



Research Ethics Board Standard Operating Policies and Procedures

Research Ethics Board (REB) and Research Ethics Office (REO) Role in Use and Disclosure of Personal Health Information (PHI)

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APPROVED BY:	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to describe the duties of Women's College Hospital (WCH) Research Ethics Board (REB) and the Research Ethics Office (REO) in the protection of personal health information (PHI) disclosed to the REB by physicians, staff and trainees of Women's College Hospital. *See also associated Research Ethics Board Guidelines for Unique Study Identifiers, Key Files and Access Logs.*

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, it is the policy of the REO that 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 local, provincial and federal privacy policies and regulations including but not limited to the Women's College Hospital's Privacy Policy (1.20.001), Women's College Hospital's Security of Personal Health Information Policy (1.20.002), the Ontario Personal Health Information Protection Act (PHIPA) and the Personal Health Information Protection and Electronic Documents Act (PIPEDA).

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 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 use of their personal health information and they should expect that their rights to privacy and confidentiality are respected.

2.0 DEFINITION(S):

See also Glossary of Terms



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Anonymized Information: the information that has been 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: 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: 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 (also referred to as “personal information”): information that may reasonably be expected to identify an individual, alone or in combination with other available information.

Personal health information (PHI): 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, privacy is about having the ability to control or influence the way in which information about a person is collected, used and disclosed by consenting to or withholding consent for, the collection, use and/or disclosure of information.

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB members, Research Ethics Office (REO) staff as well as all Investigators and their research teams.



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

The REB Chair, REB members and REO staff are responsible for maintaining the confidentiality of any personal health information received by the REO during the course of the research.

Women's College Hospital's privacy office is available to respond to requests and consult with investigators and research staff about relevant corporate privacy policies and regulations.

4.0 PROCEDURES:

4.1. REB Reviewing of Privacy Concerns

4.1.1. 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;

4.1.2. In reviewing the research, the REB will include such privacy considerations including but limited to:

- 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 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,



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- Risk 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.

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

- 4.2.1. The REB Chair, REB members and the REO staff are bound by confidentiality agreements signed prior to commencement of their duties;
- 4.2.2. The REB does not intentionally collect personal health information (PHI);
- 4.2.3. The REB is permitted to access PHI for the purposes of review, approval, ongoing monitoring, and/or auditing of the conduct of the research;
- 4.2.4. The REB members or REO staff must consult with the REB Chair if they are uncertain about the appropriate use or disclosure of PHI;
- 4.2.5. If any PHI is received inadvertently in the REO, the REB Chair will be notified. The REB Chair will determine the corrective action required and whether to involve the hospital's Privacy Office. 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.
- 4.2.6. Upon receipt of notice of a privacy breach related to the conduct of the study, the REB will communicate with PI and the Privacy Office will be notified accordingly. The Privacy Office in conjunction with the REB will determine the appropriate management plan.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapter 5
2. Ontario's Personal Health Information Protection Act (PHIPA)
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)
5. Sunnybrook Health Sciences Centre, Research Ethics Board and Research Ethics Office Role in Use and Disclosure of Personal Health Information (REB-SOP-X-01.003).
6. Women's College Hospital, Privacy Policy (1.20.001).
7. Women's College Hospital, Privacy and Security of Personal Health Information (1.20.002);