IWK Research Ethics
Standard Operating Procedures

Document # **RE 10.1001**	Title: **Use and Disclosure of Personal Health Information**	Effective Date: **February 1, 2023**
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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 health information (PHI) 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 health 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 health information used for research purposes.

The Nova Scotia Personal Health Information Act (PHIA) governs the collection, use, disclosure, retention, disposal and destruction of personal health information. The Act recognized both the rights of individuals to protect their personal health information and the need of custodians to collect, use, and disclose personal health information to provide, support and manage health care.

PHIA defines "Personal health information" as identifying information about an individual, whether living or deceased (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*
- *Relates to the application, assessment, eligibility and provision of health to the individual, including the identification of a person as a provider of health care to the individual*
- *Relates to payments or eligibility for health care in respect of the individual*

- *Relates to 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*
- *Is the individual's registration information, including the individual's health-card number; or identifies an individual's substitute decision-maker*

Identifying information is information that identifies an individual, or where it is reasonably foreseeable could identify an individual when used alone or with other information.
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 health information and they should expect that their rights to privacy and confidentiality are respected.

DEFINITIONS
See Glossary of Terms

RESPONSIBILITY
This SOP applies to the REB Chair, Manager, REB members, and Research Ethics Office (REO) staff.

PROCEDURES
REB Review of Privacy Concerns
The REB shall review the research submitted to determine if the investigator has access to and/or is using PHI and whether appropriate privacy legislation is adhered to.
In reviewing the research, the REB will include such privacy considerations as:

- The type of PHI to be collected
- Whether the research objectives can reasonably be accomplished without using the PHI that is to be disclosed
- The research objectives and justification for the requested personal data needed to fulfill these objectives
- 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 recording of observations (e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants
- Any anticipated secondary uses of identifiable data from the research
- Any anticipated linkage of personal data gathered in the research with other data about study 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 is managed and documented

- Risks to participants should the security of the data be breached, including risks or re-identification of individuals
- 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, encryption and managed linkages to identifiable data
- How accountability and transparency in the management of personal data will be ensured
- How long PHI is to be retained and method of destruction at the end of the retention period

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

Receipt, Collection, Use and Disclosure of PHI by the REB and REO

The REB is permitted to access PHI for the purposes of the review, the approval, the ongoing monitoring, and/or the auditing of the conduct of the research.

The REO must adopt reasonable safeguards and training to ensure that members of its staff protect PHI from unauthorized access.

Any breach of PHI related to research, and/or inadvertently received by the REO must be reported to the IWK Privacy Officer using the Adverse Event Management System (AEMS). Additionally, the REB Chair will be notified for consideration of any additional corrective action. The facts surrounding the breach, the appropriate steps taken to manage the breach and the outcome will be documented. The PHI will be destroyed in a secure manner.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:
(short name: TCPS 2), Chapter 5;
2. Nova Scotia's Personal Health Information Protection Act (PHIA);
3. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
4. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005).

Forms/Records:

Form #	Form/Record Name
SOP 1001	Use and Disclosure of Personal Health Information

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo