

Original Approval Date: August 1, 2017

Most Recent Approval Date: February 22, 2021

Most Recent Editorial Date: November 13, 2020

Next Review Date: February 22, 2024

Parent Policy: Health Information Privacy and Security Policy

Health Research Information Management Procedure

| | |
|---|---|
| Office of Administrative Responsibility: | Dean's Office, Faculty of Medicine & Dentistry |
| Approver: | Dean's Executive Committee, Faculty of Medicine & Dentistry |
| Scope: | Compliance with this Faculty policy extends to all members of the Faculty of Medicine & Dentistry |

Overview

The *Health Information Act* (HIA) sets out rules for the collection, use and disclosure of health information for research purposes. These rules are in sections 27 (1)(d) and 48 – 56 of the HIA.

For the purpose of this procedure, the term “researcher” means a principal investigator (or co-investigators, if multiple researchers share primary responsibility for the research) conducting research that necessitates the use of Health Information. Researchers, research staff and students are responsible for adhering to the HIA and this procedure.

This procedure sets out guidelines for the following clinical research scenarios:

- **Collection of Health Information by a Faculty member, who is a researcher, from a custodian:** Faculty member requests access to patient records from a custodian. The custodian of the records may be Alberta Health Services (AHS), Covenant Health, a physician in the community, or a colleague within the Faculty. Faculty members should be aware that AHS and Covenant Health are typically the custodians of patient records within their respective facilities. The use of an AHS managed Clinical Information System (CIS) such as Connect Care will have access defined under the applicable AHS policies & procedures, in addition to any applicable agreements or memorandums of understanding.
- **Collection and use of Health Information by a Faculty member, who is a custodian, for his/her own research purposes:** Faculty member, who is a custodian, uses patient records that are in his/her custody and control for his/her own research purposes.
- **Disclosure of Health Information by a Faculty member, who is a custodian, to a researcher:** Faculty member, who is a custodian, provides Health Information or patient records that are in his/her custody and control to another Faculty member, or an external researcher, for research purposes.

Procedure

1 Collection of Health Information for Research by a Researcher

- 1.1 Before collecting Health Information for research purposes, researchers shall obtain approval from the Health Research Ethics Board.
- 1.2 Researchers shall submit a written application to all custodians in order to request disclosure of Health Information to be used in research. Applications may vary depending on the custodian's requirements, but should include the following at a minimum:
 - 1.2.1 a copy of the research proposal;
 - 1.2.2 a copy of the Research Ethics Board's response to the research proposal; and
 - 1.2.3 a summary of Health Information that is to be used in the research project.

- 1.3 If the custodian(s) agree to disclose the requested health information, the researcher shall sign a research agreement that complies with section 54 of HIA.
- 1.4 All research requests for Health Information in the custody and control of AHS must be made by submitting a [Questionnaire](#) to AHS¹.

2 Collection and Use of Health Information for Research by a Custodian

- 2.1 Before using Health Information from health records in his/her own custody for research purposes, a custodian must determine whether the research purposes can be achieved without using identifying Health Information. If so, the Custodian must strip, encode or otherwise transform the individually identifying Health Information to create non-identifying health information. If it is not possible to achieve the research purposes with non-identifying health information, the Custodian must submit a research proposal to the Health Research Ethics Board and include with that proposal the consent form that will be used to obtain individual consent or the rationale for not requiring such consent. The Custodian must receive the Health Research Ethics Board's approval letter prior to commencing the research.
- 2.2 Before collecting or using Health Information in the custody and control of AHS, the Custodian must submit a request for that information by submitting a [Questionnaire](#) to AHS².

3 Disclosure of Health Information for Research by a Custodian

- 3.1 If a Custodian receives a written application from a researcher for disclosure of Health Information to be used in research, and a copy of the researcher's research proposal and Health Research Ethics Board approval, then the Custodian may disclose that information to the researcher, subject to the requirements set out in this section 3 and any conditions in the Health Research Ethics Board approval.
- 3.2 Upon receipt of a request for disclosure, the Custodian may, but is not required to, disclose the Health Information applied for. If the Custodian decides to disclose the Health Information, he or she may impose any conditions on the researcher that he or she feels necessary in addition to any conditions imposed by the Health Research Ethics Board.
- 3.3 The Health Research Ethics Board may require that the patients provide consent to having their Health Information disclosed for the purpose of the research project, or it may waive the requirement of consent. If consents are required from the individuals whose Health Information is being disclosed, the Custodian must verify that consent has been obtained.
- 3.4 Custodians may assign costs associated with preparing the records for disclosure, copying Health Information and obtaining consent. Such costs must not exceed the actual cost of the work.
- 3.5 In compliance with section 54 of the HIA, before the Custodian can disclose the Health Information to the researcher, a research agreement must be entered into between the Custodian and the researcher in which the researcher agrees to:
 - 3.5.1 comply with the HIA and its regulations;
 - 3.5.2 comply with any conditions imposed by the Custodian relating to the use, protection, disclosure, return or disposal of the Health Information;
 - 3.5.3 comply with 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;
 - 3.5.4 use the Health Information only for the purpose of conducting the proposed research;
 - 3.5.5 not to publish the Health Information in a form that could reasonably enable the identification of individuals to be readily ascertained;
 - 3.5.6 only contact individuals to obtain additional Health Information if the individuals consent to being contacted;
 - 3.5.7 allow the Custodian to access or inspect the researcher's premises to ensure that researcher is complying with the terms of the agreement, and

¹ The Questionnaire can be found via embedded link above, or at the following URL:
https://extranet.ahsnet.ca/teams/AHSRA/PRA_Resources/PRA%20Pages/PRA%20Questionnaire.aspx

² See footnote 1, above.

- 3.5.8 to pay any costs related to preparing the records for disclosure, copying the Health Information or obtaining consents for further contact of individuals.
- 3.6 If the Custodian receives a request to disclose Health Information from an AHS CIS, the Custodian should refer the requestor to AHS.
- 3.7 If the researcher wishes to contact the subject individuals of the Health Information disclosed by the Custodian to the researcher to obtain additional Health Information, the Custodian must first obtain consent from the subject individuals before the researcher contacts them.
- 3.8 Wherever possible, Custodians should disclose only non-identifying health information to researchers.

4 Protection of Health Research Information

- 4.1 Health Information that is collected by researchers, research staff and students must be protected using the administrative, technical, and physical safeguards outlined in the Faculty Health Information Handling and Security Procedure.

DEFINITIONS

| | |
|-------------------------|--|
| <p>Consent</p> | <p>Agreement by an individual to the disclosure of their own health information to a third party. The consent must include:</p> <ul style="list-style-type: none"> • An authorization for the custodian to disclose the information specified in the consent • The purpose for which the information may be disclosed • The identity of the person to whom the information may be disclosed • An acknowledgement that the individual providing the consent has been made aware of the reasons why the information is needed and the risks and benefits to the individual of consenting or refusing to consent • The date the consent is effective and the date, if any, on which the consent expires • A statement that the consent may be revoked at any time by the individual providing it. <p>A consent or revocation of consent can be provided in writing or electronically.</p> <p>Electronic consent is valid only if the level of authentication is sufficient to identify the individual who is granting the consent or revoking the consent.</p> <p>In the case of a minor who has consented for diagnosis or health services, consent for the release of information must be obtained from the minor (not the parent or guardian).</p> |
| <p>Custodian</p> | <p>Includes health service providers who receive and use health information and are responsible for ensuring that it is protected, used, and disclosed appropriately. In the context of the Faculty of Medicine and Dentistry, custodians may include:</p> <ul style="list-style-type: none"> • regulated members of the College of Physicians and Surgeons of Alberta • regulated members of the College of Alberta Denturists; • regulated members of the Alberta Dental Association and College; |

| | |
|---|---|
| | <ul style="list-style-type: none"> • regulated members of the College of Registered Dental Hygienists of Alberta; • regulated members of the Alberta College of Pharmacists; • Alberta Health Services; • Covenant Health. <p>Please note this is not an exhaustive list. For full list of custodians, please refer to definitions in the HIA and its regulations.</p> |
| Diagnostic, treatment and care information | <p>Includes information about the following:</p> <ul style="list-style-type: none"> • the physical and mental health of an individual; • a health service provided to an individual • information about the health service provider who provided a health service to an individual • donation by an individual of a body part or substance, including information derived from the testing or examination of a body part or bodily substance; • a drug as defined in the <i>Pharmacy and Drug Act</i> provided to an individual; • a health care aid, device, product, equipment or other item provided to an individual pursuant to a prescription or other authorization; • the amount of any benefit paid or payable under the <i>Alberta Health Care Insurance Act</i> or any other amount paid or payable in respect of a health service provided to an individual; • any other information about an individual that is collected when a health service is provided to the individual but does not include information that is not written, photographed, recorded or stored in some manner in a record. |
| Disclosure | <p>Means the release, transmittal, exposure, revealing, showing, providing copies of, telling the contents of, or giving health information by any means to any person or organization. It includes disclosure to another custodian or to a non-custodian. A custodian making health information accessible to other custodians via the Alberta electronic health record does not constitute a “disclosure”.</p> |
| Health Information | <p>Information that identifies an individual and is stored in any format that relates to: diagnostic, treatment and care information; registration information (e.g. demographics, residency, health services eligibility, or billing).</p> |
| Health Research Ethics Board | <p>The research ethics board designated under section 2 of the Designation Regulation, Alta Reg 69/2001, to review research projects involving Health Information in accordance with the HIA.</p> |
| Non-identifying health information | <p>Information in which the identity of an individual cannot be readily ascertained.</p> |
| Record | <p>Means a record of health information in any form and includes notes, images, audiovisual recordings, x-rays, books, documents, maps, drawings, photographs, letters, vouchers and papers and any information that is written, photographed, recorded or stored in any manner.</p> |

| | |
|---------------------------------|---|
| Registration Information | <p>Includes information relating to an individual that falls within the following general categories:</p> <ul style="list-style-type: none"> • Demographic information, including the individual's personal health number • Location information • Telecommunications information • Residency information • Health services eligibility information • Billing information |
| Researcher | <p>Principal investigator (or co-investigators) involved in clinical research of any kind that necessitates the use of individually identifying diagnostic, treatment and care information or individually identifying registration information, or both.</p> |
| Use | <p>Means applying health information for a purpose and includes reproducing the information, but does not include disclosing the information.</p> |

Related Links

[College of Physicians and Surgeons of Alberta Patient Record Retention Standard of Practice](#)

[Information Privacy Office - HIA webpage](#)

[Faculty of Medicine & Dentistry - Informatics webpage](#)

[Health Information Act](#)

[Health Information Act Designation Regulation](#)

[Health Information Act Alberta Electronic Health Record Regulation](#)

[Health Information Regulation](#)

[Health Information Act Guidelines and Practices](#) (Alberta Health)

[Use and Disclosure of Health Information for Research](#) (OIPC)