TITLE:	Use and Disclosure of Personal Health Information	**NUMBER**	NSHA REB-SOP-1-008
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	All NSHA REB Members, REB Office Personnel, and Researchers.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the duties of the Nova Scotia Health Authority Research Ethics Board (NSHA REB) and the NSHA REB office in the protection of personal health information (PHI) of research participants.

2. POLICY:

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 regulations.

Privacy regulations permit the use and the limited disclosure of personal information (including personal health information (PHI)) 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.

The Principal Investigator is responsible for submitting information to the REB and to the participant regarding the nature of the personal information that will be collected for the research study, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected.

The REB is responsible for assessing research submissions for privacy concerns. The REB must find that that there are adequate provisions to protect the privacy interests of participants before approving the research.

3. DEFINITIONS:

Confidentiality: refers to the agreement between the Investigator and the participant as to how personal data will be managed and used, and an ethical and/or legal responsibility to safeguard information from unauthorized use, disclosure, modification, loss or theft. The term also refers to the REB's ethical and/or legal responsibility to safeguard information in its custody from unauthorized use, disclosure, modification, loss or theft.

De-identification: means to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual.

Identifiable information: means information that may reasonably be expected to identify an individual, alone or in combination with other available information; also referred to as "personal information."

Personal Health Information (PHI): Identifying information, (i.e. information that identifies or could reasonably be used to identify an individual either alone or with other information), whether living or deceased, and in both recorded and unrecorded forms, if the information relates to:

- The physical or mental health of the individual, including information that consists of the health history of the individual's family,
- The application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,
- Payments or eligibility for health care in respect of the individual,
- The donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
- The individual's registration information, including the individual's health-card number,
- Identification of an individual's substitute decision-maker.

Personal Health Information Act (PHIA): Nova Scotia's legislation that governs the access, storage, disclosure and transportation of personal information outside of Canada, including personal health information.

Privacy: an individual's right to be free from intrusion or interference by others. In the context of personal information, privacy is about having the ability to control or influence the way in which information about you is collected, used and disclosed by consenting to or withholding consent for, the collection, use and/or disclosure of information.

4. PROCEDURES:

4.1. REB Review of Privacy Concerns

4.1.1. The REB will review the research submitted to determine if the Principal Investigator has access to and /or is using the personal information and whether appropriate privacy legislation is adhered to;

4.1.2. 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,
- Whether the use of personal information is justifiable within the circle of care,
- Whether consent for access to, or the collection of personal data from participants is required,
- If and how prospective research participants will be informed of the research,
- How prospective research participants will be recruited,
- The purpose for which the data will be used,
- How the personal data will be controlled, accessed, disclosed, and de-identified,
- 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 subjects is required and if not, why it would be impractical to do so,
- How consent will be managed and documented,
- The administrative, technical and physical safeguards and practices in place to protect the personal data including de-identification strategies, encryption and managed linkages to identifiable data,
- How accountability and transparency in the management of personal data will be ensured.

4.1.3. The REB must find that there are adequate provisions to protect the privacy interests of participants before approving the research.

4.2. Transmitting Identifiable Information

4.2.1. Personal information must not be transferred to parties outside NSHA without the participant's written permission unless otherwise approved by the REB.

4.2.2. *Nova Scotia's Personal Information International Disclosure Protection Act (PIIDPA)* restricts the transfer and storage of, and access to personal information outside Canada.

4.3. Receipt, Collection, Use and Disclosure of PHI by the REB and the Research Ethics Office

4.3.1. The REB Executive Chair, Co-Chairs, REB members and the REB Office Personnel are bound by confidentiality agreements signed prior to commencement of their duties;

4.3.2. The REB does not intentionally collect personal information;

4.3.3. Subject to consent, as applicable, the REB is permitted to access personal information for the purposes of the review, the approval, the ongoing monitoring, and/or the auditing of the conduct of the research;

4.3.4. The REB office must adopt reasonable safeguards and ensure that there is training for REB Office Personnel to protect personal information from unauthorized access;

4.3.5. REB members or REB Office Personnel may consult with the REB Executive Chair or designee if they are uncertain about the appropriate or disclosure of personal information;

4.3.6. 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 the appropriate Organizational Official. 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 the organizational policies and procedures;

4.3.7. If there is an internal breach involving the use or dissemination of personal information, the REB Executive Chair or designee will be notified, and if applicable, notification of the appropriate Organizational Official; and a determination will be made in a timely manner regarding a corrective action plan. This process may include notification, containment, investigation 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 the organizational policies and procedures;

4.3.8. Upon receipt of notice of a privacy breach related to the conduct of the study, the REB will communicate with the Principal Investigator and the NSHA Privacy Officer will be notified accordingly;

4.3.9. At the discretion of the REB Chair or designee, in consultation with the organization, the provincial privacy office (or equivalent) may be notified.

5. REFERENCES

I. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Chapter 5;
II. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
III. Nova Scotia's Personal Health Information Act (PHIA, Bill No. 89)
IV. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005).

5 RELATED DOCUMENTS:

I. NSHA REB-SOP-7-001

Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
June 3, 2016		Reflect the change from nine DHA's to one
September 29, 2017		Harmonize with CAREB/N2 SOP's, updated terminology/roles to remain consistent