

<b>Title</b>	<b>Use and Disclosure of Personal Information</b>
<b>SOP Code</b>	107.001
<b>Effective Date</b>	2023-APR-14

### Site Approvals

<b>Name and Title</b>	<b>Signature</b>	<b>Date (yyyy.mm.dd)</b>
Dr. Lynne Lafave CHAIR, HREB	<i>L Lafave</i>	2023.04.14
Dr. Priscilla Wamucii RESEARCH COMPLIANCE OFFICER	<i>Priscilla Wamucii</i>	2023.04.14

## 1.0 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 of research participants.

## 2.0 SCOPE

This SOP pertains to the Human Research Ethics Board (HREB), Mount Royal University.

## 3.0 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 *personal information* (including personal health information (PHI)) that will be collected for the research project, including the manner in which 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' *personal information* is appropriate, while ensuring that any *personal information* received or accessed by the REB office, whether in the process of ethics review, inadvertently, or for other purposes is protected.

Mount Royal University Information Management and Privacy Office is responsible for providing Researchers and research team members with guidance on privacy policies and regulations.

## **4.0 DEFINITIONS**

See Glossary of Terms.

## **5.0 PROCEDURE**

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 federal and provincial privacy regulations.

*Personal information* may be obtained directly from research participants or through data stewards or custodians.

Privacy regulations permit the use and the limited disclosure of *personal information* 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 *personal 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 unauthorized use of their *personal information* 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 *personal information* 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 *personal information* 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 personal information 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 *personal information*;

5.2.3 Subject to consent, as applicable, the REB is permitted to access *personal information* 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 *personal information* 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 *personal information*;

5.2.6 If any *personal information* 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 *personal information* 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 *personal information*, 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 *personal information* 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.

## 6.0 REFERENCES

See References.

## 7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 107.001	2023.04.14	Original version