**Research and the *Health Information Act***

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This document identifies the key sections of the *Health Information Act* [[1]](#footnote-1)that may be referred to by a custodian when managing requests for information for research purposes. It does not cover every section that may need to be considered in every situation.

**Health Information Act**

**Definitions**

1(1)

1. “**affiliate**”, in relation to a custodian, means

(i) an individual employed by the custodian,

(ii) a person who performs a service for the custodian as an appointee, volunteer or student or under a contract or agency relationship with the custodian,

(iii) a health services provider who is exercising the right to admit and treat patients at a hospital as defined in the Hospitals Act,

(iv) an information manager as defined in section 66(1), and

(v) a person who is designated under the regulations to be an affiliate, but does not include

(vi) an agent as defined in the Health Insurance

Premiums Act, or

(vii) a health information repository other than a health information repository that is designated in the regulations as an affiliate;

(f) “**custodian**” is defined in the *Health Information Act*.

(g) “**data matching**” means the creation of individually identifying health information by combining individually identifying or non-identifying health information or other information from 2 or more electronic databases, without the consent of the individuals who are the subjects of the information;

(k) “**health information**” means one or both of the following:

(i) diagnostic, treatment and care information;

(ii) registration information;

(p) “**individually identifying**”, when used to describe health information, means that the identity of the individual who is the subject of the information can be readily ascertained from the information;

(r) “**non-identifying**”, when used to describe health information, means that the identity of the individual who is the subject of the information cannot be readily ascertained from the information;

(v) “**research**” means academic, applied or scientific research that necessitates the use of individually identifying health information;

(v.1) “**research ethics board**” means a body designated by the regulations as a research ethics board;

**Use of individually identifying health information**

26 A custodian may use non-identifying health information for any purpose.

27(1) A custodian may use individually identifying health information in its custody or under its control for the following purposes:

(d) conducting research or performing data matching or other services to facilitate another person’s research

(i) if the custodian or researcher has submitted a proposal to a research ethics board in accordance with section 49,

(ii) if the research ethics board is satisfied as to the matters referred to in section 50(1)(b),

(iii) if the custodian or researcher has complied with or undertaken to comply with the conditions, if any, suggested by the research ethics board, and

(iv) where the research ethics board recommends that consents should be obtained from the individuals who are the subjects of the health information to be used in the research, if those consents have been obtained;

28 An affiliate of a custodian must not use health information in any manner that is not in accordance with the affiliate’s duties to the custodian.

**Disclosure of non-identifying health information**

32(1) A custodian may disclose non-identifying health information for any purpose.

(2) If a disclosure under subsection (1) is to a person that is not a custodian, the custodian must inform the person that the person must notify the Commissioner of an intention to use the information for data matching before performing the data matching.

**Disclosure of individually identifying health information to be with consent**

34(1) Subject to sections 35 to 40, a custodian may disclose individually identifying health information to a person other than the individual who is the subject of the information if the individual has consented to the disclosure.

(2) A consent referred to in subsection (1) must be provided in writing or electronically and must include

(a) an authorization for the custodian to disclose the health information specified in the consent,

(b) the purpose for which the health information may be disclosed,

(c) the identity of the person to whom the health information may be disclosed,

(d) an acknowledgment that the individual providing the consent has been made aware of the reasons why the

health information is needed and the risks and benefits to the individual of consenting or refusing to consent,

(e) the date the consent is effective and the date, if any, on which the consent expires, and

(f) a statement that the consent may be revoked at any time by the individual providing it.

(3) A disclosure of health information pursuant to this section must be carried out in accordance with the terms of the consent.

(4) A revocation of a consent must be provided in writing or electronically.

(5) A consent or revocation of a consent that is provided in writing must be signed by the person providing it.

(6) A consent or revocation of a consent that is provided electronically is valid only if it complies with the requirements set out in the regulations.

**Division 3 Disclosure for Research Purposes**

48 Repealed 2009 c25 s13.

Research proposal

49 A person who intends to conduct research using health information in the custody or under the control of a custodian or health information repository must submit a proposal to a research ethics board for review by that board containing

1. the information specified by the regulations, and

(b) any other information required by the research ethics board.

Role of research ethics board

50(1) The research ethics board must

(a) consider whether the researcher should be required to obtain consents for the disclosure of the health

information to be used in the research from the individuals who are the subjects of the information, and

(b) assess whether, in the opinion of the research ethics board,

(i) the proposed research is of sufficient importance that the public interest in the proposed research outweighs to a substantial degree the public interest in protecting the privacy of the individuals who are the subjects of the health information to be used in the research,

(ii) the researcher is qualified to carry out the research,

(iii) adequate safeguards will be in place at the time the research will be carried out to protect the privacy of the individuals who are the subjects of the health information to be used in the research and the confidentiality of that information, and

(iv) obtaining the consents referred to in clause (a) is unreasonable, impractical or not feasible.

(2) In making an assessment under subsection (1)(b), the research ethics board must consider the degree to which the proposed research may contribute to

(a) identification, prevention or treatment of illness or disease,

(b) scientific understanding relating to health,

(c) promotion and protection of the health of individuals and communities,

(d) improved delivery of health services, or

(e) improvements in health system management.

(3) The research ethics board must prepare a response setting out

(a) its recommendation under subsection (1)(a),

(b) its assessment of the matters set out in subsection (1)(b), and

(c) any conditions that the research ethics board considers should be imposed on the researcher.

(4) The research ethics board must send a copy of the response required in subsection (3) to the Commissioner.

Publication of response

50.1 If the response of the research ethics board sent to the Commissioner under section 50(4) indicates that the research ethics board is satisfied as to the matters referred to in section 50(1)(b), the Commissioner may publish the response in any manner the Commissioner considers appropriate.

Bar to research

51 If the research ethics board is not satisfied as to any of the matters referred to in section 50(1)(b), the researcher may not apply to a custodian or health information repository under section 52.

Application for disclosure of health information or to perform data matching

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 or health information repositories

(a) the researcher’s proposal referred to in section 49,

(b) the response of the research ethics board to the researcher’s proposal, and

(c) a written application for one or more of the following:

(i) disclosure of the health information to be used in the research;

(ii) performance of data matching;

(iii) performance of any other service to facilitate the research.

Conditions and consents

53(1) A custodian who has received the documents referred to in section 52 may, but is not required to, disclose the health information or perform data matching or other services to facilitate the research.

(2) If the custodian decides to disclose the health information or perform data matching or other services to facilitate the research,

(a) the custodian

(i) must impose on the researcher the conditions suggested by the research ethics board, and

(ii) may impose other conditions on the researcher, and

(b) if the research ethics board recommended that consents referred to in section 50(1)(a) be obtained, the researcher must obtain the consents before the disclosure of the health information or performance of data matching or other services.

(3) A health information repository that has received the documents referred to in section 52 may disclose the health information or perform data matching or other services to facilitate the research only in accordance with the regulations.

Agreement between custodian and researcher

54(1) If the custodian decides to disclose health information to a researcher or perform data matching or other services to facilitate the research, the researcher must enter into an agreement with the custodian in which the researcher agrees

(a) to comply with

(i) this Act and the regulations made under this Act,

(ii) any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information, and

(iii) any requirement imposed by the custodian to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information,

(b) to use the health information only for the purpose of conducting the proposed research,

(c) not to publish the health information in a form that could reasonably enable the identity of an individual who is the subject of the information to be readily ascertained,

(d) not to make any attempt to contact an individual who is the subject of the health information to obtain additional health information unless the individual has provided the custodian with the consent referred to in section 55,

(e) to allow the custodian to access or inspect the researcher’s premises to confirm that the researcher is complying with the enactments, conditions and requirements referred to in clause (a), and

(f) to pay the costs referred to in subsection (3).

(2) When an agreement referred to in subsection (1) has been entered into, the custodian may disclose to the researcher the health information requested under section 52 or perform data matching or other services to facilitate the research

(a) with the consent of the individuals who are the subjects of the information, where the research ethics board recommends that consents should be obtained, or

(b) without the consent of the individuals who are the subjects of the information, where the research ethics board does not recommend that consents be obtained.

(3) The custodian may set the costs of

(a) preparing information for disclosure, or performing data matching or other services

(b) making copies of health information, and

(c) obtaining the consents referred to in section 55, which must not exceed the actual cost of providing that service.

(4) If the researcher contravenes or fails to meet the terms and conditions of an agreement under this section, the agreement is cancelled.

Consent for additional information

55 If the researcher wishes to contact the individuals who are the subjects of the information disclosed under section 54(2) to obtain additional health information, the custodian or an affiliate of the custodian must first obtain consents from those individuals to their being contacted for that purpose.

Court order

56(1) If a researcher refuses to allow a custodian or health information repository to access or inspect its premises in accordance with the agreement referred to in section 54, the custodian or health information repository may apply to the Court of Queen’s Bench for an order under subsection (2).

(2) If the Court is satisfied that there are reasonable and probable grounds to believe that access to premises or the production or removal of documents is necessary for the purpose of determining whether an agreement referred to in section 54 is being complied with, the Court may make any order it considers necessary to

enforce compliance with the agreement.

(3) Where authorized to do so by an order under subsection (2), a custodian or health information repository may

(a) enter and search any premises of the researcher where the research is conducted,

(b) operate or cause to be operated any computer system of the researcher to search any data contained in or available to the system and produce a document from the data, and

(c) seize and make copies of any documents of the researcher that are or may be relevant to the investigation.

(4) An application for an order under this section may be made ex parte unless the Court orders otherwise.

(5) The custodian or health information repository must return any documents seized pursuant to a court order within 60 days after the conclusion of the investigation that gave rise to the seizure, including any hearing or appeal.

(6) In this section, “document” includes any correspondence, memorandum, book, plan, map, drawing, diagram, pictorial or graphic work, photograph, film, microfilm, sound recording, videotape, machine readable record or other material or thing, regardless of physical form or characteristics.

**Collection, Use or Disclosure by Affiliate**

**[*IPO note: relevant if an affiliate is conducting research or providing services to facilitate research, in accordance with the affiliate’s duties to custodian]***

62 (2) 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.

**Data matching for research**

72 If data matching is performed for the purpose of conducting research, sections 48 to 56 must be complied with before the data matching is performed.

**Offences and penalties**

107 (2)(f) No person shall knowingly use individually identifying health information to market any service for a commercial purpose or to solicit money unless the individual who is the subject of the health information has specifically consented to its use for that purpose.

(3) No researcher shall knowingly breach the terms and conditions of an agreement entered into with a custodian pursuant to section 54.

(4) No information manager shall knowingly breach the terms and conditions of an agreement entered into with a custodian pursuant to section 66.

(5) No person to whom non-identifying health information is disclosed and who intends to use the information to perform data matching shall fail to comply with section 32(2).

(6) A person who contravenes this section, except subsection (5.1), is guilty of an offence and liable to a fine of not more than $50 000.

**HIA Health Information Regulation – Disclosure of Health Information Outside Alberta**

**Disclosure of Health Information Outside of Alberta**

8 (4) In order to ensure the privacy and confidentiality of health information that is to be stored or used by a person in a jurisdiction outside Alberta or that is to be disclosed to a person in a jurisdiction outside Alberta, the custodian must, prior to the storage, use or disclosure of the information, enter into a written agreement with the person that

1. provides for the custodian to retain control over the health information,
2. adequately addresses the risks associated with the storage, use or disclosure of the health information,
3. requires the person to implement and maintain adequate safeguards for the security and protection of the health information,
4. allows the custodian to monitor compliance with the terms and conditions of the agreement, and

(e) contains remedies to address any non-compliance with or breach of the terms and conditions of the agreement by the other person.

1. Health Information Act of Alberta, Revised Statutes of Alberta 2000 Chapter H-5, Current as of June 17, 2014 [↑](#footnote-ref-1)