

**Procedures: Human Research Ethics****SOP 107 Use and Disclosure of Personal Information (PI)****Associated Policy**

Human Research Ethics Policy AR-03

**Procedure Holder**

Associate Vice President Research

**Executive Lead**

Research Services

**Approval Authority**

President

**Original Date**

Replaces AR-03 procedures (May 2009, Oct. 2014)

**Effective Date**

July 2022

**1.0 PURPOSE**

The purpose of this standard operating procedure (SOP) is to describe the duties of the Research Ethics Board (REB) and the REB office in the protection of the Personal Information (PI) of research participants.

**2.0 SCOPE**

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

**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 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 Co-Chairs, REB members and the Research Ethics Coordinator are responsible for ensuring that the plan to protect confidentiality of participants' of PI is appropriate, while ensuring that any PI received or assessed by the REB office, whether in the process of ethics review, inadvertently, or for other purposes is protected.

The YukonU privacy office is responsible for providing Researchers and research staff 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, 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 territorial 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 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.

### 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 Co-Chairs, REB members and the Research Ethics Coordinator 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 or other Quality Assurance activities of the conduct of the research;

5.2.4. The YukonU Research Ethics Office

5.2.4.1. Shall treat all information received from investigators as confidential and shall use or disclose such information only as necessary for the purpose of REB operations;

5.2.4.2. Must adopt reasonable safeguards and ensure that there is training for Research Ethics office Personnel to protect PI from unauthorized access;

5.2.4.3. Shall maintain and properly secure research files and other records related to REB operations, to ensure competent record-keeping and to avoid unintentional disclosures.

5.2.4.4. Arrange for copies of REB minutes and approved attachments to be distributed to authorized persons only

5.2.4.5. Shall ensure the confidential disposal/destruction of all confidential records related to the review of research studies and other REB operations.

5.2.5. Training on the policies and procedures set forth in this document will be provided for the Research Ethics Coordinator, the REB Co-Chairs and the REB members to the extent applicable for their respective positions.

5.2.6. REB members or Research Ethics Coordinator may consult with the REB Co-Chairs or designee if they are uncertain about the appropriate use or disclosure of PI;

- 5.2.7. The REB Co-Chairs will ensure that reports to researchers on REB decisions do not contain any personal identifiers of individual reviewers;
- 5.2.8. In the event that a Principal Investigator is invited to attend an REB meeting to address questions about his/her research application, ensure the Principal Investigator attends only that portion of the meeting necessary to address questions or concerns. A Principal Investigator cannot attend the reviewer's presentations, the vote or discussion of any study including their own;
- 5.2.9. The REB Co-Chairs, in collaboration with the Research Ethics Coordinator, the Privacy Officer of the institution, and any other applicable Institutional Officer, shall manage all requests for release of documents that are under the custody and/or control of the REB;
- 5.2.10. 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 University 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 Yukon University policies and procedures;
- 5.2.11. If there is an internal breach involving the use or dissemination of PI, the REB Co-Chairs or designee will be notified, and if applicable, notification of the appropriate University 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;
- 5.2.12. At the discretion of the REB Co-Chairs or designee, in consultation with the organization, the territorial privacy office (or equivalent) may be notified.

## **6.0 REFERENCES**

See References.

## **7.0 REVISION HISTORY**

<b>SOP Code</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
SOP 107	July 2022	YukonU version adapted from the N2/CAREB SOP 107.003 (October 8, 2019) and CAREB SOP 107.001 (2021)