

Title	Use and Disclosure of Personal Information
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1 PURPOSE

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

2 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All REB members, designated REB staff 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 personal information (including personal health information) that will be collected for the research. The REB reviews the measures taken by the Researcher to safeguard personal information for the full life cycle of information, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected.¹ The REB verifies the measures taken by the Researcher for meeting confidentiality obligations and any reasonably foreseeable disclosure requirements.²

The REB Chair, REB members and the REB Support Staff are responsible for maintaining the confidentiality of any personal information received by the REB office during the course of the research.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

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 privacy standards.³

Privacy regulations permit the use and the limited disclosure of personal information for research purposes as long as certain requirements are met. Privacy risks in research arise at all stages of the research life cycle and relate to the identifiability of participants and the potential harms that they, or groups to which they belong, may experience from the collection, use and disclosure of personal information.⁴ One of the key ethical challenges for the health research community is in appropriately protecting the privacy and confidentiality of personal information used for research purposes.

¹ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014, hereafter "TCPS2", art. 5.3.

² TCPS2, art. 5.2 (a).

³ Charter of Human Rights and Freedoms, CQLR, c. C -12, art. 5; Civil Code of Québec (CCQ), art. 35, 37; Act Respecting Health Services and Social Services, CQLR, c. S-4.2, art. 19 and 19.2; Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, CQLR, c. A-2.1, art. 53, 59, 125.

⁴ TCPS2, p. 57.

The REB plays an important role in balancing the need for research against the risk of the infringement of privacy, in accordance with applicable standards. The REB supports the use of a proportionate approach.⁵

5.1 REB Review of Privacy Concerns

5.1.1 In reviewing the research, the REB will consider a number of factors affecting privacy protection,⁶ such as:

- The type of personal information collected,
- The research objectives and justification for the requested personal data needed to fulfill these objectives,
- Respect for applicable privacy laws and the protection of confidentiality,⁷
- Intended uses of personal information derived from the research,
- How the personal data will be controlled, accessed, disclosed, and de-identified,
- Limits on the use, disclosure and retention of personal data,
- Any anticipated secondary uses of identifiable data from the research,
- Risks to participants in the case of a data security breach, including the risk of personal re-identification,
- Security measures as appropriate for the life cycle of the information,
- 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,
- Recordings used for research observations (e.g. photos, videos, and audio recordings), that may potentially identify individual participants,
- Whether consent is required for access to, or collection of, personal data from participants,⁸
- How consent is managed and documented,
- If and how prospective research participants will be informed of the research,

⁵ TCPS2, p. 9.

⁶ TCPS2, p. 62. For further details on the secondary use of identifiable information and on data linkage, see also art. 5.5A, 5.5B, 5.7.

⁷ *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "Modèle", s. 10.3; Civil Code of Québec (CCQ), art. 35, 37; Act Respecting Health Services and Social Services, CQLR, c. S-4.2, art. 19, 19.2; Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, CQLR, c. A-2.1, art. 53, 59, 125; Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec, Part I, vol. 35, 1998, hereafter "Avis", p. 1039; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 6.2.4 and 6.2.4.2; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, hereafter "PAM", p. 23.*

⁸ Act Respecting Health Services and Social Services, CQLR, c. S-4.2, art. 19, 19.2; Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, CQLR, c. A-2.1, art. 53, 59, 125.

- 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;

5.1.2 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 Personal Information

5.2.1 The REB Chair, REB members and REB Support Staff are bound by confidentiality agreements signed prior to commencement of their duties⁹;

5.2.2 If need be, 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;

5.2.3 The REB office must adopt reasonable safeguards and ensure that there is training for REB Support Staff to protect personal information from unauthorized access;

5.2.4 REB members or REB Support Staff may consult with the REB Chair or designee if they are uncertain about the appropriate use or disclosure of personal information;

5.2.5 If any personal information is received inadvertently in the REB office (e.g. disclosed by a Researcher), 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 policies and procedures of the institution;

5.2.6 If there is a breach internal to the institution, involving the use or dissemination of personal information associated with research, the REB Chair or designee will be notified. If applicable, the REB will help develop a corrective action plan in a timely manner. 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;

5.2.7 If there is a breach internal to the REB, involving the use or dissemination of personal information, the REB Chair or designee will be notified, and if applicable, notification will be sent to the appropriate Official(s) of the institution; 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, if

⁹ TDR, s. 4.3.3.

any, will be destroyed in a secure manner as per the policies and procedures of the institution;

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

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 107.001	2020-03-20	Original version

8 APPENDICES