
Saskatchewan Cancer Agency

Privacy, Security and Standards in Research



Research

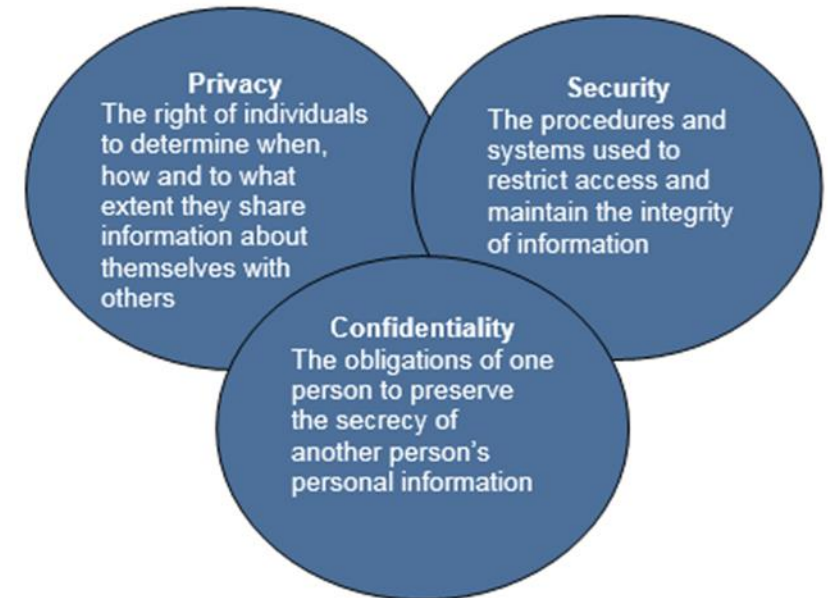
- Research is defined as an undertaking to extend knowledge through a disciplined inquiry or systematic investigation.
- If personal health information (PHI) is used for the purposes of research, there are special provisions that a trustee must follow, even if the subject individual has given express consent.
- Research requires ethics approval as per Section 29 of *The Health Information Protection Act* of Saskatchewan (HIPA).
- Section 29 of HIPA also requires agreements for research.

Importance of Research

- Health research is positive and necessary to achieve results including:
 - Better health care;
 - Improved patient outcomes; and,
 - Increased efficiencies.
- **“There cannot be a contest between privacy and research. Patients must not be asked to chose one over the other, they deserve BOTH.”** Sask Privacy Commissioner, *Prevention Program for Cervical Cancer Report* , 2005 CanLII 39924, <http://canlii.ca/t/1lwn9>

Key Concepts of Information Protection

- **Privacy:** The right of an individual to determine when, how and to what extent he/she shares information about themselves with others.
- **Confidentiality:** The obligation of an individual or organization to safeguard entrusted information
- **Security:** The measures used to protect information, including physical, administrative and technical safeguards.



Health Information Protection Act (HIPA)

- Saskatchewan's health specific privacy legislation.
- Applies to health regions and health information trustees such as physicians, pharmacies, laboratories, and diagnostic clinics.



PHI Is Information...

- About a person's physical or mental health
- About any health service a person receives
- About the donation of a person's body part or bodily substance
- Derived from testing or examination of a person's body part or bodily substance
- Registration Information (regardless if it is in the public domain or not)

The Cancer Agency is a Trustee

A trustee under HIPA is an institution or person who has custody or control of personal health information (PHI), such as:

- Government institution (e.g. Ministry of Health).
- Provincial health authority (e.g., Saskatchewan Health Authority, Cancer Agency).
- Physician (EMR/records in their office).
- eHealth Sask (e.g. eHR Viewer – Viewer information (as well as the data in most provincial repositories) cannot be used for secondary use without authorization).

Duties of a Trustee

“The disclosure of information to a researcher does not transfer “ownership”. Researchers should anticipate that the trustee will establish expectations regarding the handling of the information including breach notification and future uses, amongst other things”.

(Newfoundland OIPC, “*Use of PHI for Research Purposes*”)

- Safeguard Information
 - (Technical, physical and administrative safeguards)
- Data minimization and need to know
 - Applies to data elements in research
- Use and disclosure rules for primary and secondary use.
 - Section 27(4)(k)(ii) and 29 of HIPA.
- Obligation to advise an individual how information is collected, used and disclosed
- Consent for research. (Express and no consent)

HIPA Section 29

Summary Points

- Outlines when and how a trustee may use or disclose PHI for research purposes.
- Express consent is required, but HIPA includes provisions for when it is not reasonably practicable to obtain consent.
- REB approval is required for research.
- Agreements are required, including confidentiality agreements.
- Good reference to navigate research/legislation is the OIPC's Guide to HIPA
<https://oipc.sk.ca/assets/ipc-guide-to-hipa.pdf>

Trustee Agreement with Researcher

Trustee agreement with the researcher should include the following to meet HIPA compliance:

- Must not disclose the information outside the research purposes.
- Information will be used only for the purpose set out in the agreement (ethics application).
- Ensure security and confidentiality of the information.
- Return or destroy records with PHI.
- The Agency has a simplified agreement document to assist with comprehension of the agreements.

Other Agreements?

- REB focuses on protection of the patient/participant; however, the trustee or person/institution responsible for the data may have additional responsibilities as trustees/stewards of the data.
- Additional approvals may be required along with the REB. (e.g. Saskatchewan Health Authority operational approval, Ministry of Health approval)
- Data sharing and/or transfer agreements may be required.
- Data sharing agreements are used when there is a need to share identifiable PHI in order to link data sets, or to provide data to a researcher that includes identifiable PHI.

TCPS2

- Tri-Council policy statement: Ethical conduct for research involving humans
- TCPS2 is the joint policy of Canada's three federal research funding agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC)
- All institutions that receive Tri-Council funding must sign the memorandum of understanding which mandates the application of the TCPS2 to all human research



Activities Not Requiring REB Review

- Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research under HIPA, and do not fall within the scope of REB review. (Article 2.5, TCPS2, 2014)
- Often these projects are submitted to the REB to be reviewed for an exemption letter.
- Most peer reviewed journals require an exemption letter in order to publish.
- The exemption letter is not the final/only approval required for the trustee/data steward to disclose the data.

Quality Assurance

- A process in which the activities and performance of an organization and/or program are systematically monitored, reported and evaluated to determine the effectiveness and efficiency of care and service provided.
- The results of a quality assurance project could lead to a quality improvement or research project.



Quality Improvement

- Quality improvement is a management process which uses tools and methods to achieve measurable improvement in the effectiveness, efficiency, accountability, and safety of health care delivery processes and systems, as well as the performance of internal resources in delivering care and service.
- A quality improvement project would include an intervention intended to improve care/systems. (Langley, Nolan & Nolan. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*; 1996)

Data Security

- The Research Ethics Office strongly recommends that master lists and data collection tools be stored separately.
- The data collection tool should not contain any *directly identifying* PHI. It should contain the data elements to be collected from the charts and a unique ID linking it back to the Master List.
- However, if in the course of gathering data, if both are saved together on a device that travels out of the Agency, the device must be encrypted and Agency approval given.
- Any electronic devices that will contain data (e.g. desktop and laptop computers, memory sticks) must be password protected and/or encrypted.



Data Collection Tool

Data Collection Tool					
Unique Identifier	Data 1 (Year of Birth)	Data 2 (Gender)	Data 3	Data 4	Data4
001					
002					
003					
004					
005					
006					
007					

Master List

Master List					
Medical File Number	Unique Identifier		Medical File Number	Unique Identifier	
	001			008	
	002			009	
	003			010	
	004			011	
	005			012	
	006			013	
	007			014	

Data Destruction

- Research agreements may request that data must be destroyed/returned once the research project is complete as per the agreement.
- Written confirmation from the researcher of such destruction will also be required.
- Please note that for electronic data, deleting the file from the computer or device still leaves information that can allow files to be retrieved using sophisticated methods.
- Free file eraser programs are available that can overwrite the deleted files on personal computers/laptops and portable media. IT/IM members at the Agency can be contacted to assist with this.

De-identifying Information

An Overview of Techniques for De-identifying Personal Health Information

14th August 2009

Khaled El Emam
*CHEO Research Institute &
University of Ottawa*

Anita Fineberg
Anita Fineberg & Associates Inc.

This report was funded by the Access to Information and Privacy Division of Health Canada.

<http://www.ehealthinformation.ca/wp-content/uploads/2014/07/2010-An-Overview-of-Techniques-for-De-identifying-personal-health-information.pdf>

Managing Information for Research

- **Directly identifying information** - the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- **Indirectly identifying information** - the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- **Coded information** - direct identifiers are removed and replaced with a code.
- **Anonymized information** - the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous information** - the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Research Identifiers

- Identifying variables or quasi-identifiers in the dataset.
- An identifying variable would be, for example, a name, full address, telephone number, email address, health insurance number, and social insurance number. This type of information directly identifies an individual.
- A quasi-identifier means a variable that can indirectly identify an individual, such as a date (birth, death, admission, discharge, autopsy, specimen collection, or visit), full postal code or other location information, profession, and diagnosis information.

Inferred Identifiers

- It is also important to note that some quasi-identifiers can be inferred from other variables in the data.
- For example, age can be inferred from graduation year, date of death from autopsy date, baby's date of birth from mother's discharge date, and disease or condition from drug taken.
- Inferred quasi-identifiers should also be included in the de-identification analysis.
- **For the Cancer Agency, patient visits can be inferred as a cancer diagnosis.**

Cell Suppression Requirements (Small Cell Counts) for Displaying Cancer Agency Data

- When displaying data, for confidentiality:
 - Suppress cells with single or multi-year counts of 1-5 cases; denote such cells as “<6”.
 - Suppress a cell containing a multi-year average if the total case count for all years combined is 1-5 cases in that cell.
 - If the count of cases in a cell with 1-5 cases can be “back calculated” by subtraction from the total, employ complementary suppression of data in an additional cell (e.g. denoted as “s”).
 - Do not publish rates based on 1-15 cancer cases (in numerator). Rates based on small numbers have poor reliability.

References

1. [Maryland Cancer Registry Data Use Manual and Procedures, Maryland Cancer Registry, October 2012](#)
2. [Statistical Policy Working Paper 22 \(Second Version, 2005\) Report on Statistical Disclosure Limitation Methodology, US Federal Committee on Statistical Methodology, December 2005](#)

Informed Consent

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WWW.ANDERTOONS.COM



"Before I write my name on the board, I'll need to know how you're planning to use that data."

Health Canada – Informed Consent Documents

Note to Researchers:

- Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues until the study is complete or the participant withdraws. Any discussion of informed consent with the participant, the written informed consent form and any other written information given to participants should provide adequate information for the participant to make an informed decision about his/her participation.
- <https://www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/requirements-informed-consent-documents.html>



The screenshot shows the top navigation bar of the Health Canada website. It includes the Government of Canada logo and the text 'Government of Canada' and 'Gouvernement du Canada'. Below this is a horizontal menu with dropdown arrows for 'Jobs', 'Immigration', 'Travel', 'Business', 'Benefits', and 'Health'. A breadcrumb trail reads: 'Home → Health Canada → Health Science and Research → Science Advice and Decision Making → Health Canada and the Public Health Agency of Canada's (PHAC) Research Ethics Board'. The main heading of the page is 'Requirements for Informed Consent Documents'.

OIPC - Consent Forms

BEST PRACTICES FOR GATHERING INFORMED CONSENT AND THE CONTENT OF CONSENT FORMS



Office of the
Saskatchewan Information
and Privacy Commissioner

<https://oipc.sk.ca/assets/best-practices-for-gathering-informed-consent.pdf>

Additional Training Resources for Researchers

- The Alberta Clinical Research Consortium (ACRC) has endorsed and recommended a series of training resources for researchers.
- “*High quality research stems from training and a knowledgeable research team.*” Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).” [ICH GCP E6 (2.8)]”.
- **For privacy/security training recommendations recommended in the link below, please ensure this is compliant/applicable with Saskatchewan legislation.**
- <https://albertainnovates.ca/wp-content/uploads/2017/11/Traning-Endorsement-Letter-V2-April-2015.pdf>

Saskatchewan Cancer Agency Contacts

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