OFFICE OF THE INFORMATION AND PRIVACY COMMISSIONER

NEWFOUNDLAND AND LABRADOR

Use of Personal Health Information for Research Purposes

Research on the Rock Conference CARA East 2017

Donovan Molloy, Q.C. – Commissioner November 14, 2017

OIPC's Views on 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.** (*Prevention Program for Cervical Cancer, Re*, 2005 CanLII 39924 (SK IPC), http://canlii.ca/t/1lwn9)

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

- Privacy refers to an individual's right to be free from intrusion or interference by others…Individuals have privacy interests in relation to their bodies, personal information… Research affects these various domains of privacy in different ways, depending on its objectives and methods. **An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy.** Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information.

The Personal Health Information Act

- *PHIA* came into force in 2011. The Act contains rules surrounding the handling of personal health information in both public and private settings.

- Similar to the concept of patient confidentiality; however, the rules under *PHIA* are more specific.

- *PHIA* strikes a balance between:
  1. protecting individuals' privacy, and
  2. using personal health information for legitimate health-related purposes including health research reviewed as approved by a Research Ethics Board (REB).

Application – Who?

- Custodian means a person listed in section 4 who has custody or control of **personal health information** as a result of or in connection with the performance of their powers/duties or the work described in the provision.

- Examples of custodians under *PHIA* include:
  - the Regional Health Authorities;
  - the Department of Health and Community Services;
  - Health Care Professionals;
  - Health Care Providers;
  - the Centre for Health Information;
  - **Memorial University of Newfoundland-Faculty of Medicine, School of Nursing, School of Pharmacy, School of Human Kinetics and Recreation.**

- Custodians may be held accountable for the actions of their employees. Employees are agents of the custodian.

Application – What?

- Personal Health Information - **identifying** information in **oral or recorded** form about an individual that **relates to**:
  - physical and mental health including their status, history and family history,
  - identity of the health care provider,
  - blood and organ donation,
  - registration information (incl. MCP# or other identifier),
  - payments or eligibility for insurance coverage,
  - information collected incidental to health care or payment
  - prescriptions, a health care aid, device, product, equipment or other item provided to an individual under a prescription or other authorization issued by a health care professional,
  - identity of a representative authorized to act on their behalf.

Application – Where?

- *PHIA* applies to custodians involved in the delivery of health care services in both the public and private sectors in Newfoundland and Labrador;
- *ATIPPA* – provincial public-sector privacy law, **personal information**;
- *PIPEDA* – federal private-sector privacy law;
- *PHIA* prevails over *ATIPPA* and *PIPEDA* in respect of **personal health information.**

Health Research Ethics Authority Act and *PHIA*

- The *HREAA* and *PHIA* address obligations of the Health Research Ethics Authority (HREA), custodians and researchers.

- The HREA is empowered to ensure that health research involving human subjects is conducted in an ethical manner.
  - This is achieved primarily via the requirement that all research in the Province involving human subjects be reviewed and approved by an REB established under the *HREAA*.

- *PHIA* governs the privacy of personal health information and imposes legal duties on researchers and custodians.

- HREA approval **does not** relieve researchers and custodians from their *PHIA* obligations related to the collection, use and disclosure of personal health information.

OIPC Guidance

- OIPC's preference is to be proactive.
- Avoiding breaches is in the best interest of the public, custodians and the research community.
- A recent inquiry led to the development of a new Guidance document, ***Disclosure of Personal Health Information for Research Purposes: Guidance for Researchers and Custodians of Personal Health Information***:

http://www.oipc.nl.ca/pdfs/disclosure_personal_health_info.pdf

Collection, Use and Disclosure of PHI

- A researcher may collect or access personal health information under *PHIA* in 2 ways:

  1) **Disclosure Without Consent:** personal health information may be disclosed by a custodian to a researcher without consent, but ***only*** where the disclosure has been approved as part of a research project by the REB.
  2) **Collection With Consent:** personal health information may be collected by researchers with the consent of research subjects, however, approval of the collection by the REB is required.

- The approaches may be used separately or in combination; however, researchers and custodians need to be aware of their duty to protect the privacy of research subjects' personal health information.

Consent

- Even in circumstances where consent is provided, the same privacy principles and expectations apply (e.g minimum amount of information necessary.)

- Where consent is required, consent must be:
  1. of the individual the info is about.
  2. knowledgeable, which means the individual knows:
     - the purpose of the collection/use/disclosure.
     - that they can withhold their consent, and
     - that *PHIA* applies.
  3. not obtained through deception or coercion.

Consent

- The OIPC will consider consent to be knowledgeable only if:
  - the sources of personal health information are explicitly stated in the consent form, and REB documentation; and
  - details as to how the information is being collected (directly or indirectly) are provided.

- Consent that does not comply with *PHIA* requirements may result in the researcher and his or her employer (if the employer is a custodian under *PHIA*) being audited or investigated. Willful breaches could result in prosecution under *PHIA*.

Security Obligations

- The disclosure of information to a researcher does not transfer "ownership". Researchers should anticipate that the custodian will establish expectations regarding the handling of the information including breach notification and future uses, among other things.

- Researchers should take reasonable steps to ensure that personal health information is protected against theft; loss; unauthorized access, use or disclosure; unauthorized copying or modification; and is retained, transferred and disposed of in a secure manner.

- De-identification can assist in protecting personal health information in a researcher's custody and control.

Physical, Administrative and Technical Safeguards

Physical: -Securing physical premises appropriately.
-Retaining records of PHI in a secure area.

Administrative: -de-identifying personal health information where possible.
-Signing confidentiality agreements.
-Attending privacy and security training.
-Developing, monitoring and enforcing privacy and security policies.
-Conducting privacy impact assessments on information systems and technologies that involve personal health information.

Technical: -Instituting strong authentication measures.
-Implementing encryption where appropriate.

Research Proposals to REB

- Researchers must be explicit and identify in detail the specific information:
  - that they intend to access (or collect) from the custodian and and/or
  - that they intend to collect directly from participants.

- Research proposals which **imply** access to certain personal health information will not be sufficient. Further, if the research involves both direct and indirect collection, it must indicate what information will be directly collected from participants and what information will be indirectly collected from other sources.

- If the scope of a research project changes after REB approval has been granted, it is the responsibility of the researcher to return to the REB to seek an amendment.

Research Proposals to REB - Example

- During the approval process the researcher failed to indicate that health records would be accessed. REB approval was granted on the basis that the information would be accessed directly from the patients.

  The researcher later accessed patient files based on the belief that it was apparent the research could not be completed without such access and the REB should have assumed that this was part of the research when it granted its approval.

- Researchers must be explicitly clear what information they intend to access, not only in the REB process but when they approach the custodian to request access.

- Custodians are the ultimate gatekeeper, and should not view REB approval as removing the requirement for the custodian to do its own assessment.

Need to Submit Amendments

- If the scope of a research project changes after REB approval has been granted, it is the responsibility of the researcher to return to the REB to seek an amendment.

- Amended approval, if granted, must also be brought to the custodian and custodians must review any such amended approval in the same way they would a new application.

Need for Amendments - Example

- After determining that the data they were approved to access had a number of limitations that undermined the value of their work, researchers proceeded to access other data of the custodian that was located in the same area, even though it was not explicitly part of the REB approval.

  The Custodian was found to be the source of the breach through its disclosure of personal information, but it had taken steps to remedy the privacy breach and to avoid a reoccurrence in the future.

- *PHIA* not in force at the time.

- Commissioner's Report P-2011-002 (http://www.oipc.nl.ca/pdfs/P-2011-002MUN.pdf).

Accountability

- Researchers who access or attempt to access personal health information beyond what has been explicitly approved by the REB are accountable under *PHIA* and to the REB.

- Custodians who provide access to personal health information beyond what has been explicitly approved by the REB, are accountable for that disclosure as it is contrary to *PHIA*.

- Employers of researchers may also be held accountable if the research occurs in the course of employment by a custodian.

Two-Step Process

- Physicians with access to personal health information related to their area of practice are not entitled to disclose information to researchers proactively. REB approval is still required, even with patient consent.

- Consent would avoid a violation of *PHIA*, however it is a two-step process. Disclosures for research purposes must:
  - be approved by an REB **and**
  - be carried out in accordance with *PHIA*.

Review by Custodian

- Custodians cannot rely on REB approval to satisfy their *PHIA* obligations. Disclosure is **DISCRETIONARY** (s.44).
- Custodians should have an established review process that should ensure that the information being requested matches the information approved by the REB.
- Researchers should expect to have their REB approval documents reviewed and be prepared to answer additional questions and/or meet additional requirements or restrictions placed on the project in order to ensure that the requirements and obligations of *PHIA* are met.
- Custodians must be advised by the researcher if additional or expanded access to personal health information is required beyond that previously approved by the custodian.

Review by Custodian

- When considering a request from a researcher, after REB approval, the decision whether to disclose the information is a discretionary decision by the custodian.

- Before granting access to personal health information on the basis that a research subject has provided consent for the access, there is an onus on the custodian to review the consent to ensure that it meets the requirements of *PHIA*, including that the consent form be explicitly clear as to what information is intended to be accessed by the researcher.

- Implied consent to access information is not acceptable.

Oversight by Privacy Commissioner

- *PHIA* identifies the powers, responsibilities and accountabilities of the Office of the Information and Privacy Commissioner (OIPC).

- The OIPC can investigate any alleged breach of the Act, inform the public about the Act and make recommendations to ensure compliance.

- For matters involving access to or correction of a record, an individual may make an appeal directly to the Supreme Court, Trial Division or following a review by the OIPC.

The Future…

PHIA Review Committee has completed the first 5 year review (section 91) (http://www.phiareviewnl.ca/documents/PHIA_Review_Report_Final_2017-05-29-Amended-2017-09-15.pdf)

Recommendations include:

- **#7** Broaden the application of custodianship within the post-secondary academic community.

The Future continued …

- #7a Amend the Act to replace the custodial designations associated with Memorial University (i.e. the four schools/faculties currently designated under the Act) with custodial designation of the **entire institution** with respect to all activities conducted under its teaching and research mandates.
- #9 To ensure legislative protection of personal health information across the health research community, amend the Act to designate all health researchers as custodians (whether or not the health researcher is a natural person)

The Future continued …

- **#14** To clearly include information of a genetic nature in the definition of "personal health information", amend the Act to include the phrase "genetics, including genes, genetic variation and genetic heredity;" as a subsection under Section 5(1) of the Act.
- **#60** To maintain appropriate independence between the PHIA and the HREAA, do not amend the Act to allow a custodian to disclose personal health information without consent for research purposes and without approval by a research ethics board or body, even if the research only involves publically available information.

Predictions/Prognostications

- The recommendations, if any, that become part of an amended *PHIA* will be decided by the House of Assembly.
- Commissioner's predictions:

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Questions