

INFORMATION AND PRIVACY COMMISSIONER OF ALBERTA

Report of an investigation concerning health information and research

August 3, 2011

Covenant Health

Investigation Report H2011-IR-002

(Investigations H3176 and H3448)

Introduction

- [1] A potential research subject (i.e. “the complainant”) complained to the Information and Privacy Commissioner that a researcher had sent her a letter, asking her to participate in a study. In her letter to the Commissioner, the complainant wanted to know how the researcher was able to access her health record to select her for the study. The complainant stated, “I feel that my privacy was invaded and my health information was shared without my knowledge.”
- [2] The letter the complainant received names a physician (i.e. “the physician,” or “the researcher”) as the Principal Investigator for the study. Initially, the Commissioner authorized me to conduct an investigation of the physician under section 85(e) of the *Health Information Act* (HIA) (file H3176). This provision allows the Commissioner to investigate complaints that health information has been collected, used or disclosed by a custodian in contravention of the HIA. After conducting a preliminary review, it became apparent that another party was involved in this case, Covenant Health. It also became apparent that the physician may not have been acting in the capacity of a “custodian” as defined in the HIA. The Commissioner therefore initiated a second investigation under section 84(a) of the HIA. This is a broader provision which allows the Commissioner to conduct investigations on his own motion to ensure compliance with any provision of the HIA. This second investigation reviewed Covenant Health’s role in this matter (file H3448).

Background

- [3] The complainant had been a patient at a clinic at the Grey Nuns Community Hospital (i.e. “the clinic”) six-and-a-half years previous to being contacted to participate in the study. This particular clinic at the Grey Nuns Community Hospital is a Covenant Health facility.
- [4] The physician was the Director of the clinic from 1996 to 2009 and had full privileges with Covenant Health between 1996 and 2009. The physician is also a Professor at the University of Alberta and the Principal Investigator for the study.
- [5] The physician obtained the list of patients to contact the complainant as follows, “...patients with [diagnosis] have an increased risk of developing [diagnosis] in the future and likely will benefit from additional management such as lifestyle modification. With this in mind, I have kept a list of patients that were seen at the Grey Nuns clinic.”
- [6] I verified that the study received approval from the University of Alberta’s Health Research Ethics Board (REB) in 2008. This approval was renewed in 2009 and extended until June of 2010.
- [7] While this case was under investigation, amendments to the HIA were proclaimed in force on September 1, 2010, under the *Health Information Amendment Act*. The letter inviting the complainant to participate in the study was dated September 14, 2009. Therefore, the physician obtained the complainant’s health information prior to September 14, 2009. Throughout this Investigation Report, I refer to the wording of the HIA in force at the time the physician obtained the complainant’s health information to contact her, rather than the currently amended version of the HIA.

Application of HIA

- [8] The *Health Information Act* applies to “health information” in the custody or control of “custodians.” “Health information” is generated through the provision of a “health service.”
- [9] The complainant was treated for a medical condition at a Covenant Health facility. Covenant Health is a custodian under section 1(1)(f)(i) of the HIA. (At the time the complainant was treated, Covenant Health was named Caritas Health Group).
- [10] The complainant was treated for the medical condition prior to being contacted by the physician. The definition of “health service” in section 1(1)(m) of the HIA includes (among other things) protecting, promoting or maintaining physical health, preventing illness and diagnosing and treating illness. The treatment received by the complainant falls within this definition.

- [11] The complainant's name and address were used to contact her as a potential participant in the study. I reviewed the letter sent to the complainant and it begins with, "Dr. [physician] is contacting you as someone who has had [diagnosis] in the past." Name, address and the complainant's diagnosis all fall within the definition of health information under section 1(1)(k) of the HIA. This health information was originally generated when the complainant was treated at Covenant Health's clinic.

Physician's roles

- [12] The physician played two roles in this matter. Initially, the physician was the Director of the clinic at Covenant Health. Later, when the physician contacted the complainant to solicit her participation in the study, the physician was the study's Principal Investigator.

The physician's role at Covenant Health

- [13] The physician served as Director of the clinic from 1996 to 2009 at Covenant Health's Grey Nuns Hospital and continues to provide health services at that hospital. The physician provided these services under the University of Alberta's Department of Medicine Academic Alternate Relationship Plan¹ (AARP) which is a contractual agreement with Covenant Health (among other parties). A person who performs a service for another custodian under a contract or agency relationship is an "affiliate" of that custodian, per section 1(1)(a)(ii) of the HIA. When the physician provided health services to the complainant under a contractual arrangement with Covenant Health (the AARP), the physician was acting as Covenant Health's affiliate. Therefore, in this role, the physician was an affiliate of Covenant Health.
- [14] Pursuant to section 62(2) of the HIA, any collection, use or disclosure of health information by an affiliate of a custodian is considered to be collection, use or disclosure by the custodian. Therefore, Covenant Health remains responsible for any actions taken by the physician in relation to the health information in question while the physician worked as Covenant Health's affiliate.

¹ According to Alberta Health and Wellness' website, "Academic ARPs are inclusive agreements that engage all relevant stakeholders including but not limited to: the involved university and faculty of medicine, the participating physicians, Alberta Health and Wellness, Alberta Health Services, the Alberta Medical Association, and other funding bodies and related ministries such as Advanced Education and Technology."
<http://www.health.alberta.ca/professionals/ARP-Academic.html>, accessed July 18, 2011.

Physician's role as researcher

- [15] The HIA does not define the term “researcher.” However, Part 5, Division 3 (sections 48-56) of the HIA, which covers disclosure to researchers, uses the term “researcher” throughout. Section 49 says,

Research Proposal

49 A person who intends to conduct research may submit a proposal to a research ethics board for review by that board.

If I conclude the physician is a “person who intends to conduct research” and the study is, in fact, “research,” then I will consider the physician a “researcher” under the HIA.

- [16] The physician submitted a proposal for the study to the University of Alberta Health Research Ethics Board, which approved the proposal and issued a response. The physician is therefore “a person who intends to conduct research.”

- [17] The term, “research” is defined in section 1(1)(v) of the HIA as:
(v) “research” means academic, applied or scientific health related research that necessitates the use of individually identifying diagnostic, treatment and care information or individually identifying registration information, or both;

In my opinion, the study falls within the above definition of “research”. Further, the physician’s study was considered to be “research” by the REB, a body with expertise in determining what constitutes research. Because the physician is a “person who intends to conduct research” and the proposed study is “research,” I conclude the physician is a “researcher” as contemplated in Part 5, Division 3 of the HIA.

- [18] Under different circumstances, the physician could be considered an independent custodian. For clarity, there is no evidence to suggest the physician was acting as an independent custodian in this matter. When working at the clinic, the physician was an “affiliate” of Covenant Health. When contacting the complainant to invite her to participate in the study, the physician was acting as a “researcher.”

Research disclosures under the HIA

- [19] The HIA establishes a process for researchers to request health information from custodians in Part 5 Division 3. The process can be summarized as follows (with reference to the corresponding sections of the HIA):
- i. Researcher submits research proposal to research ethics board (REB) (s. 49)
 - ii. REB reviews proposal, weighing public interest and privacy impacts, including patient consent (s. 50(1)-(2))
 - iii. REB issues response to researcher, stating whether the project is acceptable and whether the researcher needs to obtain patient consent (s. 50(3))
 - iv. REB sends copy of its response to the Information and Privacy Commissioner (s. 50(4))

- v. Researcher applies in writing to the custodian(s) who have custody of the health information needed for the research (s. 52), including a copy of the REB response
- vi. Custodian considers researcher's application and may decide to disclose the requested health information to researcher (s. 53)
- vii. If the custodian decides to disclose the health information to the researcher, the custodian and the researcher must enter into an agreement (s. 54(1))
- viii. When the above agreement has been entered into, the custodian may disclose the health information to the researcher (s. 54(2)).

[20] In summary, the HIA applies to this matter because the information in question was generated through the provision of a health service and falls within the definition of health information. Covenant Health is the custodian responsible for the health information in question. Finally, the health information in question was disclosed from the custodian (Covenant Health) to a researcher (the physician) for the purpose of conducting research.

Issues

[21] The researcher (in this context, the physician is "the researcher") prepared a research proposal, submitted it to an REB for approval, the REB approved the proposal and the approval was forwarded to the Information and Privacy Commissioner. In other words, steps i. through iv. in the research disclosure process summarized above at paragraph 19 were duly carried out. Therefore, my analysis focuses on the three following issues:

- A. Did the researcher fail to forward to the custodian a written application for disclosure of the health information to be used in the research, as required by section 52 of the HIA?
- B. Did the researcher and custodian fail to enter into a written agreement, as required by section 54(1) of the HIA?
- C. Did Covenant Health disclose health information to the researcher in contravention of section 54(2) of the HIA?

Analysis

A. Did the researcher fail to apply for disclosure of the health information?

[22] I have reviewed the physician's research ethics board approvals. There is no question that the physician's study was approved by a REB. However, REB approval is only one of the pre-requisites to obtaining health information to perform research. Once a researcher obtains REB approval, the researcher must then apply to a custodian to disclose the health information. Section 52 of the HIA says:

Application for disclosure of health information

52 If the research ethics board is satisfied as to the matters referred to in section 50(1)(b), the researcher may forward to one or more custodians

- (a) the response of the research ethics board to the researcher's proposal, and
- (b) a written application for disclosure of the health information to be used in the research.

[23] I asked whether the physician had applied to Covenant Health for the health information needed to contact potential research subjects. In response, the physician provided a signed Alberta Health Services' (AHS) "Administrative Approval for Proposed Research" form. This AHS form is used when researchers need to use clinical or information technology resources to conduct their research project. An AHS form was used in this case because AHS provides these resources to Covenant Health under contract. The physician understands that this form does not constitute an application for disclosure under section 52 of the HIA, but assumed this form would also instigate a proper research approval. It did not.

[24] The Covenant Health Research Centre approves applications for disclosure of health information from researchers. The Covenant Health Research Centre did not receive an application from the physician for this project. Therefore, I find the physician, as researcher, failed to forward to the custodian a written application for disclosure of the health information to be used in the research, as required by section 52 of the HIA.

B. *Did the researcher and custodian fail to enter into a written agreement?*

[25] If a custodian decides to disclose health information to a researcher after considering an application under section 52, the custodian and the researcher must then enter into an agreement as described in section 54(1) of the HIA. This agreement needs to cover several topics listed in section 54(1), including

- compliance with the HIA
- meeting any conditions the custodian sets to protect the confidentiality and security of the information, including eventual return or disposal of the information
- an agreement to use the information only for the purposes of the approved research
- an agreement not to publish information that can readily identify research subjects
- an agreement not to contact research subjects without prior consent,
- an agreement to allow the custodian to inspect the researcher's premises to confirm compliance
- costs
- termination of the agreement in the event of non-compliance.

[26] Both the physician and Covenant Health confirm that no such agreement was in place. Therefore, I find the researcher and custodian failed to enter into a written agreement, as required by section 54(1) of the HIA.

C. *Did Covenant Health disclose health information in contravention of section 54(2) of the HIA?*

- [27] Section 54(2) of the HIA says that when the custodian and the researcher enter into an agreement as described under section 54(1), the custodian may then disclose the requested health information to the researcher. This also means the custodian may not disclose health information to a researcher unless this step is taken.
- [28] As previously noted, the complainant's health information originated from Covenant Health. By virtue of the physician's working relationship with Covenant Health, the physician had access to health information at the clinic. However, Covenant Health was (and still is) the custodian of this health information. When the physician created the patient contact list, the physician did not do so as part of the physician's duties to Covenant Health. In fact, Covenant Health was unaware of the existence of the list. When the patient list was employed to contact potential research subjects, health information passed from the custody of Covenant Health into the hands of a researcher. In my opinion, this constitutes a disclosure of health information from Covenant Health to a researcher.
- [29] I asked Covenant Health whether it had authorized this disclosure of health information for the purposes of the study. Covenant Health reported that it had not authorized the disclosure, nor was it aware of the study.
- [30] Covenant Health, while unfortunately unaware of this disclosure, remains responsible for the actions of its affiliate (in this context, the physician). In the absence of a formal request from the researcher under section 52 and an agreement under section 54(1), I can see no other provision in the HIA that would have authorized this disclosure of health information from Covenant Health to the researcher. Therefore, I find that Covenant Health disclosed health information in contravention of section 54(2) of the HIA.

Actions taken by the Physician

- [31] On being informed of the complaint, the physician immediately suspended the research project, pending the outcome of this Investigation.
- [32] After reviewing this matter at a meeting I facilitated with the physician and Covenant Health officials, the physician agreed to make an application to the Covenant Health Research Centre pursuant to HIA section 52 for disclosure of the health information needed to support the study. Further, if Covenant Health decides to disclose the requested information, the physician committed to entering into a research agreement with Covenant Health, pursuant to HIA section 54(1).
- [33] Finally, the physician removed the complainant's health information from the research database.

[34] In my opinion, the physician responded to this incident responsibly and has taken appropriate corrective actions. I note that the physician cooperated fully and openly with this investigation.

Actions taken by the Custodian

[35] As noted above, Covenant Health has agreed to receive and consider a section 52 request from the physician to disclose health information to conduct the study and, if appropriate, enter into a research agreement with the physician pursuant to section 54(1) of the HIA.

[36] I reviewed Covenant Health's policy regarding research, "Disclosure for Research Purposes," dated March 25, 2004. This policy outlines the steps Covenant Health staff must take on receipt of a request for health information from a researcher. In my opinion, this policy complies with the HIA. Unfortunately, Covenant Health was not able to exercise this policy as it was not aware of the disclosure at the root of this incident.

[37] Covenant Health cooperated fully and openly with this investigation.

Recommendations

[38] At paragraph 5, I noted the physician's reason for maintaining the list of patients from the clinic. To recap, the physician would potentially use this information for ongoing patient care because patients with the complainant's medical condition have a higher chance of developing a related medical condition and could benefit from further interventions. This list was subsequently employed to contact former patients to ask them to participate in the study. Covenant Health advised that it was not aware that the physician was maintaining the list. I have found that this list was disclosed for research purposes in contravention of the HIA, which puts the list's existence and eventual disposition in question.

- A. If the physician and Covenant Health enter into a research agreement pursuant to HIA s. 54(1), the use, protection and eventual return or disposition of the list must be covered in the agreement.
- B. In the interim, I recommend that the physician return the list to Covenant Health and destroy any copies until an appropriate agreement is executed. As custodian of the health information, it is Covenant Health's responsibility to ensure the list is returned for appropriate records management.
- C. The physician says the list was created for on-going patient care, which is not a purpose I have reviewed in this Investigation Report. I recommend that Covenant Health consider whether the physician should have access to former patients' health information for the purpose of on-going patient care.

If Covenant Health agrees with this purpose, Covenant Health should consider whether there is some other more appropriate and secure way to give the physician access to this information.

[39] I am pleased to report that both the physician and Covenant Health have agreed to implement my recommendations.

Conclusion

[40] This investigation highlighted the process in the HIA that allows custodians to disclose health information to researchers.² This process includes three steps:

- Research Ethics Board approval of the research
- Formal request from the researcher to the custodian to disclose information
- Execution of an agreement between the researcher and the custodian, which enables the disclosure.

[41] In this case, the researcher began work after receiving REB approval, but without taking the next two steps.

[42] The distinction between conducting research and providing health services is clear when the researcher and the custodian are separate entities. When the researcher also has a role as an affiliate of the custodian, this distinction is blurred. This case serves as a reminder to researchers who have access to health information through their work as health services providers. When conducting research with data they routinely employ to provide health services, researchers still need to follow the HIA research process and execute a research agreement with the custodian of the health information. The HIA makes custodians responsible for considering research requests before health information may be disclosed to researchers. Custodians are the gatekeepers in this regard and have a responsibility to ensure researchers follow the rules of the HIA through a formal agreement.

Brian Hamilton
Director, Health Information Act

² At paragraph 7 I noted the HIA was amended in September 2010. These amendments changed some of the wording in the HIA's research provisions. However, none of these amendments would alter my findings in any material way, had I investigated this matter under the HIA as it currently stands.