SOP Title	**Uses and Disclosure of Personal Information and/or Personal Health Information**
Number.Version	N106.004
Effective Date	02/21/2025

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

This standard operating procedure (SOP) describes the duties of Non-Medical Research Ethics board (NMREB) and the Office of Research Ethics (OHRE) in the protection of personal information and/or personal health information of research participants.

2. GENERAL POLICY STATEMENT

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 and/or personal health 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 and/or personal health information for research purposes as long as certain requirements are met. One of the key ethical challenges for the research community is in protecting appropriately the privacy and confidentiality of personal information and/or personal health information used for research purposes. The NMREB 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/or personal health information and they should expect that their rights to privacy and confidentiality are respected.

3. RESPONSIBILITY

This SOP applies to the NMREB Chair, Vice-Chair(s), NMREB members, and Office of Human Research Ethics (OHRE) staff.

The investigator is responsible for submitting information to the NMREB and to the participant regarding the nature of the personal information and/or personal health 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 NMREB is responsible for assessing research proposals for privacy concerns. The NMREB must find that that there are adequate provisions to protect the privacy interests of participants before approving the research.

The NMREB Chair, NMREB members and OHRE staff are responsible for maintaining the confidentiality of any personal information and/or personal health information received by the OHRE during the course of the research.

4. DEFINITIONS

See also Glossary of Terms

Anonymized information: the information is irrevocably stripped of direct identifiers, a code is NOT kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

Confidentiality: refers to the obligation of an individual or organization to safeguard entrusted information and includes the obligation to protect information from unauthorized access, 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): means identifying information about an individual in either an oral or in a recorded form, if the information:

- relates to the *individual's* physical or mental health, including family health history,
- relates to the provision of health care, including the identification of *persons* providing care,
- is a plan of service for an *individual* requiring long-term care,
- relates to payment or eligibility for health care,
- relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances,
- is the *individual's Provincial health number*, or
- Identifies an individual's *substitute decision-maker*.

Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.

Privacy: refers to an individual's right to be free from intrusion or interference by others. In the context of personal information and/or personal health 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.

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. NMREB Review of Privacy Concerns

5.1.1. The NMREB shall review the research submitted to determine if the investigator has access to and/or is using PI and whether appropriate privacy legislation is adhered to;

5.1.2. In reviewing the research, the NMREB will include such privacy considerations as:

- The type of PI to be collected,
- Whether the research objectives can reasonably be accomplished without using the PI 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 participants 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 of 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.

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

5.2. Receipt, Collection, Use and Disclosure of PI by the NMREB and OHRE

5.2.1. The NMREB Chair, NMREB members and the OHRE staff are bound by confidentiality agreements signed prior to commencement of their duties;

5.2.2. The NMREB does not intentionally collect personal information (PI) and/or personal health information;

5.2.3. The NMREB is permitted to access PI for the purposes of the review, the approval, the ongoing monitoring, and/or the auditing of the conduct of the research;

5.2.4. The NMREB members or OHRE staff must consult with the NMREB Chair if they are uncertain about the appropriate use or disclosure of PI;

5.2.5. If any PI is received inadvertently in the OHRE, the NMREB Chair will be notified. The NMREB Chair will determine the corrective action required and whether to involve the Western University privacy officer or its affiliated institutions' privacy officer. The facts surrounding the breach, the appropriate steps taken to manage the breach and the outcome will be documented. The PI will be destroyed in a secure manner.

5.2.6. Upon receipt of notice of a privacy breach related to the conduct of the study, the NMREB will communicate with Principal Investigator and the Privacy Office will be notified accordingly. The Privacy Office in conjunction with the NMREB will determine the appropriate management plan.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), Chapter 5;
6.2. Ontario's Personal Health Information Protection Act (PHIPA);
6.3. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
6.4. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005).

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N106.001	Original	12/07/2015
N106.002	Change ORE to OHRE	06/09/2016
N106.003	Update to NMREB Chair & Administrative Corrections	05/11/2018
N106.004	Update to NMREB Chair & Added definition PHI	02/21/2025