NEWFOUNDLAND AND LABRADOR
HREB
HEALTH RESEARCH ETHICS BOARD

Personal Health Information Act (PHIA) Review Submission

Introduction

The Personal Health Information Act (PHIA) is a health-sector specific privacy law that establishes rules that custodians of personal health information must follow when collecting, using and disclosing individuals' confidential personal health information. PHIA was proclaimed in 2011, the same year as the Health Research Ethics Authority (HREA) Act which established the HREA – a provincial, not-for-profit corporation.

The HREA Act requires that all health research involving human participants conducted in the province be reviewed and approved by a Newfoundland and Labrador research ethics board (REB) established in accordance with the HREA Act. The HREA has the power and mandate to ensure that participants in health research in Newfoundland and Labrador are protected and to facilitate health research in the province. The HREA is also responsible for providing public awareness and education on ethics issues related to health research involving human participants.

Under the HREA Act, the HREA is responsible for appointing the Health Research Ethics Board (HREB). The HREB has the legislated authority and responsibility for the ethics review and approval of applications for health research projects involving human participants. By regulation, all clinical trials and genetics research conducted in Newfoundland and Labrador must be reviewed by the HREB. Other forms of health research may be reviewed by the HREB or by other approved research ethics bodies established pursuant to Section 8 of the HREA Act. The HREB, and any approved research ethics body under the Act, are accountable to the Authority.

Neither the HREA nor the HREB are data custodians of personal health information. As such, this submission is reflecting observations from the ethics review process of proposals to collect or have personal health information disclosed for the purposes of health research and observations of how PHIA is interpreted in the context of conducting health research.

Interpretation

Section 2(v)

PHIA includes a definition of research in section 2(v)[1]. This definition is potentially broader than other working definitions of research being used by regulatory bodies (e.g. the definition of research[2] in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) and the definition of health research[3] in the HREA Act). The PHIA review committee may consider reviewing the definition of research in PHIA to evaluate the implications of inconsistent definitions in the practical implementation of PHIA for those who are also applying the principles of TCPS2 (e.g. HREB, approved research ethics bodies under the HREA Act, Memorial University).

[1] "research" means a systematic investigation designed to develop or establish principles or facts or to generate knowledge, or any combination of principles, facts and knowledge, and includes the development, testing and evaluation of research

[2] For the purposes of TCPS2, "research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation

[3] 2(d) "health research involving human subjects" means activities whose primary goal is to generate knowledge in relation to human health, health care and health care systems, and involving human beings as research subjects, health care information respecting human beings and human biological material

Also, the HREB and approved research ethics bodies under the HREA Act apply the principles outlined in the TCSP2. As such, there are research activities that are exempt from REB review where protections are available by other means (e.g. Articles 2.2 – 2.4 of TCPS2). The PHIA review committee may want to evaluate the current governance environment of research activities that are exempt from REB review that rely on the use or disclosure of personal health information.

Lastly, the TCPS2 also exempts non-research activities from REB review, for example 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 (Article 2.5 of TCPS2). Such activities may, however, raise ethical issues that would benefit from careful consideration by an individual or a body, other than the REB, capable of providing some independent guidance e.g., in professional or disciplinary associations. The PHIA review committee may want to evaluate the current governance environment of these non-research activities that are exempt from REB review that rely on the use or disclosure of personal health information.

Sections 2(w) and (y)

The above two sections define the REB or research ethics body that is charged to review research projects where personal health information may be disclosed for research purposes (e.g. section 44). It is important to note that these REBs are appointed by the HREA under the HREA Act and therefore their mandate is limited to the review of health research. Currently there are gaps in the ethics review of non-health research in the province. The internal REBs at Memorial University (specifically, the Interdisciplinary Committee on Ethics in Human Research (ICEHR) and the Grenfell Campus REB) are responsible for reviewing non-health research being conducted by faculty, students, and staff. The PHIA review committee may consider whether there are any associated gaps in the governance of non-health research that is proposing to use personal health information.

Part I: Purpose, Interpretation and Application

Section 4, Custodian

There is a practical problem of not being able to identify appropriate data custodians for the secondary use of personal health information for research purposes. It is also unclear what the processes are (beyond the research ethics review process) for the research community to gain access to personal health information held by certain data custodians (e.g. Memorial University, Regional Health Authorities, etc.) for research purposes. The PHIA review committee may want to evaluate whether the current provisions in PHIA are prescriptive enough to ensure that personal health information collected and later used for research purposes is adequately protected.

Section 5, Personal Health Information

It is unclear who has ongoing governance under PHIA of personal health information once it is disclosed to a non-custodian for research purposes, if this data is then requested to be used for a subsequent, and distinct research purpose. The PHIA review committee may want to consider this possibility and determine whether the current provisions under PHIA require modification for clarity.

Part IV: Collection, Use and Disclosure of Personal Health Information

Section 39, Disclosure for health related purposes

Subsection (1)(d) indicates that a custodian may disclose personal health information without the consent of the individual who is the subject of the information for the purpose of delivering, evaluating or monitoring a program of the custodian that relates to the provision of health care or payment for heath[4] care. There needs to be further clarity on whether a custodian may disclose personal health information to a third party who is conducting these types of activities on behalf of a custodian.

Section 44, Disclosure for research purposes

Section 44[5] is the only provision in PHIA related to the disclosure of personal health information for research purposes. It is felt that there is an inadequacy of provisions in PHIA re: the collection, use and disclosure of personal health information for research purposes (particularly compared to other province's privacy legislation). The PHIA review committee may want to consider whether PHIA currently safeguards the collection, use and disclosure of personal health information for research purposes.

As written, section 44 is a discretionary clause. Currently, this provision is being interpreted by the research community and data custodians that the disclosure is discretionary based on REB approval. Any disclosures under this section should not be discretionary upon the REB; disclosures should be discretionary upon the data custodian determining whether the request can be accommodated by their obligations under PHIA. REB review does not absolve institutions from their own responsibilities under applicable legislation (i.e. responsibilities of data custodians under PHIA). The HREB is provincial in scope and external to any one organization/data custodian. The HREB's mandate is to review the ethical acceptability of research and the privacy obligations imposed on researchers for safeguarding research data. The HREB does not review whether disclosures of personal health information for research is permitted under PHIA. The relevant data custodian has the obligation to apply PHIA in determining whether to disclose personal health information for research purposes. As such, the research ethics review process relies on the corresponding research review process (i.e. organizational review process) whereby organizations/data custodians evaluate the approved research in the context of their responsibilities under applicable legislation.

The PHIA review committee may want to review section 44 and consider revisions to emphasize that while research may require REB review, the disclosure of personal health information is discretionary upon the custodian determining whether the use is permitted. Therefore, it is possible that despite a project receiving ethics approval from an REB, a data custodian could potentially not disclose personal health information for that research purpose.

The PHIA review committee may also review the responsibilities of data custodians in the context of research to ensure that they are clear and provide adequate guidance in decision making.

[4] A typo was identified - the word 'health'

[5] A custodian may disclose personal health information without the consent of the individual who is the subject of the information for research purposes but only where the research project has been approved by a research ethics board or research ethics body under the Health Research Ethics Authority Act

Frequently Asked Questions

There is a PHIA Frequently Asked Questions (FAQ) document[6] available on the Government website to provide general information about the requirements of PHIA and help residents of the province understand their rights under PHIA and help custodians understand their obligations under the Act.

One section of the document is dedicated to research (p.27). Below are comments for possible revisions to this section to better align the content to PHIA and current practice.

'Strict conditions'

2nd paragraph on page 27 states "*PHIA permits the use or disclosure of personal health information for research purposes without an individual's consent if strict conditions are met*." These strict conditions are not further described in this document nor are they referenced in PHIA. This statement should be revised for clarity.

REB considerations

3rd paragraph outlines things an REB may consider when reviewing a research proposal involving the use and disclosure of personal health records. These considerations are not prescribed in PHIA. As such, this list should be replaced with a reference to ethics guidelines that would guide the decision-making of an REB in these circumstances (e.g. TCPS2).

Conclusion

PHIA recognizes that people expect their health information to be kept confidential. PHIA balances an individual's right to privacy with the legitimate needs of persons and organizations to collect, use and disclose their information. Similarly, the respect for privacy in research is an internationally recognized norm and ethical standard. The HREB aims to protect the rights of research participants, and part of this mandate is to ensure that the interests of participants regarding privacy is protected and to ensure researchers are treating personal information in a confidential manner. To this end, this submission is respectfully submitted to the PHIA review committee in the hopes of enhancing the legislative framework for research in this province that plays an important role in facilitating good research while protecting and respecting participants' rights.

Key point summary

- The PHIA review committee may consider reviewing the definition of research in PHIA to evaluate the implications of inconsistent definitions.
- The PHIA review committee may want to evaluate the current governance environment of research activities that are exempt from REB review that rely on the use or disclosure of personal health information.
- The PHIA review committee may want to evaluate the current governance environment of non-research activities that are exempt from REB review that rely on the use or disclosure of personal health information.
- The PHIA review committee may consider whether there are any gaps in the governance of non-health research that is proposing to use personal health information.

[6] http://www.health.gov.nl.ca/health/phia/PHIA_FAQs_Feb_2011.pdf

- The PHIA review committee may want to evaluate whether the current provisions in PHIA are prescriptive enough to ensure that personal health information collected and later used for research purposes is adequately protected.
- The PHIA review committee may want to consider the possibility of subsequent requests of secondary data for research purposes and determine whether the current provisions under PHIA require modification.
- There needs to be further clarity on whether a custodian may disclose personal health information to a third party who is conducting quality improvement/program evaluation activities on behalf of a custodian.
- The PHIA review committee may want to consider whether PHIA currently adequately safeguards the collection, use and disclosure of personal health information for research purposes.
- The PHIA review committee may want to review section 44 and consider revisions to emphasize that while research may require REB review, the disclosure of personal health information is discretionary upon the custodian determining whether the use is permitted.
- The PHIA review committee may also review the responsibilities of data custodians in the context of research to ensure that they are clear and provide adequate guidance in decision making.
- The PHIA review committee may take into consideration the comments for possible revisions to the PHIA FAQ guidance document.

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