



Personal Health Information Act (PHIA) and Research

Dalhousie Research Ethics Board

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Presentation Overview

- What is *PHIA*?
- PHIA – purpose and scope
- Consent
 - Standards and models
- PHIA and Research
 - Considerations
- Group discussion
- Moving forward

What is PHIA?

BILL NO. 89

(as passed, with amendments)



*2nd Session, 61st General Assembly
Nova Scotia
59 Elizabeth II, 2010*

Government Bill

Personal Health Information Act

CHAPTER 41 OF THE ACTS OF 2010

The Honourable Maureen MacDonald
Minister of Health

- The *Personal Health Information Act*
 - Provincial privacy legislation under the Nova Scotia Department of Health and Wellness
- Aims to achieve a balance between an individual's right to privacy and the benefits of use of personal health information for planning or research.
- Follows the pattern of protection adopted by various jurisdictions across Canada.

PHIA: Purpose

“ ...to govern the collection, use, disclosure, retention, disposal and destruction of personal health information in a manner that recognizes both the right of individuals to protect their personal health information and the need of custodians to collect, use and disclose personal health information to provide, support and manage health care.”

PHIA s.2

PHIA: Scope

PHIA applies to:

- “*custodians*” and “*agents*”
- “*personal health information*”
- “*health care*”

Scope – who is covered?

“Custodians”

- Custodians must have “**custody or control**” of the personal health information/record
 - DHW and any of its programs, including Provincial Programs, DHAs, regulated health professionals, pharmacies, etc.

“Agents”

- Agents *act for or on behalf* of the Custodian in respect to personal health information *for the Custodian’s purposes* and not the Agent’s purposes
 - DHW agents include, for example, Medavie Blue Cross, Quikcard, EMC, consultants, volunteers, etc.

Scope – what is covered?

- Applies to “**personal health information**” which means “*identifying information about an individual, whether living or deceased...*”
- “**Identifying information**” means “*information that identifies an individual or, where it is reasonably foreseeable in the circumstances, could be utilized, either alone or with other information, to identify an individual*”

PHIA s. 3 (f), 3(l)

Scope – Health Care

“Health Care” - *an observation, examination, assessment, care, service or procedure in relation to an individual that is carried out, provided or undertaken for one or more of the following health related purposes:*

- a) the diagnosis, treatment or maintenance of an individual's physical or mental condition,*
- b) the prevention of disease or injury,*
- c) the promotion and protection of health,*

Scope – Health Care

- d) *palliative care,*
- e) *the compounding, dispensing or selling of a drug, health-care aid, device, product, equipment or other item to an individual or for the use of an individual, under a prescription, or*
- f) *a program or service designated as a health-care service in the regulations (e.g. Adult Protection assessments)*

PHIA s. 3(k)

PHIA does not apply

- To:
 - Statistical, aggregate or de-identified information; or
 - Personal health information about an individual after the earlier of one hundred and twenty years after a record containing the information was created and fifty years after the death of the individual.



Consent Standards, Principles and Models

Consent Standards

PHIA relates only to consent for the management of personal health information, not consent to treatment

Consent must be:

- given by the individual
 - or substitute decision maker
- knowledgeable
- information specific
- given freely



Consent Principles

- A custodian shall not collect, use or disclose personal health information if other information would serve the purpose (s.24)
- Collection, use and disclosure of personal health information shall be limited to the minimum amount of personal health information necessary to achieve the purpose (s.25)

Consent Models

Collection, Use & Disclosure *Without* Consent

- As permitted by *PHIA* (s. 31, 35 and 38)
 - Planning and management of the health system
 - Planning or delivering programs/services
 - Administration of payment for health care
 - Disclosure to NSPMP

Collection, Use & Disclosure *With* Consent

- In some cases consent must be express (verbal or written)
 - Fund-raising
 - Market Research or marketing for commercial purposes
 - From a custodian to a non-custodian
 - To the media
 - Research

Knowledgeable implied consent

- Used only within “circle of care”
- Custodian may collect, use and disclose without consent, but may also choose to seek consent.

PHIA and Research

Definitions

“**research**” means a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research; *PHIA* s.52 (c)

“**research ethics board**” means a research ethics board established and operating in conformity with the Tri-Council Policy Statement; *PHIA* s. 52(d)

“**impracticable**” means a degree of difficulty higher than inconvenience or impracticality but lower than impossibility *PHIA* s.52 (b)

PHIA contemplates both the “**use**” of personal health information by the custodian for research purposes, as well as the “**disclosure**” by custodians to others for research purposes

PHIA & Research : Use

S. 35 (1) A custodian may **use** personal health information about an individual without the individual's consent

- e) for the purpose of seeking the individual's consent, when the personal health information used by the custodian for this purpose is limited to the individual's name and contact information;
- h) for research conducted by the custodian, in accordance with Sections **52 to 60**;

S. 55 A custodian may **use** personal health information for research if, before commencing the research, the custodian

- a) prepares a research plan that meets the requirements in Section 59;
- b) submits the research plan to a research ethics board;
- c) receives the approval of the research ethics board; and
- d) meets any conditions imposed by the research ethics board.

PHIA & Research: Use

59 (1) Before commencing research, a researcher seeking to conduct research utilizing personal health information shall submit a research plan to a research ethics board.

(2) The research plan must be in writing.

(3) In order to meet the requirements for a custodian under this Act, the research plan must include

- a) a description of the research proposed to be conducted;
- b) a statement regarding the duration of the research;
- c) a description of the personal health information required and the potential sources of the information;
- d) a description as to how the personal information will be used in the research;
- e) where the personal health information will be linked to other information, a description of the other information as well as how the linkage will be conducted;
- f) where the researcher is conducting the research on behalf of or with the support of a person or organization, the name of the person or organization;
- g) the nature and objectives of the research and the public or scientific benefit anticipated as a result of the research;

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- h) where consent is not being sought, an explanation as to why seeking consent is impracticable;
- i) an explanation as to why the research cannot reasonably be accomplished without the use of personal health information;
- j) where there is to be data matching, an explanation of why data matching is required;
- k) a description of the reasonably foreseeable risks arising from the use of personal health information and how those risks are to be mitigated;
- l) a statement that the personal health information is to be used in the most de-identified form possible for the conduct of the research;
- m) a description of all individuals who will have access to the information, and
 - (i) why their access is necessary,
 - (ii) their roles in relation to the research, and
 - (iii) their qualifications;

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- n) a description of the safeguards that the researcher will impose to protect the confidentiality and security of the personal health information;
- o) information as to how and when the personal health information will be destroyed or returned to the custodian
- p) the funding source of the research;
- q) whether the researcher has applied for the approval of another research ethics board and, if so, the response to or status of the application; and
- r) whether the researcher's interest in the disclosure of the personal health information or the conduct of the research would potentially result in an actual or perceived conflict of interest on the part of the researcher.

PHIA & Research: Disclosure

S. 43 Express consent of the individual to whom personal health information relates is required for the disclosure of the information

f) to a person or organization for the purpose of research unless provided for in Section 57.

57 A custodian may disclose personal health information about an individual to a researcher without the consent of the subject individual if

- a) the researcher has met the requirements in Section 55;
- b) a research ethics board** has determined that the consent of the subject individuals is not required;
- c) the custodian is satisfied that
 - i. the research cannot be conducted without using the personal health information,
 - ii. the personal health information is limited to that necessary to accomplish the purpose of the research,
 - iii. the personal health information is in the most de-identified form possible for the conduct of the research
 - iv. the personal health information will be used in a manner that ensures its confidentiality, and
 - v. it is **impracticable** to obtain consent; and
- d) the custodian informs the Review Officer.

PHIA & Research: Impracticable

“**impracticable**” means a degree of difficulty higher than inconvenience or impracticality but lower than impossibility *PHIA* s.52 (b)

Seeking consent from individuals for the use of their personal data may be considered **impracticable** when there are difficulties in contacting or notifying individuals for reasons such as:

- the size of the population being researched;
- the proportion of prospective participants likely to have relocated or died since the time the personal information was originally collected; or
- the lack of an existing or continuing relationship between prospective participants and the data holder who would need to contact them (e.g. a patient database that does not have a regular follow-up program to maintain a complete and accurate record of changes in registrants' contact information over time);

such that:

- a. there is a risk of introducing bias into the research because of the loss of data from segments of the population that cannot be contacted to seek their consent, thereby affecting the validity of results and/or defeating the purpose of the study; or
- b. the additional financial, material, human, organizational and other resources needed to obtain consent could impose a hardship or burden on the researchers or organization so burdensome that the research could not be done.

Questions for Discussion

- Retrospective collection of non-identified (data) for research
- Consent for research – role of the REB re:
 - Determination of “impracticable” to seek consent
 - Use of demographic information to seek consent for use by custodian
- Data Access Committees: expectations on REB approvals.
 - Resources: Toolkit “Research” chapter, templates
 - Status of DHW Data Access Committee
- Other

Moving forward...

- In light of PHIA and our discussion today
 - Are there any opportunities to come to common understandings that need to be developed?
- Are there opportunities to collaborate?

**Thank you for your
invitation!**