Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.107**
Title	Uses and Disclosure of Personal Information
Effective Date	July 1, 2021
Next Review	2026
Next Administrative Review	2023

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

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

4. **Responsibilities**
   All REB members, REB Office 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 project, including the way it is identified, collected, accessed, used, disclosed, retained, disposed of, and protected.

   The REB Chair, REB members and the REB Office Personnel are responsible for ensuring that the plan to protect confidentiality of participants' PI is appropriate, while ensuring that any PI received or accessed by the REB office, whether in the process of ethics review, inadvertently, or for other purposes is protected.

   The Organization's privacy office is responsible for providing Researchers and research team members with guidance on privacy policies and regulations.

5. **Procedures and/or Specific Policies**
   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.

PI may be obtained directly from research participants or through data stewards or custodians.

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 research community is in appropriately protecting 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.

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,
- If, and how, PI will be shared with other areas (e.g., Financial Services for monetary incentives/reimbursement; FOIPOP contact in the event of a privacy breach; contact for the purposes of contact tracing during events like COVID-19)
- 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 by the REB Office**

5.2.1. The REB Chair, REB members and the REB Office Personnel are bound by confidentiality agreements signed or implicitly understood as a condition of employment prior to commencement of their duties;

5.2.2. The REB does not intentionally collect participant 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/auditing, and/or other Quality Assurance activities;

5.2.4. The REB office must adopt reasonable safeguards and ensure that there is training for REB Office Personnel to protect PI from unauthorized access;

5.2.5. REB members or REB Office 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 REB Office (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 representative. 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 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 representative, 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 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. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.107	New - Implementation of new SOP outlining Uses and Disclosures of Personal Information.	July 1, 2021