Capital Health

MEMORANDUM

To: Researchers

From: Legal Services and Research Services

Date: May 21, 2013

Subject: Research and the New *Personal Health Information Act*

On June 1, 2013, the *Personal Health Information Act* ("PHIA") will become law in Nova Scotia. This legislation, similar to that in existence in other provinces, deals with the collection, use and disclosure of personal health information in a comprehensive manner. PHIA introduces a number of new requirements and changes in relation to the collection, use and disclosure of personal health information. A number of these changes affect research activities, and Capital Health will be modifying some of its research policies and practices to ensure compliance with PHIA.

We want to take the opportunity to highlight some of the key requirements and information you should know about PHIA in relation to research activities. This memo also provides information on additional resources and responses to frequently asked questions. (See Appendix B attached)

PHIA – GENERAL INFORMATION

- PHIA governs the collection, use and disclosure of personal health information. Personal health information includes any information collected for the purposes of providing healthcare services that is identifiable or could reasonably lead to the identification of an individual.
- PHIA applies to all regulated healthcare professionals, DHAs, staff, physicians and agents of DHAs and researchers seeking access to personal information collected by these groups.
- PHIA introduces additional requirements for DHAs to undertake pro-active auditing and review processes for access to electronic information systems. Accordingly, anyone accessing personal health information through CDHA systems may be audited and will have to provide valid reasons, compliant with CDHA policies to establish the appropriateness of the access, including for research purposes.
- CDHA is mandated to disclose any breaches of personal health information to individuals, including unauthorized access for research purposes. There are exceptional circumstances where disclosure of a breach may not be required but in that instance we must advise the Provincial Privacy Review Officer.
- Although this has always been the case, PHIA legally confirms that **CDHA is the custodian of the personal health information collected from patients who receive care within CDHA facilities. Individual services/health professionals are not the custodians of information related care provided to DHA patients and do not have the right to collect, use or disclose personal health information except as permitted by CDHA and in compliance with the requirements of PHIA.**

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PHIA AND RESEARCH

- PHIA contains particular requirements in relation to research.
- The requirements and expectations of DHAs, physicians and healthcare providers are different when providing clinical care versus when doing research. Although it is recognized that there is often overlap, it is important for any healthcare provider involved in research to consider when the collection, use and disclosure of information is for research purposes and not only for the purpose of providing clinical care.
- The first question that should arise for health care professionals in this context is "Is this **research**"?
- Patient consent is not required for the use of personal health information for quality review and quality improvement initiatives which fall within Capital Health's quality program.
- Unless a waiver of consent is approved by the REB**, patient consent is required for any access, collection or use of personal information for research purposes. Patient consent in relation to the access, collection and use of personal health information for research purposes must be express and cannot be implied.** This includes chart reviews for research including reviews to determine research feasibility if the information is being reviewed in a patient identifiable format.
- Pursuant to PHIA, and where in compliance with the Tri-Council Policy Statement (TCPS) and ethical standards, patient contact information **only** may be shared without consent for the purpose of seeking consent to participate in research.
- In all instances, researchers are to use the minimum amount of personal health information required to achieve the research goal. As personal health information of CDHA patients is in the custody and control of CDHA, any access to personal health information for research purposes must be approved by CDHA.
- In addition to PHIA requirements, researchers should also be aware of the requirements of the Personal Information International Disclosure Protection Act which requires individual consent for the storing, accessing, or transferring of personal information outside of Canada by CDHA unless it is a mandatory operational requirement approved by the CEO.
- For decision-making as to what you need to do now – you will want to consider the questions outlined in Appendix A.
- Talk to your research team about these new requirements and share this information with them.
- Ensure that you and your research team take the PHIA training course on LMS.
- If you have questions call: Janet Gallant, Research Services, 473-2118 or Stacy Ackroyd, Research Scientist 473-3565

APPENDIX A

Decision- Making Considerations for Research and PHIA

1) Am I accessing, collecting or using personal health information for a purpose other than providing a healthcare service to a patient I am treating?

2) If yes, what is my purpose? Is it for research?

3) If for research, do I have the patient's informed consent to collect, view and use this information?

4) Could I get consent?

5) Is the consent for all of the collection and use that I am doing?

6) Am I asking anyone else to collect or use personal health information? If so, is there informed consent for their activities?

7) Am I disclosing personal health information to anyone?

8) Do I have informed consent for disclosure?

9) If I can't get consent, do I need to get REB to approve a waiver of consent for ongoing research?

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Appendix B

FAQs

1. What does PHIA say specifically about research? The provisions of PHIA in relation specifically to research are attached as Appendix B1.

2. I have research which is already started which does not appear to comply with PHIA. What do I do now?

    - PHIA does not apply retroactively, but ongoing use and disclosure should comply with PHIA
    - Previously obtained patient consent for the collection and use of personal health information in relation to research continues to be valid and new consents are not required unless there has been a material change to the nature of the information, its use, collection or disclosure since consent was obtained.
    - If you have questions, contact Janet Gallant, Research Services, 473-2118 or Stacy Ackroyd, Research Scientist 473-3565.

3. If I am not sure about my compliance with PHIA, do I need to stop my research?

    - No
    - You do need to take steps to inform yourself about PHIA and try to determine if you are currently compliant
    - If you are not, think about what steps you can reasonably take immediately to comply
    - If you cannot immediately comply, consider what steps you can reasonably take to show you are aware of your obligations and are looking to move to compliance
    - Seek help from available resources as indicated in these FAQs and other materials

4. What are the possible consequences for not complying with PHIA requirements?

    - PHIA contains a number of penalties for non-compliance including charging with a summary offence, fines and jail time.
    - PHIA also requires mandatory reporting of inappropriate accesses to personal health information.
    - Investigations into personal health information management processes may be initiated by the provincial privacy review officer.
    - In addition to PHIA requirements, breaches of Capital Health policies and procedures are subject to corrective action and disciplinary processes.

5. How does PHIA apply to members of my research team who are not part of CDHA?

    - It is the responsibility of CDHA as the custodian and the Researcher, to ensure that any collection, use and disclosure of personal health information complies with PHIA.

This obligation extends to collection, use and disclosure by members of the research team.

6. Which research related policies and procedures have changed as a result of PHIA?

    - A number of forms and processes have been or are in the process of being revised including:

        - EAS forms
        - Consent templates for collection of information for future research
        - CDHA Release of Information policy
        - Introduction of a CDHA Auditing policy
        - Process for accessing records for research purposes through HIS and other electronic information management systems

7. Does PHIA apply to tissue, specimens and samples?

    - PHIA applies to personal health information in any recorded or unrecorded form.
    - While it does not technically apply solely to tissue, specimens and samples, PHIA would apply to any personal health information associated with tissue, specimens and samples
    - In addition to PHIA requirements, the use and sharing of tissue, specimens and samples are subject to CDHA policies and other legislative requirements.
    - Pursuant to the *Hospitals Act*, tissue are required to the sent to the lab for examination
    - Further, there is no legal ownership by clinicians of patient tissue, specimens and samples and therefore patient consent should be obtained prior to the use or disclosure of samples
    - Researchers should also ensure that material transfer agreements are in place to address ongoing use and disclosure of tissue, specimen and samples

8. What constitutes de-identified information?

    PHIA defines de-identified information as follows:

    “De-identified information" is information that has had all identifiers removed that:

    (i) identify the individual, or

    (ii) where it is reasonably foreseeable in the circumstances, could be utilized, either alone or with other information, to identify the individual;

9. Given the nature of my research, it is not possible for me to get consent from research participants. Can the research proceed?

   PHIA permits the disclosure of personal health information by a DHA to a researcher without patient consent where obtaining consent is impracticable, a waiver of consent is approved by the REB and the researcher signs an agreement with the DHA as custodian

10. Do I need consent for a chart review?

    Yes, unless this is clearly for purposes of quality review/improvement and not for other purposes; or unless a waiver of consent is approved by the REB; or unless the review is by a treating healthcare professional for the purpose of providing clinical care to the patient.

11. I have or want to establish a database of patient information for ongoing research activities. Is this permissible?

    - Yes, assuming PHIA requirements are met
    - Consent of patients is required, unless consent is impracticable and approval of REB is granted
    - You can obtain consent for collection, use and disclosure for research purposes. Documentation of the nature and scope of consent is required and should be on the patient's health record
    - If you have an existing database, without consent, it is recommended that you obtain the consent of the included patients or seek approval from the REB for an exemption
    - All electronic information systems at CDHA should have auditing capabilities and be able to produce a record of user activity to comply with PHIA requirements

12. My work is designed to improve the quality of care, is it research?

    - Most research has as its ultimate goal the improvement of patient care. Other factors must be considered in determining whether a project is research or quality improvement.
    - Work is currently under way to provide additional information and resources for making these determinations, and it is anticipated that their information will be available in the coming months.
    - In the interim, current practices continue to apply. For more information, consult the REB Jurisdiction policy.

13. This legislation is going to stop valuable research, why?

    - Comparable legislation is in place in all provinces and it has not stopped research
    - The legal requirements for consent to access and use personal health information are not significantly changed by PHIA though the oversight of compliance is increased.

- Access without consent for research purposes has always been a violation of the law
- Engagement of patients and obtaining of consent is not an impediment to research, but a means of ensuring that patients and citizens are aware of the valuable work being done, while also balancing their rights to the privacy of their information
- This legislation offers clarification of everyone's obligations
- There will be a transition with this legislation and CDHA is committed to its academic and research mandate and will continue to support researchers in reducing impediments to the extent possible

14. Where can I go to get help with figuring out my requirements?

- You can review the legislation and information provided by the Department of Health and Wellness at http://novascotia.ca/dhw/phia/

- You can review the CDHA toolkits and FAQs at http://chdintra.cdha.nshealth.ca/departmentservices/legalServices/personalHealthInfoAct.html

- You can contact Janet Gallant, Research Services at 473-2118.

- You can contact the REB at 473-5620

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APPENDIX B1 – RESEARCH PROVISIONS OF THE NOVA SCOTIA PERSONAL HEALTH INFORMATION ACT

RESEARCH

52 In Sections 53 to 60,

(a) "data matching" means the creation of individual identifying health information by combining individual identifying or non-identifying health information or other information from two or more databases without the consent of the individuals who are the subjects of the information;

(b) "impracticable" means a degree of difficulty higher than inconvenience or impracticality but lower than impossibility;

(c) "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;

(d) "research ethics board" means a research ethics board established and operating in conformity with the Tri-Council Policy Statement;

(e) "Tri-Council Policy Statement" means the Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans" adopted in August 1998 by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada, and includes any amendments or successor statements.

53 Planning and management of the health system does not constitute research for the purpose of this Act.

54 The use and disclosure of personal health information by a custodian is limited to the minimum amount of information necessary to accomplish the research purposes for which it is to be used or disclosed.

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.

56 A custodian may disclose personal health information about an individual to a researcher if the researcher

(a) submits to the custodian

(i) an application in writing,

(ii) a research plan that meets the requirements of Section 59, and

(iii) a copy of the submission to and decision of a research ethics board that approves the research plan; and

(b) enters into the agreement required by Section 60.

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.

58 A custodian may prescribe forms for use by researchers for

(a) an application under clause 56(a)(i);

(b) a research plan under Section 59; and

(c) a disclosure agreement under Section 60.

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;

(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;

(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.

60 (1) Where a custodian discloses personal health information to a researcher, the researcher shall enter into an agreement with the custodian to adhere to the requirements in subsection (2).

(2) An agreement referred to in subsection (1) must include a commitment by the researcher

(a) to comply with any terms and conditions imposed by a research ethics board;

(b) to comply with any terms and conditions imposed by the custodian;

(c) to 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 this Act 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; and

(h) not to attempt to identify or contact the individuals unless the custodian or researcher has obtained prior consent by the individuals.