The Health Information Act

Use and Disclosure of Health Information for Research

Office of the Information
and Privacy Commissioner

The Health Information Act (HIA) sets out rules respecting the use and disclosure of health information for research purposes in Alberta.

"***Health information***" is defined as individually identifying diagnostic, treatment and care and/or registration information but does not include health service provider information.

"***Research***" is defined as 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.

The HIA states that a person who intends to conduct research may submit a proposal to an ethics committee for review. Although the wording appears to be discretionary, it is mandatory when the health information to be used in the research is individually identifying.

The ethics committees (EC) referred to in the HIA are commonly referred to as research ethics boards. There are six boards listed in the Designation Regulation as ethics committees which can meet the requirements of the Act for reviewing research proposals addressing use or disclosure of health information. They are:

1. Alberta Cancer Board – Research Ethics Committee;
2. College of Physicians and Surgeons of Alberta – Research Ethics Review Committee;
3. Alberta Heritage Foundation for Medical Research – Community Health Ethics Research Review Committee; also known as – Community Research Ethics Board of Alberta
4. University of Alberta – Health Research Ethics Board;
5. University of Calgary – Conjoint Health Research Ethics Board;
6. University of Lethbridge – Human Subject Research Committee.

Use versus Disclosure of Health Information for Research

The concept of ***use*** means internal sharing of health information by a custodian and a custodian's affiliates.

The concept of ***disclosure*** means external sharing of health information by a custodian with another custodian or with a non-custodian.

Disclosure of Health Information for Research

The following illustrates the HIA roles and responsibilities relating to the **disclosure** of health information for research including the party responsible for the obligation described.

Considerations for Disclosure of Health Information in Research	Ethics Committee (EC)	Researcher	Custodian
Ethics approval	• review required by EC	• submission to EC required	• must review EC approval letter and may consider imposing any other conditions on the researcher
Consent for the disclosure of health information to be used in research	• decide whether or not to require consent to disclose health information	• submits consent form (HIA compliant) or provide rationale to EC if seeking waiver • retain consents; provide copies as requested by custodian for verification purposes	• must require consent if EC dictates • may waive consent if EC approves • may impose consent requirement even if EC waived it • verification of consents either from a random sample or from full study population
Privacy and Security Safeguards	• must consider the adequacy of proposed administrative, technical and physical safeguards of the health information used during research	• must provide detail of administrative, technical and physical safeguards of the health information used to EC	• must impose safeguards set by EC and may impose any other safeguards for the disclosure of the health information to be used in research
EC approval letter	• must forward a copy of the EC approval to the Information and Privacy Commissioner	• must submit EC approval letter to custodian	• must review EC approval letter submitted by researcher
Application to Custodian	N/A	• must submit written application and EC approval letter to custodian	• must review both application and EC approval letter received from researcher
Costs	N/A	• may anticipate custodian fees and build into budget	• may set costs for disclosure of health information • costs must not exceed actual cost of providing disclosure
Research Agreement	N/A	• must sign research agreement with custodian prior to disclosure	• must sign research agreement with researcher prior to disclosure
Consent for additional information	N/A	• anticipate the costs of obtaining consents referred to in section 55	• if the researcher wishes to contact the individuals who are the subjects of the information disclosed to obtain additional health information, the custodian or an affiliate of a custodian must first obtain consent from the individuals to their being contacted for that purpose.
Data Matching*	N/A	• must ensure HIA research sections 48 – 56 are complied with before data matching is performed	• must ensure HIA research sections 48 – 56 are complied with before data matching is performed

*__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.

Use of Health Information for Research

The following illustrates the HIA roles and responsibilities for the **use** of health information for research including the party responsible for the obligation described.

Considerations for Disclosure of Health Information in Research	**Ethics Committee (EC)**	**Custodian Researcher** (including custodians who intend to conduct research or an affiliate of a custodian who intends to conduct research)
Ethics approval	• must conduct review	• submission to EC required
Consent for the disclosure of health information to be used in research	• must decide whether to require consent or not	• must submit consent form (HIA compliant) or rationale if seeking waiver of consent • must adhere to EC decision on consent
Privacy and Security Safeguards	• must consider the adequacy of proposed administrative, technical and physical safeguards of health information used during research	• must provide detail on proposed administrative, technical and physical safeguards of the health information to EC
EC approval letter	• must forward a copy of the EC approval to the Information and Privacy Commissioner	• must receive EC approval letter prior to commencing research
Application to Custodian	N/A	• affiliate researcher of large custodians may still need to apply in writing to the custodian for disclosure of health information*
Costs	N/A	• affiliates must confirm with custodian re: costs of internal research*
Research Agreement	N/A	*

* although the HIA does not require a research agreement for custodians when health information is used for internal research purposes, many custodians have found it operationally efficient to have all their research affiliates sign a research agreement. Custodians such as physicians or pharmacists who receive ethics committee approval to use health information for research may follow their own internal research policy.

RESEARCH ETHICS BOARD OBLIGATIONS
for use and disclosure of health information for research

- **review research proposals that involve using or disclosing health information**

- **review must look at:**
  - whether consent from individuals is needed before disclosing the health information
  - whether getting such consent would be unreasonable, impractical or not feasible
  - whether the public interest in the proposed research substantially outweighs the public interest in protecting individuals privacy
  - the researchers' qualifications
  - safeguards (administrative, technical and physical) to protect individual privacy and confidentiality and whether they are adequate.

- **in making the above assessment, the ethics committee must consider the degree to which the proposed research would contribute to:**
  - identification, prevention or treatment of illness or disease,
  - scientific understanding relating to health,
  - promotion and protection of the health of individuals and communities,
  - improved delivery of health services, or
  - improvements in health system management.

- **The ethics committee must prepare a response setting out:**
  - its decision regarding consent
  - a summary of the review assessment
  - any other conditions the ethics committee decides to impose on the researcher.

- **The ethics committee must forward the response to the researcher and a copy to the Information and Privacy Commissioner.**

RESEARCHER OBLIGATIONS
for use and disclosure of health information for research

- **Submit research proposals involving use or disclosure of health information to a designated HIA ethics committee.**

- **Proposal to include the following:**
  - consent considerations
    - if proceeding on a consent basis for use or disclosure, include the consent form which meets s. 34 consent requirements.
    - if seeking a waiver, provide a rationale for why obtaining consent is unreasonable, impractical or not feasible.
  - rationale for how the importance of the public interest in the proposed research substantially outweighs the public interest in protecting individual privacy by explaining to what degree the proposed research may contribute to the following:
    - identification, prevention or treatment of illness or disease,
    - scientific understanding relating to health,
    - promotion and protection of the health of individuals and communities,
    - improved delivery of health services, or
    - improvements in health system management.

- provide qualifications to demonstrate the researcher is qualified to carry out the research.

- document adequate safeguards to protect individual privacy and confidentiality by providing detail for
  - administrative
  - technical and
  - physical safeguards.

→ **May approach custodians for disclosure of health information upon receipt of approval letter from ethics committee.**

→ **Apply for disclosure of health information from custodians by submitting:**
- ethics committee response letter to the researcher and
- written application for disclosure of health information

→ **Anticipate costs set by the custodian to:**
- obtain consents, if applicable,
- prepare information for disclosure, and
- make copies of the health information

→ **Ensure research provisions (sections 48-56) are complied with before data matching is performed.**

→ **Enter into a research agreement with the custodian which must include agreement to**
- comply with:
  - HIA and regulations,
  - any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information, and
  - 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,
- to use the health information only for the purpose of conducting research for which it was requested,
- not to publish the health information in an identifiable form,
- not to contact the research subjects to obtain additional health information unless the individual has provided the custodian with consent,
- to allow custodians access to the researcher's premises to confirm HIA compliance and any other conditions or requirements,
- to pay costs set out by the custodian.

CUSTODIAN OBLIGATIONS
for diclosure of health information for research

→ **Ensure receipt of documents from researcher wishing to access health information for the purpose of research which must include:**
- ethics committee response letter to the researcher and
- written application for disclosure of health information.

- **Decide on whether to disclose the health information to the researcher**
  - If decision is to disclose, then
    - impose any ethics committee conditions,
    - impose any other conditions set out by the custodian,
      - e.g. submission to a custodian ethics committee
    - obtain consents if researcher wishes to contact individuals for additional health information,
    - set costs, if applicable,
    - sign research agreement with researcher,
    - if consent based disclosure, verify consent has been obtained
    - ensure data prepared for disclosure is the least amount, at the highest level of anonymity, based on the need to know,
    - must ensure sections 48-56 are complied with before data matching is performed,

- **If the agreement is breached**
  - the agreement is cancelled.

- **If researcher denies access to premises, custodian can obtain a Court Order.**

- **Court may order a researcher to comply with the research agreement.**

- **Court may authorize custodian to:**
  - enter and search research premises,
  - operate any computer system and produce documents,
  - seize and make copies of any documents relevant to the investigation.

- **Custodian must return seized documents within 60 days after conclusion of investigation.**

CUSTODIAN OBLIGATIONS
for use of health information in research

- **Submit research proposals referencing use of health information to a designated HIA ethics committee.**

- **Proposal to the ethics committee to include the following:**
  - consent considerations:
    - if proceeding on a consent basis for use, include the consent form which meets s. 34 consent requirements.
    - if seeking a waiver, provide a rationale for why obtaining consent is unreasonable, impractical or not feasible.

- rationale for how the importance of the public interest in the proposed research substantially outweighs the public interest in protecting individual privacy by explaining to what degree the proposed research may contribute to the following:
  - identification, prevention or treatment of illness or disease,
  - scientific understanding relating to health,
  - promotion and protection of the health of individuals and communities,
  - improved delivery of health services, or
  - improvements in health system management.
- provide qualifications to demonstrate the custodian researcher is qualified to carry out the research.
- document adequate safeguards to protect individual privacy and confidentiality by providing detail for
  - administrative
  - technical and
  - physical safeguards.

Ensure custodian's research affiliates adhere to EC conditions, including consent considerations prior to using health information for research.

Ensure custodians develop an internal research policy addressing both use and disclosure of health information for research.

Ensure custodian research affiliates who conduct research adhere to the research policy which must include an agreement to comply with:
  - HIA and regulations
  - safeguards relating to the use, protection, disclosure, return or disposal of the health information, and
  - safeguards against the identification, direct or indirect, of an individual who is the subject of the health information,
- to use the health information only for the purpose of conducting research
- not to publish the health information in an identifiable form,
- not to contact the research subjects to obtain additional health information unless the individual has provided the custodian with consent,
- to ensure researcher's premises are HIA compliant and any other conditions or requirements are being followed.

Office of the Information and Privacy Commissioner

For further information, contact:

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