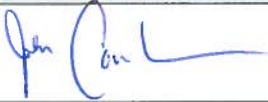




Section 100:	General Administration
Title:	Use and Disclosure of Personal Information
SOP Code:	107.001
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015 MAY 22 Date
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015 Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015 Date
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the duties of the HSREB and the HSREB office in the protection of the Personal Information (PI) of research participants.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members, HSREB 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 HSREB 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 HSREB Chair, HSREB members and the HSREB Office Personnel are responsible for maintaining the confidentiality of any PI received by the HSREB office during the course of the research.

Queen's University's Access and Privacy office is responsible for providing Researchers and research staff with guidance on privacy policies and regulations:
<http://www.queensu.ca/accessandprivacy/>

4.0 DEFINITIONS

See Glossary of Terms

5.0 PROCEDURES

Personal information is any identifiable information that is recorded in any form. Information is identifiable if it may reasonably be expected to identify an individual, when used alone or in combination with other available information. Examples may include, but are not limited to, name, race, religion, age, marital status, address, blood type, education, financial status, etc.

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 HSREB plays an important role in balancing the need for research and societal benefit 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 be respected.

5.1 HSREB Review of Privacy Concerns

- 5.1.1 The HSREB 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. Additional privacy considerations for the collection of PI can be referenced in SOP 403 Initial Review - Criteria for HSREB Ethical Clearance (section 5.3);
- 5.1.2 In reviewing the research, the HSREB will include such privacy considerations as:
 - The type of PI to be collected,
 - The method of identifying and contacting potential participants,

- The research objectives and justification for the requested personal and/or biological information needed to fulfill these objectives,
- The purpose for which the personal and/or biological information will be used,
- How the personal and/or biological information will be obtained, controlled, accessed, stored, disclosed, and de-identified (the process used to prevent a person's identity from being connected with the information),
- Limits on the use, disclosure and retention of the personal and/or biological information,
- Anticipated secondary uses (the use of information or human biological materials originally collected for a purpose other than the current research purpose) of identifiable information from the research, and additional considerations must be made if consent is not obtained for the secondary use of information, such that:
 - Identifiable information is essential to the research,
 - The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of the individuals to whom the information relates,
 - The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information,
 - The researchers will comply with any known preference previously expressed by individuals about any use of their information,
 - It is impossible or impracticable to seek consent from individuals to whom this information relates, and,
 - The researchers have obtained any other necessary permission for secondary use of information for research purposes and entered into an agreement with the information custodian,
 - If applicable, the researchers have submitted a plan to the HSREB for the Health Information Custodian (HIC) to contact individuals for permission for the researcher to contact them for additional information in situations, as noted above. The HIC and/or participant have the right to refuse to provide PI at any time,
- Any anticipated linkage of personal and/or biological information gathered in the research with other information about research participants, whether the information is contained in public or in personal records,
- Whether consent for access to, or the collection of personal and/or biological information 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 PI including de-identification strategies and managed linkages to identifiable information,
 - How accountability and transparency in the management of personal and/or biological information will be ensured;
- 5.1.3 The HSREB must find that there are adequate provisions to protect the privacy interests of participants before granting ethical clearance to conduct the research.
- 5.2 Receipt, Use and Disclosure of PI**
- 5.2.1 The HSREB Chair, HSREB members and the HSREB Office Personnel are bound by confidentiality agreements signed prior to commencement of their duties;
- 5.2.2 The HSREB does not intentionally collect PI;
- 5.2.3 Subject to consent, as applicable, the HSREB is permitted to access PI for the purposes of the review, the ethical clearance, the ongoing monitoring, and/or the auditing of the conduct of the research;
- 5.2.4 The HSREB office must adopt reasonable safeguards and ensure that there is training for HSREB Office Personnel to protect PI from unauthorized access;
- 5.2.5 HSREB members or HSREB Office Personnel may consult with the HSREB 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 HSREB 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 Queen's University and/or Affiliated Teaching Hospital Official(s). 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 Queen's University and/or Affiliated Teaching Hospital(s) policies and procedures;
- 5.2.7 If there is an internal breach involving the use or dissemination of PI, the HSREB Chair or designee will be notified, and if applicable, notification of the appropriate Queen's University and/or Affiliated Teaching Hospital Official(s), 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 Queen's University and/or Affiliated Teaching Hospital(s) policies and procedures;
- 5.2.8 At the discretion of the HSREB Chair or designee and/or the Director of Research Ethics Compliance, there may be a need to consult with the Queen's University and/or Affiliated Teaching Hospitals Privacy Offices, and/or with the Information and Privacy Commissioner of Ontario, if disagreements arise with respect to privacy issues between HSREB members and/or for additional guidance on privacy issues.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Use and Disclosure of Personal Information	v.107.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

