowledge, Practice and Chief Nurse Executive						
Version No.:	1.0	Last Revised:	N/A	Last Reviewed:	N/A	First Issued:	09 AUG 2021
							Page 1 of 5



Privacy is a fundamental value that is essential for the protection and promotion of human dignity. Breaches in privacy and confidentiality may cause harm to individuals or groups of individuals. Hence, personal information must be collected, used and disclosed in a manner that respects a research participant’s right to privacy, and in accordance with applicable federal and provincial privacy law and regulations.

Privacy regulations permit the use and the limited disclosure of personal information for research purposes as long as certain requirements are met. One of the key ethical challenges for the health research community is in protecting appropriately the privacy and confidentiality of personal information used for research purposes. The REB plays an important role in balancing the need for research against the risk of the infringement of privacy and in minimizing invasions of privacy for research participants. Individuals should be protected from any harm that may be caused by the unauthorized use of their personal information and they should expect that their rights to privacy and confidentiality are respected.

2.1 REB Review of Privacy Concerns

- a) The REB shall review the research submitted to determine if the Researcher has access to and/or is using personal information and whether appropriate B.C. privacy legislation is adhered to;
- b) In reviewing the research, the REB will include such privacy considerations as:
 - The type of personal information to be collected,
 - The research objectives and justification for the requested personal data needed to fulfill these objectives,
 - The purpose for which the personal data will be used,
 - How the personal data will be controlled, accessed, disclosed, and deidentified,
 - Limits on the use, disclosure and retention of the personal data,
 - Any anticipated secondary uses of identifiable data from the research,
 - Any anticipated linkage of personal data gathered in the research with other data about research participants, whether those data are contained in public or in personal records,
 - Whether consent for access to, or the collection of personal data from participants is required,
 - How consent is managed and documented,
 - If and how prospective research participants will be informed of the research,
 - How prospective research participants will be recruited,
 - The administrative, technical and physical safeguards and practices in place to protect the personal data including de-identification strategies and managed linkages to identifiable data,
 - How accountability and transparency in the management of personal data will be ensured;
- c) The REB must find that there are adequate provisions to protect the privacy interests of participants before approving the research.

2.2 Receipt, Use and Disclosure of Personal Information by the Research Ethics & Compliance office

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice-President, Knowledge, Practice and Chief Nurse Executive						
Version No.:	1.0	Last Revised:	N/A	Last Reviewed:	N/A	First Issued:	09 AUG 2021
							Page 2 of 5



- a) The REB Chair(s), REB Members, and the REB Office Personnel are bound by confidentiality agreements signed prior to commencement of their duties;
- b) REB members shall review Island Health Research Ethics and Information Management/Information Technology policies on privacy and confidentiality and acceptable use of information systems and shall sign related acknowledgement/agreement forms;
- c) The REB does not intentionally collect personal information;
- d) REB Chair(s), REB members, and REB Office Personnel are permitted to receive personal information from an Island Health entity and use or disclose such personal information for purposes necessary for the review, approval, ongoing monitoring and auditing of REB reviewed protocols;
- e) The Research Ethics & Compliance office shall treat all information received from Researchers as confidential and shall use or disclose such information only as necessary for the purpose of REB operations and in accordance with Island Health Confidential Information – Third Party, VIHA business and Other Non-personal Information Policy – 1.5.2;
- f) The Research Ethics & Compliance office must adopt reasonable safeguards to ensure that members of its workforce protect personal information from unauthorized access. REB Office Personnel who receive personal information for REB review activity shall not share such personal information with any person, including any other member of the workforce of the REB itself or REB members, that does not require such personal information for such activity;
- g) The Research Ethics & Compliance office shall arrange for copies of REB minutes and approved attachments to be distributed to authorized persons only.
- h) The Research Ethics & Compliance office shall ensure the confidential disposal/destruction of all confidential records related to the review of research studies and other REB operations;
- i) Training on the policies and procedures set forth in this document will be provided for the existing REB Office Personnel, the REB Chair(s) and the REB members to the extent applicable for their respective positions;
- j) REB members or REB Office Personnel may consult with the REB Chair(s) or designate, or the Research Privacy Specialist if they are uncertain about the appropriate use or disclosure of personal information;
- k) The REB Chair(s) will ensure that reports to Researchers on REB decisions do not contain any personal identifiers of individual reviewers;
- l) In the event that a Principal Investigator/Qualified Investigator is invited to attend an REB meeting to address questions about their research application, measures shall be taken to ensure the Principal Investigator/Qualified Investigator attends only that portion of the meeting necessary to address their

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice-President, Knowledge, Practice and Chief Nurse Executive						
Version No.:	1.0	Last Revised:	N/A	Last Reviewed:	N/A	First Issued:	09 AUG 2021
							Page 3 of 5

concerns. A Principal Investigator/Qualified Investigator cannot attend the reviewer’s presentation, the vote or discussion of any study, including their own;

- m) The REB Chair(s), in collaboration with REB Office Personnel, ISAP or their designate, the Manager, Research Ethics & Compliance, and any other applicable Institutional Officer, shall manage all requests for release of documents that are under the custody and/or control of the REB;
- n) If any personal information is received inadvertently in the REB office (e.g. disclosed by a Researcher), appropriate notification must take place and any corrective action that is required including, if applicable, notification to ISAP. The facts surrounding the breach, the appropriate steps taken to manage the breach, remedial activities to address the breach and the outcome will be documented. The personal information will be destroyed in a secure manner as per Island Health policies and procedures;
- o) If there is an internal breach involving the use or dissemination of personal information, the REB Chair(s) or designate will be notified and will notify ISAP and a determination will be made in a timely manner regarding a corrective action plan per Island Health policies and procedures . This process may include notification of containment, mitigation, and remediation, and strategies for prevention. The facts surrounding the breach, the appropriate steps taken to manage the breach and the outcome will be documented. The personal information will be destroyed in a secure manner as per Island Health policies and procedures;
- p) At the discretion of ISAP, in consultation with the REB Chair(s) or designate, individuals and the Office of the Information and Privacy Commissioner for B.C. may be notified.

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

See Glossary of Terms – Research Ethics

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice-President, Knowledge, Practice and Chief Nurse Executive						
Version No.:	1.0	Last Revised:	N/A	Last Reviewed:	N/A	First Issued:	09 AUG 2021
							Page 4 of 5



6 RELATED ISLAND HEALTH POLICIES & PROCEDURES

- Island Health, Confidential Information – Third Party, VIHA Business, and Other Non-Personal Information Policy 1.5.2:
<https://intranet.viha.ca/pnp/pnpdocs/confidential-information-third-party-viha-business-other-non-personal-policy.pdf>
- Island Health, Privacy and Related Information Security Breaches: Reporting, Investigation and Management Policy 1.5.4
<https://intranet.islandhealth.ca/pnp/pnpdocs/privacy-related-information-security-breaches-reporting-investigation-management.pdf>
- Island Health, Acceptable Use of Assets and Resources Policy 16.4.2.3
<https://intranet.islandhealth.ca/pnp/pnpdocs/acceptable-use-assets-resources.pdf>
- Island Health, Confidential Information – Privacy Rights of Personal Information Policy 1.5.1:
<https://intranet.viha.ca/pnp/pnpdocs/confidential-information-privacy-rights-personal-policy.pdf>

7 REFERENCES

- *Freedom of Information and Protection of Privacy Act, British Columbia:*
http://www.bclaws.ca/civix/document/id/complete/statreg/96165_01
- *Personal Information Protection and Electronic Documents Act:*
<https://laws-lois.justice.gc.ca/ENG/ACTS/P-8.6/index.html>
- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0

8 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	09 AUG 2021	New procedure

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice-President, Knowledge, Practice and Chief Nurse Executive						
Version No.:	1.0	Last Revised:	N/A	Last Reviewed:	N/A	First Issued:	09 AUG 2021
							Page 5 of 5