Personal Health Information Act

Disclosures to Researchers

Office of the Information and Privacy Commissioner for Nova Scotia

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INTRODUCTION

Health custodians are entrusted with some of our most private and sensitive personal information. Traditionally, health custodians have carefully guarded that personal health information. From time to time, researchers may ask custodians for access to the personal health information in their custody and control for the purpose of conducting research.

Research has an important societal benefit. Naturally, research conducted to better understand population health, disease progression, and treatment efficacy can benefit from analyzing information collected by custodians in the course of providing treatment to patients. If a custodian is approached by a researcher or if a custodian is planning to conduct research directly, the research plan must be thoroughly assessed to ensure it meets Research Ethics Board requirements and the requirements of the *Personal Health Information Act* (*PHIA*) before any personal health information can be disclosed to the researcher or used for a research purpose.

This guideline has been developed to assist custodians who are contemplating disclosing personal health information to a researcher. Health custodians should always take the time to read the exact section of *PHIA* they are relying on to authorize a disclosure to ensure that the circumstances fit. A custodian who decides there is authority to disclose personal health information to a researcher without the consent of the subject individual is required to notify the Office of the Information and Privacy Commissioner (OIPC) of the disclosure using the form available on our website or by contacting oipc@novascotia.ca. The OIPC will require sufficient evidence and documentation that the requirements in *PHIA* are met. This guide walks custodians through those requirements.

GENERAL RULE

Under *PHIA*, a custodian must have the individual's consent to collect, use or disclose personal health information, or the collection, use or disclosure must be permitted or required by law (s. 11).

Express consent is required for the disclosure of personal health information by a custodian to a non-custodian unless required or authorized by law (s. 43). *PHIA* and other statutes provide authority for disclosures without consent in limited circumstances. Researchers are a specific type of non-custodian that *PHIA* provides a process and requirements for disclosing personal health information to, both with and without the consent of the individual.

A custodian may disclose personal health information about an individual to a researcher with the consent of the subject individual if the researcher meets the requirements in *PHIA* s. 56.

A custodian may disclose personal health information about an individual to a researcher without the consent of the subject individual if the custodian is satisfied the requirements in *PHIA* s. 57 are met and the custodian maintains documentation of the disclosure. Section 35(1)(h) of *PHIA* allows a custodian to use personal health information it has collected for research purposes without the consent of the individual, but the custodian must still comply with ss. 52 to 60 which include the requirement for a detailed written research plan and approval by a duly constituted research ethics board. The remainder of this document focuses on disclosures to researchers outside of the custodian, but many of those rules apply if the custodian is conducting research.

APPROACH

The analysis of whether or not a disclosure of personal health information to a researcher is authorized under *PHIA* involves a three-step process. Step 4 is required following a disclosure to a researcher without consent.

1. Is the information in question "personal health information" within the meaning of *PHIA*?
2. Has the researcher met the requirements of s. 56?
3. If the disclosure is without the consent of the individual, has the custodian satisfied the requirements in s. 57?
4. Create a record of a disclosure without consent to a researcher and notify the OIPC.

PHIA defines disclosure as making the information available or releasing it to another person. Keep in mind that even if *PHIA* permits disclosure without consent, best practice is to get consent whenever possible (s. 41(1)). Where express consent is required, it can be given orally or in writing (s. 16).

PHIA DISCLOSURES TO RESEARCHERS DECISION TABLE	
Step 1: Is the information "personal health information" (both recorded & unrecorded)?	
If one or more of the following statements apply, the requested information is personal health information (phi) and so the *PHIA* disclosure rules also apply.	
1. The information relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family.	√*PHIA*
2. The information relates to the application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual.	√*PHIA*
3. The information relates to payments or eligibility for health care in respect of the individual.	√*PHIA*
4. The information relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance.	√*PHIA*
5. The information is the individual's registration information, including the individual's health card number.	√*PHIA*
6. The information identifies an individual's substitute decision-maker.	√*PHIA*

If one or more of the following statements apply, the *PHIA* disclosure rules do not apply.	
1. **Employee information:** Personal health information (phi) does not include the identifying information contained in the record if the record relates primarily to an employee or agent of the custodian and the record is created or maintained primarily for a purpose other than the provision of health care or assistance in providing health care to the employee or agent.	Not phi
2. **Aggregate information:** *PHIA* does not apply to statistical, aggregate or de-identified health information.	Not *PHIA*
3. **Age of records:** *PHIA* does not apply to records that are 120 years old or 50 years after the death of an individual (whichever is earlier).	Not *PHIA*

Step 2: Has the researcher met the requirements of s. 56?
If the information in question is personal health information within the meaning of *PHIA* (Step 1), even if you have the consent of the subject individual and even if you are the custodian, you must ensure that the researcher has met the requirements in s. 56. Section 56 requires that the researcher provide details of the proposed research, proof that the research is approved by a research ethics board following the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and must enter an agreement with the custodian. **Here is a summary of the requirements for a researcher applying to a custodian:**
(a) an application to the custodian in writing
(b) a research plan that meets the requirements of s. 59 (see requirements below)
(c) a copy of the submission to and the decision of a research ethics board that approves the research plan
(d) custodian and researcher enter an agreement that meets the requirements of s. 60(2) (see requirements below)

Requirements of the research plan s. 59
Research plans must lay out researchers' intentions, what they plan to study and how the personal health information requested is necessary. They must also describe how they will safeguard the personal health information entrusted to them. Section 59 requires research plans to be in writing and sets out specific requirements. Here is a summary of the s. 59 requirements:
(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
(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 • Why their access is necessary • Their roles in relation to the research • Their qualifications
(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
(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

Requirements of the Custodian-Researcher Agreement s. 60(2)
Where a custodian discloses personal health information to a researcher (either with or without consent), the researcher must enter a research agreement with the custodian, in the which the researcher must commit to required terms and conditions. Here is a summary of the s. 60(2) minimum commitments the researcher is required to make:
(a) Comply with any terms and conditions imposed by a research ethics board
(b) Comply with any terms and conditions imposed by the custodian
(c) Use the information only for the purposes outlined in the research plan as approved by a research ethics board
(d) Not to publish the information in a form where it is reasonably foreseeable in the circumstances, that it could be utilized either alone or with other information, to identify an individual
(e) To allow the custodian to access or inspect the researcher's premises to confirm that the researcher is complying with the terms and conditions of *PHIA* and of the agreement between the custodian and the researcher
(f) To notify the custodian immediately and in writing if the personal health information is stolen, lost or subject to unauthorized access, use, disclosure, copying or modification
(g) To notify the custodian immediately and in writing of any known or suspected breach of the agreement between the custodian and the researcher
(h) Not to attempt to identify or contact the individuals unless the custodian or researcher has obtained prior consent by the individuals

Step 3: Has the custodian satisfied the requirements of s. 57 to disclose without consent?
PHIA recognizes that there are circumstances where it would be near impossible to obtain the consent of individuals whose personal health information is of interest to researchers. *PHIA* strikes a balance in these circumstances which allows the custodian to disclose personal health information to a researcher without consent, if the criteria are met. The criteria in *PHIA* sets out required considerations, documentation, and a process, but leaves the final judgement of each researcher's request to the custodian. Here is a summary of the s. 57 criteria a custodian must assess <u>before</u> disclosing to a researcher without the subject individual's consent:
(a) The researcher has met the requirements in s. 56 (see above)
(b) A research ethics board has determined that the consent of the subject individuals is not required
(c) The custodian is satisfied the research cannot be conducted without using the personal health information
(d) The custodian is satisfied the personal health information is limited to that necessary to accomplish the purpose of the research
(e) The custodian is satisfied the personal health information is in the most de-identified form possible for the conduct of the research
(f) The custodian is satisfied the personal health information will be used in a manner that ensures its confidentiality
(g) The custodian is satisfied it is impracticable to obtain consent

Step 4: Requirements following a disclosure to a researcher without consent
(a) Create a record of the disclosure in accordance with s. 42(2) The record must include: ✓ A description or a copy of the personal health information disclosed ✓ The name of the person or organization to whom the personal health information was disclosed ✓ The date of the disclosure ✓ The authority for the disclosure The record must be retrievable and be provided to an affected individual upon request.
(b) Notify the OIPC of the disclosure in accordance with s. 57(d) A notification form is provided on our website https://oipc.novascotia.ca or by contacting oipc@novascotia.ca.

WHEN IS IT "IMPRACTICABLE TO OBTAIN CONSENT"?

PHIA uses the term 'impracticable' in two locations in relation to the authority of the custodian to disclose personal health information to a researcher without the consent of the individual. First, in s. 59(h), the researcher is required to provide the custodian with an explanation as to why seeking consent is impracticable within the research plan submitted to the custodian if the researcher is seeking access to information without the individuals' consent. Second, in s. 57(f), the custodian must be satisfied that it is impracticable to obtain the consent of the individual before deciding that a disclosure without consent to a researcher is authorized.

Additionally, nested within the criteria, the custodian must consider the research ethics board's determination that consent of the individual is not required. Research ethics boards weigh in on the necessity of obtaining consent and tend to address the impracticability requirement. In doing so, research ethics boards may reference their guiding document, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. This policy states that 'impracticable' means: "Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience."[1]

However, *PHIA* requires custodians to come to their own conclusion about whether it is impracticable to obtain the individual's consent before deciding to disclose personal health information to a researcher. Examples of the types of circumstances where it might be impracticable to obtain consent are situations where the subject individuals are deceased, cannot be located, or where the sample size is extremely large. Sometimes, the need to include the full dataset in order to avoid biasing the research by including only participants who consent can result in a determination that it would be impracticable to obtain consent, if the research cannot be designed another way. Impracticability requires that other alternatives and possibilities be considered. When in doubt, the custodian is always authorized to contact the individual to seek consent to disclose contact information or more substantive personal health information.

[1] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada *Ethical Conduct for Research Involving Humans* TCPS22014, p. 205.

Here are some key considerations for determining when it is "impracticable to obtain consent":

- ✓ The custodian is always authorized to use (but not disclose) an individual's name and contact information for the purpose of obtaining consent s. 35(1)(e).

- ✓ The question of whether it is impracticable to seek the consent of the subject individual to disclose sensitive personal health information should not be taken lightly. It is a serious matter to disclose sensitive personal health information without consent.[2]

- ✓ Even if the custodian is authorized to disclose personal health information without consent, the custodian is not prevented from obtaining consent.

- ✓ The custodian is responsible to seek consent to disclose any personal health information or to decide that it is impracticable to obtain consent before disclosing.

- ✓ The custodian must first ensure that the minimum information tests are established (the research cannot be conducted without the personal health information; the personal health information provided is limited to that which is necessary for the research purpose; the personal health information is as de-identified as possible).

- ✓ Impracticability is more than inconvenience but less than impossibility and must be in reference to specific factors. What is making it impracticable? Why can consent not be obtained?

Other Considerations:

Researcher requesting contact information to seek consent to participate in a study

- ✓ Disclosure of an individual's contact information to facilitate the researcher seeking consent to participate in a study is a disclosure without consent so generally not authorized unless it is impracticable to obtain consent and all other requirements are met.

- ✓ Some custodians have in place a system for asking patients ahead of time if they wish to be contacted to participate in research studies. This pre-consent to be contacted can be helpful in identifying participants who do not want their information disclosed to researchers and/or do not consent to be contacted about research studies.

Request for de-identified information

- ✓ See Approach Step 1 (page 4 of this guide). Is this personal health information? Consent may not be required if it is not considered personal health information.

- ✓ Is the researcher planning to link or match the data with other information that might re-identify the data? Consent may be required if there is a reasonable likelihood the data may be re-identifiable.

[2] The Supreme Court of Canada has ruled on the need to protect the privacy of a patient's personal health information in the hands of a custodian. The integrity and public trust in the health care provider is at stake and consent should always be obtained unless the narrow exceptions provided in *PHIA* are met. *R. v. Dyment* [1988] 2 S.C.R. 417.

QUESTIONS

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