

SOP Title:	Use and Disclosure of Personal Health Information		
SOP #:	I.07.001	Original Issue Date:	February 23, 2015
Category:	General Administration	Reviewed/Effective Date:	October 1, 2019
Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of the Research Ethics Board (REB) and the REO in the protection of the Personal Information (PI) of research participants.

2.0 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, PI 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 PI 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 PI 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 PI and they should expect that their rights to privacy and confidentiality are respected.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members, REO Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for submitting information to the REB and to the participant regarding the nature of the PI (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.

The REB Chair, REB members and the REO Personnel are responsible for maintaining the confidentiality of any PI received by the REB office during the course of the research.

SickKids privacy office is available to respond to requests and consult with investigators and research staff about relevant corporate privacy policies and regulations.

5.0 PROCEDURES

5.1 REB Review of Privacy Concerns

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

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

- The type of PI 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 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 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;

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

5.2 Receipt, Use and Disclosure of PI

5.2.1 The REB Chair, REB members and the REO Personnel are bound by confidentiality agreements signed prior to commencement of their duties;

5.2.2 The REB does not intentionally collect PI;

5.2.3 Subject to consent, as applicable, the REB 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 REO must adopt reasonable safeguards and ensure that there is training for REO Personnel to protect PI from unauthorized access;

- 5.2.5 REB members or REO Personnel may consult with the REB Chair or designee if they are uncertain about the appropriate use or disclosure of PI;
- 5.2.6 If any PI is received inadvertently in the REO (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 PI will be destroyed in a secure manner as per the organizational policies and procedures;
- 5.2.7 If there is an internal breach involving the use or dissemination of PI, the REB 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 PI will be destroyed in a secure manner as per the organizational policies and procedures;
- 5.2.8 At the discretion of the REB Chair or designee, in consultation with the organization, the provincial privacy office (or equivalent) may be notified.

6.0 REFERENCES

See References