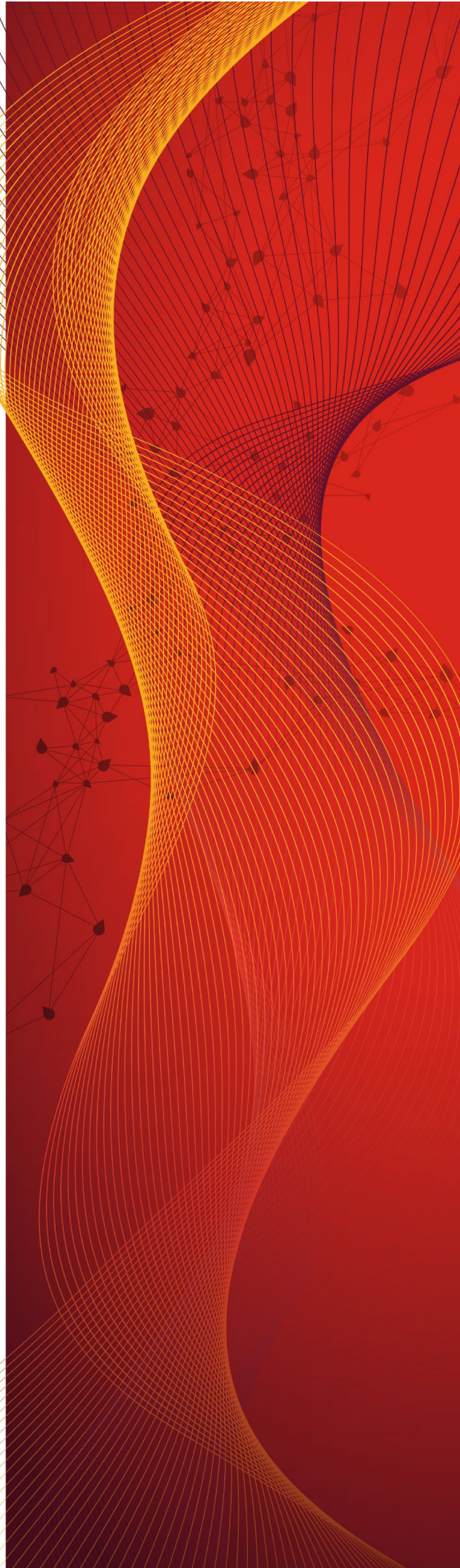

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A pRoject Ethics Community Consensus Initiative

Quality Improvement/ Program Evaluation Projects under Alberta Privacy Legislation

May 2023

Managed by

ALBERTA INNOVATES

Quality Improvement/Program Evaluation Projects under Alberta Privacy Legislation

Prepared for ARECCI (A pRoject Ethics Community Consensus Initiative) and Alberta Innovates

B W Hamilton Consulting Inc.
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Executive Summary

Quality Assurance and Program Evaluation (QI/PE) are authorized under the Health Information Act (HIA) and the Freedom of Information and Protection of Privacy Act (FOIP). Cstodians under the HIA and public bodies under FOIP collect health and personal information to deliver health and public services. Once this information has been collected custodians and public bodies may use health and personal information to carry our QI/PE projects with regards to their own operations.

Complexities arise when custodians and public bodies intend to share (i.e., disclose) health and personal information with each other to carry out QI/PE projects. Some of these include:

- Custodians and public bodies follow different privacy laws; some custodians are both public bodies and custodians
- Requirements for agreements, privacy impact assessments, information security and definition of common terms vary among QI/PE project participants
- Custodians with provincial mandates for health system management may collect health information for QI/PE from other custodians, while individual, community-level custodians may only use health information for QI/PE for internal management, but may not disclose it to each other for QI/PE

Recommendations

Because of the above complexities, parties to QI/PE projects are challenged by a patchwork of legislation, policies and procedures implemented at the individual custodian and public body level. It is therefore recommended that the ARECCI community consider adopting:

- Common definitions for such terms as “quality improvement” and “program evaluation”
- Common standards for “identifying” and “non-identifying” health and personal information
- Model information sharing agreements and privacy impact assessments geared toward QI/PE projects
- It is not clear whether the ARECCI community should press the Alberta Government to add or amend definitions of QI/PE terminology to HIA and FOIP. While consistency and clear direction in law could help the ARECCI members work together, this could introduce inflexibility. Legislative change is not a panacea – separate organizations will always have differing interpretations of laws and different risk tolerances, so will still need to collaborate to develop common approaches to QI/PE projects.

Purpose and structure of this paper

ARECCI has commissioned this paper to assess the legal authorities and requirements under Alberta's privacy legislation for Quality Improvement and Program Evaluation projects. This paper will identify any gaps in legislation and practice and make recommendations. Stakeholders from the ARECCI Second Opinion Reviewer (SORer) group were engaged in October 2022 to seek feedback on potential recommendations and confirm what tools could support privacy compliance for QI/PE projects in Alberta.

Part 1 of this paper considers the legislative framework under the Health Information Act (HIA) and the Freedom of Information and Protection of Privacy Act (FOIP) that supports QI/OE in Alberta.

Part 2 analyses the following topics as they relate to QI/PE under HIA and FOIP:

- Non-identifying information
- Service agreements
- Collection notices
- Consent
- Privacy Impact Assessments

Finally, Part 3 presents a checklist of privacy considerations regarding privacy and QI/PE.

Appendix: Case study

Privacy considerations identified in this paper are applied to a case study taken from ARECCI training materials.

Part 1: Quality Improvement and Program Evaluation under Alberta's privacy laws

Applicable Privacy Legislation

Alberta has three privacy laws: the *Health Information Act* (HIA)[1] the *Freedom of Information and Protection of Privacy Act* (FOIP)[2] and the *Protection of Personal Information Act* (PIPA)[3]. The laws most applicable to the ARECCI community are HIA and FOIP. The Personal Information Protection Act (PIPA) regulates the collection, use and disclosure of "personal information" in the private sector and is not covered in this analysis.

QI/PE Under HIA

The HIA applies to "health information" in the custody or under the control of "custodians". Health information is information about health services provided to individuals (i.e., data subjects). Health information[4] includes registration, diagnostic, treatment, and care information, recorded in any format. Health information may be "identifying" or "non-identifying" as these terms are defined in the HIA[5].

Custodian duties under the HIA

Under the HIA, custodians must collect, use, and disclose non-identifying health information wherever possible, but may use identifying health information if authorized under the HIA or other legislation. Further, custodians must limit their collection, use and disclosure of health information to what is essential to carry out the intended purpose.

Custodians are identified and listed in the HIA and are responsible for ensuring that health information is collected, used, and disclosed in accordance with the HIA and other applicable legislation. Custodians are also responsible for protecting the privacy of data subjects and protecting health information against such threats as unauthorized access, disclosure, modification, loss, or destruction. Custodians are expected to implement administrative, physical, and technical controls to protect health information.

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[1] Government of Alberta, Health Information Act (HIA), 2021, Revised Statutes of Alberta 2000, Chapter H-5, https://kings-printer.alberta.ca/570.cfm?frm_isbn=9780779837199&search_by=link, viewed December 29, 2022.
[2] Government of Alberta, Freedom of Information and Protection of Privacy Act (FOIP), 2022, Revised Statutes of Alberta 2000, Chapter F-25, https://kings-printer.alberta.ca/570.cfm?frm_isbn=9780779834839&search_by=link, viewed December 29, 2022.
[3] Government of Alberta, Protection of Personal Information Act, https://kings-printer.alberta.ca/570.cfm?frm_isbn=9780779836420&search_by=link, 2022, Statutes of Alberta 2003, Chapter P-6.5, viewed December 29, 2022.
[4] Subsections 1(1)(i), (k) and (u) of the HIA (op. cit.) define "health information"
[5] See later section in this paper regarding non-identifying information.

Examples of custodians

Many ARECCI community members, such as Alberta Health (AH), Alberta Health Services (AHS), the Health Quality Council of Alberta (HQCA), Covenant Health, and regulated health services providers listed in the HIA and its regulations are custodians (e.g., physicians, registered nurses, etc.).[6] For example, the ARECCI community includes Primary Care Networks, which are established under the responsibility of groups of physicians. Physicians are one of the regulated health professionals listed in the HIA as custodians. Physicians are therefore the custodians responsible for QI/PE projects performed by their PCNs. When custodians conduct QI/PE projects together (e.g., HQCA and a PCN), the participating custodians' responsibilities are usually governed through an agreement[7]. (ARECCI sponsor, Alberta Innovates, is not a "custodian" as defined in the HIA; rather Alberta Innovates is a "public body" under FOIP – more on this later.)

Understanding collection, use and disclosure

The HIA uses the terms, collect, use, and disclose when referring to the movement of health information among various parties and when describing the purposes to which custodians may apply health information. When conducting QI/PE projects, it is important to understand whether the activity constitutes a collection, use or disclosure of health information as these terms are contemplated in the HIA.

Two of these three terms are defined in section 1 the HIA as follows:

> "collect" means to gather, acquire, receive or obtain health information;
>
> "use" means to apply health information for a purpose and includes reproducing the information, but does not include disclosing the information.

The HIA does not define "disclose". However, the Alberta Health HIA Guidelines and Practices Manual provides a definition of disclosure:

> "Disclosure" refers to 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.[8]

As discussed in the next section, all custodians may use health information in their custody or control to support QI/PE projects without individual consent. Some custodians with provincial mandates may also collect and disclose health information to support QI/PE projects.

[6] Not a complete listing – see section 1(1)(f) of the HIA (op. cit.) for a complete listing of custodians.
[7] Agreements are covered in a later section of this paper.
[8] Ibid, p. 212.

Authority to conduct Quality Improvement and Program Evaluation under the HIA

When custodians carry out QI/PE projects they often use health information they have already collected to provide health services to individuals[9]. Once collected, section 27(1)(g) of the HIA then allows custodians to use individually identifying health information without individual consent for "internal management purposes", including, "quality improvement" and "evaluation", among other purposes[10].

It is important to emphasize that use of health information for QI/PE under section 27(1)(g) is authorized for internal management purposes only. Section 27(1)(g) does not give individual custodians the ability to disclose or share health information among themselves because this is not internal management.

In contrast, provincial-level custodians, such as AH, AHS and HQCA have additional authority to collect health information from other custodians to carry out QI/PE, in alignment with their health system mandates. In this situation[11], custodians may disclose health information to AH, AHS or HQCA to support QI/PE. For example, groups of custodians operating in a Primary Care Network (PCN) may rely on AHS' provincial-level legal authority to share (disclose) health information among themselves to support QI/PE projects. This is possible because AHS is a party to each PCN in Alberta. These arrangements are typically set out in PCN information sharing agreements.

Without involvement of AH, AHS or HQCA, groups of custodians do not have authority under the HIA to share (disclose) identifying health information among themselves for "internal management purposes". In this circumstance, custodians would first need to obtain individual consent from patients to share individually identifying health information with each other for QI/PE purposes, or share non-identifying information.

QI/PE not defined in the HIA

The terms "quality improvement" and "evaluation" are not defined in the HIA (there is no mention of "program evaluation" per se in the HIA). Alberta Health's *Health Information Act Guidelines and Practices Manual* provides examples of quality improvement and evaluation activities as follows:

> "quality improvement" – examining existing services and patient outcomes to determine how services can be improved for the future;

[9] i.e., patients or data subjects

[10] HIA (op. cit.), section 27.

[11] In this context, the QI/PE project would need to align with the objectives set out in section 27(2) of the HIA, namely: planning and resource allocation, health system management, public health surveillance, and health policy development. Community-based, individual custodians, such as physicians, pharmacists, dentists, etc. do not have authority under section 27(2) of the HIA to collect and use health information from other custodians.

"evaluation" – evaluating services to ensure they are being delivered appropriately and efficiently;[12]

Examples provided in the *HIA Guidelines and Practices Manual* do not carry the weight of law; however, the *Manual* is written by Alberta Heath, the Ministry responsible for implementing the HIA and can be used as an authoritative source to help interpret the HIA.

A search of the Canadian Legal Information Institute (CANLII) database revealed that the Alberta Information and Privacy Commissioner has not opined on the meaning of "quality improvement" or "evaluation" in the context of section 27 of the HIA.

Custodians may choose to define QI and PE in their own terms and in alignment with internal policies and programs. For example, AHS has established a QI policy[13] based on six dimensions of quality set out in the *Alberta Quality Matrix for Health*. Each custodian in Alberta should have its own definition of QI and PE set out in policies or established through practice.

There are no definitions of QI or PE in legislation or set in legal precedent for Alberta. Further, there are no commonly accepted definitions of QI or PE used in Alberta's health sector (ARECCI SORer's confirmed this point in discussion at their October forum). This is not of great concern when custodians conduct QI/PI per their internal policies, using only health information in their own custody or control. However, when custodians need to exchange health information to support QI/PE projects, this lack of common definitions can introduce complexities. For example, one custodian may consider a proposed activity to fall within the QI/PE provisions in the HIA, while another custodian may consider the activity to be "research", which is regulated differently in the HIA; one custodian may decide to prepare a Privacy Impact Assessment, while another may not, etc.

If ARECCI stakeholders intend to establish common tools and efficient, repeatable processes to work together on QI/PE projects, defining basic terminology would be a logical first step.

The ARECCI community could call for Alberta Health to add definitions of QI and PE to the HIA. While this would certainly establish common definitions, stakeholders may not be pleased with the result. Strict definitions of terms established in law may not be a good fit for all stakeholders and would be challenging to amend over time as health sector practices evolve. Alternatively, ARECCI and its stakeholders could define QI/PE through mutual agreement. In the current HIA (which does not define QI/PE), interpretation of the terms, QI/PE would be based on a standard of reasonableness. Given that ARECCI is a recognized expert authority in

[12] Government of Alberta, Alberta Health, Health Information Act Guidelines and Practices Manual – 2011, p. 204-205, https://open.alberta.ca/dataset/50877846-0fba-4dbb-a99f-eeb651533bc4/resource/3e16d527-2618-48ae-80b8-93f69973878e/download/hia-guidelines-practices-manual.pdf, viewed August 31, 2022.
[13] Alberta Health Services, Quality Improvement, policy HCS-240, https://extranet.ahsnet.ca/teams/policydocuments/1/clp-prov-sh-cont-care-qi-hcs-240.pdf, viewed December 28, 2022.

Alberta regarding QI/PE and many custodians in Alberta rely on ARECCI guidance, custodians could reasonably adopt ARECCI definitions in policies.

Understanding the parties and their relationships

A few examples of custodians were noted earlier in this report. Custodians are the "gatekeepers" of the HIA and are responsible for health information in their custody or under their control. Two other important entities are noted in the HIA, which may collect, use or disclose health information under the authority of a custodian, "affiliates" and "information managers". The HIA defines these terms, respectively:

> "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)
> ...[14]
>
> In this section, "information manager" means a person or body that
> (a) processes, stores, retrieves or disposes of health information,
> (b) in accordance with the regulations, strips, encodes or otherwise transforms individually identifying health information to create non-identifying health information, or
> (c) provides information management or information technology services in a manner that requires the use of health information
> but does not include an individual employed by a custodian who performs any of the functions listed in clauses (a) to (c).[15]

Note that the definition of affiliate above includes information manager. Therefore, an information manager is a sub-category of affiliate and is subject to the same rules under the HIA as an affiliate. Also noteworthy is that the definition of information manager above excludes those employed by the custodian who may perform information manager functions – these individuals would be employees and, therefore affiliates in relation to the custodian.

QI/PE conducted by affiliates

Affiliates may only collect, use, or disclose health information in accordance with their duties to their custodian[16]. Further, under 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, affiliates may conduct QI/PE projects if that work is part of their work responsibilities as assigned by the custodian they work for. In a smaller custodian organization such as a physician office this relationship is easily understood: QI/PE work is

[14] Not the full definition of "affiliate". Refer to section 1(1)(a) of the HIA (op. cit.) for a complete definition.
[15] HIA (op. cit.), s. 66(1).
[16] HIA (op. cit.), sections 24, 28, and 43.

assigned by the physician (the custodian) responsible for the patients whose health information is needed for the QI/PE project. In a larger healthcare organization, authority to conduct QI/PE with health information is authorized by the affiliate's supervisor, ideally within the context of a QI/PE policy and a broader privacy governance framework. Whether QI/PE work is assigned and approved within a small or large custodian, per HIA 62(2), the custodian remains responsible for the health information its affiliates need to collect, use or disclose to support QI/PE projects.

QI/PE conducted by information managers

Custodians may choose to engage an information manager to support QI/PE projects. Information managers perform information management and information technology services for the custodian under an information manager agreement. Examples could include IT service providers or data analytics platform providers. Information managers may only collect, use, or disclose health information to support QI/PE projects if this activity is described and authorized by the custodian in an information manager agreement. Information managers have a duty to follow the HIA but custodians are ultimately responsible for all collection, use and disclosure carried out by their information managers, including any work done to support the custodian's QI/PE projects.[17]

Non-identifying information

Custodians may collect, use or disclose non-identifying health information for "any purpose", which could include QI/PE projects[18]. While the HIA recognizes that non-identifying health information is not suitable for all purposes, it does require that custodians first consider using non-identifying information before using identifying health information.

When a custodian discloses non-identifying health information to a non-custodian, the custodian must inform the recipient that the recipient must notify the Commissioner if it plans to use the information for data matching. Under this provision of the HIA, the recipient must inform the Commissioner before performing any data matching.[19] Custodians normally fulfill this obligation in writing, as part of a broader agreement with the recipient of the non-identifying health information. In contrast, custodians may share non-identifying health information with each other for any purpose without having to meet this obligation.

[17] HIA (op. cit.), subsection 66(6).
[18] HIA (op. cit.), sections 19, 26, and 32.
[19] HIA (op. cit.), subsection 32(2)

QI/PE under FOIP

FOIP applies to "personal information" in the custody or under the control of "public bodies". "Personal information" is defined as "recorded information about an identifiable individual"[20]. Several types of identifying personal information are listed in the definition:

(n) "personal information" means recorded information about an identifiable individual, including

i. the individual's name, home or business address or home or business telephone number,
ii. the individual's race, national or ethnic origin, colour or religious or political beliefs or associations,
iii. the individual's age, sex, marital status or family status,
iv. an identifying number, symbol or other particular assigned to the individual,
v. the individual's fingerprints, other biometric information, blood type, genetic information or inheritable characteristics,
vi. information about the individual's health and health care history, including information about a physical or mental disability,
vii. information about the individual's educational, financial, employment or criminal history, including criminal records where a pardon has been given,
viii. anyone else's opinions about the individual, and
ix. the individual's personal views or opinions, except if they are about someone else;

Public bodies are defined and listed in FOIP[21]. Alberta Innovates (ARECCI sponsor) is a public body, as are other provincial ministries that may wish to collect, use or disclose personal information with custodians or among themselves to support QI/PE projects. These might include Education, Community and Social Services, Indigenous Relations or Seniors and Housing, for example. Other public bodies subject to FOIP include municipalities, Metis settlements, police services established under the Alberta *Police Act*, universities, colleges and schools, for example. Refer to FOIP for the complete definition of "public body", plus the listing of public bodies' related agencies, boards and commissions, which are subject to FOIP.

Authority to conduct QI/PE under FOIP

Unlike HIA, FOIP does not refer to QI/PE specifically. Rather, FOIP sets out legal authorities that allow public bodies to collect personal information and allows public bodies to use and disclose that information for consistent purposes, or with individual consent. FOIP includes other specific purposes for use and disclosure of personal information and exceptions to both, too numerous to cover here. Public bodies may collect personal information for purposes listed in section 33 of FOIP and subsequently use and disclose it for consistent purposes, or with consent. Section 33 reads as follows:

[20] FOIP (op. cit.), section 1(n).
[21] FOIP (op. cit.), subsections 1(d)(g)(i)(j)&(p) and Schedule 1 to the Freedom of Information and Protection of Privacy Regulation, https://kings-printer.alberta.ca/1266.cfm?page=2008_186.cfm&leg_type=Regs&isbncln=9780779831647&display=html, viewed January 22, 2023.

33 No personal information may be collected by or for a public body unless

(a) the collection of that information is expressly authorized by an enactment of Alberta or Canada,

(b) that information is collected for the purposes of law enforcement, or

(c) that information relates directly to and is necessary for an operating program or activity of the public body.

FOIP may allow public bodies to collect personal information to carry out QI/PE projects, provided the activity is done under a law of Alberta or Canada, for law enforcement, or the QI/PE relates to and supports an operating program or activity of the public body.

Consistent purposes

Public bodies may use and disclose personal information for purposes consistent with the purposes for the original collection of the personal information[22]. Section 41 of FOIP sets boundaries around what constitutes a "consistent purpose"[23]:

Consistent purposes
41 For the purposes of sections 39(1)(a) and 40(1)(c), a use or disclosure of personal information is consistent with the purpose for which the information was collected or compiled if the use or disclosure

(a) has a reasonable and direct connection to that purpose, and

(b) is necessary for performing the statutory duties of, or for operating a legally authorized program of, the public body that uses or discloses the information.

The *FOIP Guidelines and Practices* manual elaborates further on the concept of consistent purposes and provides an example of a consistent purpose that is pertinent to QI/PE projects:

A use or disclosure has a *reasonable and direct connection* to the original purpose if there is a logical and plausible link to the original purpose. A consistent use should grow out of or be derived from the original use; it should not be an unrelated or secondary use of the information, otherwise known as "function creep."

A use or disclosure is *necessary for performing the statutory duties of, or for operating a program of, the public body* if the public body would be unable to carry out its program without using or disclosing the personal information in the way proposed.
A consistent use or disclosure must meet both of the above conditions to be valid.

Examples of a consistent purpose
Evaluation of a program
Public bodies will have a regular need to evaluate the operation and success of their programs. This is particularly true of new programs or those that have changed in some way. Section 41

[22] FOIP (op. cit.), subsections 39(1)(a) and 40(1)(c).
[23] FOIP (op. cit.), section 41.

> allows a public body to select clients or participants who can participate in that evaluation through questionnaires or interviews. [24]

Just as with the *HIA Guidelines*, the *FOIP Guidelines* do not have the force of law but are written by the provincial government department responsible for administering the legislation, so are an authoritative source for guidance.

Public bodies' interpretation of the consistent purposes provision in FOIP may differ. Furthermore, public bodies may have specific legal authority in their own enabling legislation that would allow QI/PE projects. It is therefore critical to consult with all public bodies participating in any QI/PE project to confirm their agreement on the legal authority that allows the QI/PE project.

Collection, Use and Disclosure Limitation

Similar to HIA, FOIP obliges public bodies to limit the collection, use and disclosure of personal information to what is necessary to support purposes of its programs or activities in a reasonable manner (see ss. 33(c), 39(4) and 40(4)).

Entities that are both custodian and public body

AHS, AH, HQCA are examples of custodians under HIA that are also public bodies under FOIP. It can be challenging to determine whether HIA or FOIP rules apply when entities have this dual role. If the information includes personal identifiers but does not refer to health services provided to individuals, it is probably personal information subject to FOIP. If the information includes information about health services provided to individuals, HIA likely applies.

[24] Government of Alberta, Service Alberta and Red Tape Reduction, *FOIP Guidelines and Practices 2009*, https://open.alberta.ca/publications/9780778585633, p. 295, accessed January 17, 2023.

Part 2: QI/PE Common topics to HIA and FOIP

Part 2 of this paper reviews common topics that apply to QI/PE under HIA and FOIP.

Service agreements to conduct QI/PE

Custodians or public bodies may decide to contract out QI/PE project-related activities to a third-party vendor or service provider. A service provider may be engaged to conduct the QI/PE project itself or be involved in supporting the activity by providing such services as data storage or cloud-based analytics environment, for example. In either situation, an appropriate service agreement that includes HIA and/or FOIP requirements must be executed. Whether you represent a custodian or a public body (or both), your organization is responsible under for any actions your service provider takes (or fails to take) with regards to the collection, use, disclosure and protection of health and personal information. As a rule of thumb, consider any action taken by your service provider on your behalf to be an action taken by your organization (whether custodian, public body, or both).

Service agreements under HIA

Under the HIA, services providers that are involved in QI/PE are "information managers", or "affiliates" (both terms defined earlier). An information manager is more likely to be involved in the information technology aspects of a QI/PE project, while an affiliate could be someone contracted to conduct a survey or analyse data, for example. Review the definitions of these terms in the HIA to determine these provisions apply to your service provider. Remember, information managers are also affiliates, so information managers must follow the custodian's direction regarding the collection, use, disclosure, and protection of health information.

An "information manager agreement" must be in place between the custodian and the information manager to allow the custodian to provide identifying health information to the information manager and to allow the information manager to carry out any contracted services, including QI/PE projects. The information manager agreement does not need to be a stand-alone agreement, labelled "Information Manager Agreement". Custodians may insert the information manager agreement provisions set out in the HIA in a broader service agreement or contract with their information manager.

Section 66 of the HIA and section 7.2 of the HIA set out the provisions that must be included in an information manager agreement. If your information manager will store, use, or disclose health information outside Alberta, you will also need to ensure the provisions of subsection 8(4) of the HIA are included in your agreement, regarding out-of-province data use. Finally, it is particularly important to ensure your information manager is obliged to inform you of any

privacy and security incidents that affect your organization's identifying health information[25]. Custodians are responsible for their information manager's privacy breaches and will need this information to determine how to respond and mitigate the incident and to determine whether to inform affected individuals and other regulatory and law enforcement bodies[26].

HIA agreement guidance

Alberta Health has included guidance regarding the provisions that need to be included in an information manager agreement in its HIA Guidelines and Practices Manual.[27] While the Alberta Health guidance does not constitute legal advice or a formal requirement, many custodians follow this guidance for information manager agreements.

Service agreements under FOIP

If your organization is a public body, a contracted service provider falls within the definition of "employee" in FOIP. Like a custodian under the HIA, a public body under FOIP remains responsible for the actions its employees take with regards to personal information.

In contrast to HIA, FOIP includes little direction on what provisions need to be included in agreements with service providers. The sole mention of an agreement to disclose information in support of activities that may align with a QI/PE project in FOIP is in section 42, as follows:

> **42** A public body may disclose personal information for a research purpose, including statistical research, only if
>
> (a) the research purpose cannot reasonably be accomplished unless that information is provided in individually identifiable form or the research purpose has been approved by the Commissioner,
>
> (b) any record linkage is not harmful to the individuals the information is about and the benefits to be derived from the record linkage are clearly in the public interest,
>
> (c) the head of the public body has approved conditions relating to the following:
>
> (i) security and confidentiality,
>
> (ii) the removal or destruction of individual identifiers at the earliest reasonable time, and
>
> (iii) the prohibition of any subsequent use or disclosure of the information in individually identifiable form without the express authorization of that public body,
>
> and

[25] Subsection 60.1(1) of the HIA refers to, "any loss of individually identifying health information or any unauthorized access to or disclosure of individually identifying health information in the custody or control of the custodian" and says the matter must be reported "as soon as practicable".
[26] See OIPC guidance and AH guidance for more information on responding to privacy breaches.
[27] Op cit., pp. 164-166.

(d) the person to whom the information is disclosed has signed an agreement to comply with the approved conditions, this Act and any of the public body's policies and procedures relating to the confidentiality of personal information.

Notably, the above passage refers to disclosures for research or statistical purposes, which may or may not fall within the realm of QI/PE. The terms "research" and "statistical purposes" are not defined in FOIP.

FOIP agreement guidance

For public bodies, guidance is available in the FOIP Guidelines and Practices Manual [28] and in a special publication entitled, Managing Contracts under the FOIP Act[29], which includes model clauses and a practical checklist. A brochure to orient service providers to contracting under FOIP is also available[30].

Collection notices

Both HIA and FOIP include a requirement to notify individuals about the purposes for which their health or personal information is being collected[31]. In both statutes, the custodian or public body needs to notify the individual about:

- The purpose for which the information is collected
- The specific legal authority for the collection
- Business contact information for a position in the organization who can answer questions about the collection

Ideally, for the purposes of QI/PE, the custodian or public body would include mention in the collection notice that individuals' information may be used for QI/PE. This aligns with the privacy principle of transparency. Further, if the public is aware that their health or personal information may be used for QI/PE they are more likely to be supportive of this activity and less likely to raise complaints about it later. Finally, under FOIP in particular, it is much easier to argue that personal information is used or disclosed to support a QI/PE project for a "consistent purpose" if that purpose has been identified when the information was first collected.

[28] FOIP Guidelines and Practices 2009 (op. cit.).
[29] Government of Alberta, Service Alberta, Managing Contracts under the FOIP Act, 2010, http://www.servicealberta.ca/foip/documents/contractmanager.pdf, viewed September 12, 2022.
[30] Government of Alberta, Service Alberta, Contractor's guide to the Freedom of Information and Protection of Privacy Act, 2011, https://open.alberta.ca/dataset/1bf254db-7f2f-4980-9264-d968a330bb67/resource/8aa91489-df75-4f8c-be7c-2193a1a2fe8d/download/contractorbrochure.pdf, viewed September 12, 2022.
[31] HIA (op. cit.), subsection 22(3) and FOIP (op. cit.), subsection 34(3).

Consent

Consent under HIA

As noted earlier, the HIA does not require that custodians administer individual consent to carry out QI/PE projects using health information already in their custody or under their control. Rather than relying on consent, the HIA gives custodians explicit legal authority to conduct QI/PE using identifying health information in their custody or under their control.

As previously discussed, individual, community-level custodians without provincial mandates (i.e., not AH, AHS, or HQCA) do not have clear legal authority to disclose identifying health information to each other to support QI/PE projects without consent. Such custodians could rely on individual consent to share (disclose) information among themselves to support a QI/PE project.

The HIA sets out mandatory requirements for consent to disclose individually identifying health information. Consents may be administered electronically or in writing provided they include all of the elements listed in the HIA[32].

Consent under FOIP

Public bodies may carry out QI/PE projects using personal information in their custody or under their control without relying on individual consent. As discussed earlier, public bodies may use or disclose personal information for purposes that are consistent with the original purpose for which the information was collected under section 33 of FOIP. Consistent purposes may be viewed to include QI/PE.

Despite the above, public bodies may choose to administer an individual consent to use or disclose personal information[33] as part of their own privacy risk management, or because they are of the opinion that a QI/PE project does not align with the original purpose for which the information was collected. Under FOIP, collecting an individual consent does not provide a carte blanche for subsequent use and disclosure of personal information. Rather, the new consented purpose for use or disclosure must still align with section 33 of FOIP, which sets out the authorized purposes for collecting personal information.

[32] HIA (op. cit.), section 34, including all subsections.
[33] FOIP (op. cit.), subsections 39(1)(b) and 40(1)(d).

When a public body decides to administer individual consent, it must follow the format set out in section 7 of the FOIP Regulation[34]. Just as with the HIA, consents may be administered on paper or electronically.

Privacy Impact Assessments

The Alberta Office of the Information and Privacy Commissioner (OIPC) describes PIAs as follows,

> The PIA is a due diligence exercise, in which you identify and address potential privacy risks that may occur in the course of your operations. The PIA process requires a thorough analysis of potential impacts to privacy and a consideration of reasonable measures to mitigate these impacts.
>
> While PIAs are focused on specific projects, the process must also include an examination of organization-wide practices that have an impact on privacy.[35]

Under HIA, privacy impact assessments (PIAs) are mandatory when a planned activity triggers the PIA requirement set out in various sections of that Act. In this situation, custodians must prepare and submit a PIA to the OIPC for review and comment before implementing their new initiative. FOIP includes the ability for the OIPC to comment on the privacy implications of proposed programs and record linkages but does not make PIAs mandatory, nor does it make OIPC review of PIAs mandatory.

- A custodian under HIA may be obliged to prepare and submit a PIA to the OIPC before implementing a QI/PE project.

- A public body under FOIP may decide to prepare and/or submit a PIA to the OIPC before implementing a QI/PE project as part of its risk management decision-making, or any other reason it deems appropriate (e.g., managing privacy risk, or a desire to reassure the public that privacy has been considered appropriately).

If a QI/PE project triggers the PIA requirement, or a custodian/public body participating in the activity decides a PIA is warranted, sufficient lead-time should be built into plans to gather and confirm information needed to prepare the PIA. A typical PIA includes the following elements:

- Goals and objectives of the QI/PE project and why these goals and objectives require the collection, use and disclosure of health and personal information. Ideally, goals and objectives are established in a formal, written mandate.
- Privacy and information security policies and procedures implemented in the custodians/public bodies that will have custody of or exercise control over the health

[34] Freedom of Information and Protection of Privacy Act Regulation (op. cit.), section 7.
[35] Office of the Information and Privacy Commissioner of Alberta, Privacy Impact Assessment Requirements, 2010, p. 4, https://oipc.ab.ca/wp-content/uploads/2022/03/PIA-Requirements-2010.pdf, accessed December 30, 2022.

and personal information involved in the initiative. The PIA should describe how privacy and security will be managed among the participants in relation to the QI/PE project.

- The information to be collected, used, and disclosed for the activity (i.e., a listing of data or data categories)
- The sources of the personal and health information, the conditions under which it was originally collected, including any information collection notices or consents administered.
- An understanding of who will use or access the information and for what purposes.
- Legislative authorities that allow health and personal information to be collected, used and disclosed.
- An understanding of agreements required to allow information to be shared among participants that includes clauses on (among other things) responsibility for custody and control of the information involved, safeguarding information, managing individual requests and complaints under HIA and FOIP, managing and reporting privacy and security incidents, and records management and disposition.
- Privacy and security safeguards that protect the confidentiality, integrity and availability of the information involved.

PIA requirements in the HIA

A general PIA requirement is established in section 64 of the HIA, which says:

> **64**(1) Subject to subsection (3), each custodian must prepare a privacy impact assessment that describes how proposed administrative practices and information systems relating to the collection, use and disclosure of individually identifying health information may affect the privacy of the individual who is the subject of the information.
>
> (2) Subject to subsection (3), the custodian must submit the privacy impact assessment to the Commissioner for review and comment before implementing any proposed new practice or system described in subsection (1) or any proposed change to existing practices and systems described in subsection (1).
>
> (3) Subsections (1) and (2) do not apply to custodians described in section 1(1)(f)(iv), (ix.1) and (xii) in the collection, use or disclosure of health information between or among these custodians for a function set out in section 27(2), unless the custodians will implement a new information system or change an existing information system in conjunction with the collection, use or disclosure. [36]

The HIA also requires custodians to prepare PIAs and submit them to the OIPC before performing "data matching". Different submission requirements apply, depending on whether the custodian is performing data matching with another custodian or a non-custodian[37]. Data matching is defined in the HIA as follows:

[36] HIA (op. cit.), s. 64.
[37] HIA (op. cit.), ss. 71 and 72.

> "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;[38]

(Other sections of the HIA also trigger a PIA requirement but are not likely to relate to QI/PE projects conducted by most members of the ARECCI community.)

Therefore, a PIA is required when a QI/PE project:

- Collects, uses or discloses individually identifying health information, and
- Represents a new administrative practice, and/or
- Requires a new information system
- Necessitates "data matching" as defined in the HIA

The custodian must submit the PIA to the OIPC for review and comment before the new QI/PE project is implemented. It is not necessary to wait for OIPC to provide feedback before implementation; however, if a PIA can be prepared with enough lead-time to allow the custodian to receive OIPC feedback before implementation, this may reduce risk to the initiative. In making this decision, custodians should consult with the OIPC regarding current wait-times for PIA review.

Subsection 64(3) of the HIA provides a possible PIA exemption for Alberta Health, Alberta Health Services, and the Health Quality Council of Alberta, provided the proposed QI/PE project falls within the range of provincial health system management functions listed in section 27(2) of the HIA and does not involve a new or changed information system. This provision is a relatively new addition to the HIA. It is recommended that these custodians consult with the OIPC before deciding not to perform a PIA on the basis of HIA section 64(3).

PIA Guidance under HIA

OIPC has published a PIA Requirements Guide[39]. According the OIPC, "PIAs submitted to the OIPC under the HIA must follow the format described in the PIA Requirements."[40] Alberta Health has published an annotated PIA template[41] that follows the OIPC PIA Requirements format.

[38] HIA (op. cit.), s. 1(1)(g).
[39] Alberta Office of the Information and Privacy Commissioner, Privacy Impact Assessment Requirements, 2010, https://oipc.ab.ca/wp-content/uploads/2022/03/PIA-Requirements-2010.pdf, viewed September 13, 2022.
[40] Ibid., p. 4.
[41] Government of Alberta, Alberta Health, 2019, Completing a Privacy Impact Assessment: Annotated Template, https://open.alberta.ca/publications/completing-a-privacy-impact-assessment-annotated-template, viewed September 13, 2022.

PIAs under FOIP

As previously noted, PIAs are not mandatory under FOIP; however, they are recommended by both Service Alberta and Red Tape Reduction (the Ministry responsible for FOIP) and OIPC. Some public bodies may make PIAs mandatory by policy in certain circumstances. It is therefore important to gain an early understanding of the PIA requirements of any public body participating in a QI/PE initiative.

PIA Guidance under FOIP

According to the OIPC, public bodies may use their PIA Requirements Guide "…as a reference tool to help draft PIAs." [42] Because the OIPC format is not mandatory under FOIP, public bodies do not always use the OIPC PIA Requirements as a PIA template. Public bodies that are also custodians (e.g., Alberta Health, Alberta Health Services, Covenant Health, Health Quality Council) typically do follow the OIPC PIA Requirements. However, public bodies outside the health sector may have established their own formats.

Service Alberta and Red Tape Reduction has published PIA templates[43] that public bodies may decide to use; however public bodies are free to establish their own PIA formats. Therefore, before embarking on a PIA to support a QI/PE project involving a public body outside the health sector, it is important for the parties to agree on a PIA format, as it will affect what information is needed to prepare the PIA and how the PIA is presented.

[42] Privacy Impact Assessment Requirements 2009 (op. cit.), p. 2.
[43] Government of Alberta, Service Alberta, https://www.servicealberta.ca/foip/resources/3540.cfm, viewed September 13, 2022.

Part 3: Privacy Considerations Checklist for QI/PE projects

The following checklist may be used to guide HIA and FOIP considerations when planning a new QI/PE project. For background on the questions and comments noted in the checklist, refer to the main body of this paper.

1. Determine the status of those conducting QI/PE relative to privacy laws

a. Who exercises custody or control over the health/personal information needed for the QI/PE project?
   - Those exercising custody or control could be:
     - "Custodians" subject to HIA
     - "Public bodies" subject to FOIP.
   - Consider whether one of the parties conducting the QI/PE is the lead or whether leadership is shared
     - The organization leading the QI/PE project determines what privacy legislation and policies apply to the project
     - Under a shared leadership model, it can be challenging to determine which legislation and policies apply to QI/PE projects. The parties should consult legal counsel and execute a formal written agreement to clarify applicable legislation and policies and confirm who is ultimately responsible for legislative compliance.

b. Who is providing services to the custodians and public bodies to help conduct the QI/PE project
   - Service providers could be individuals, employees, other public bodies or custodians, non-profit community organizations, or private sector, for profit organizations, for example.
   - While these service providers may be subject to other privacy laws and policies with regards to their own operations, for the purposes of a QI/PE project led by a custodian or public body, they must follow the same legislation and policies that the custodian or public body follows, typically pursuant to a written agreement.

2. Determine nature of proposed project:

a. Is the project Quality Improvement or Program Evaluation?
   - Alberta's privacy legislation does not define these terms.
   - Rely on a definition of QI/PE accepted by the parties to the QI/PE project or rely on a commonly accepted industry definition.

b. Is the project some other activity authorized under HIA or FOIP (if applicable), e.g., research? In contrast to QI/PE, "research" is defined in the HIA.

3. Identify what information is needed to support the QI/PE project

- Custodians and public bodies have a duty to limit the amount of identifying health and personal information, collected, used and disclosed to support their activities, including QI/PE.
- Consider using non-identifying information, if possible.

4. Ensure service providers are following appropriate rules

- Custodians and public bodies may engage service providers to carry out or assist with QI/PE projects, but remain responsible for all collection, use and disclosure of personal and health information performed by their service providers.
- Custodians and public bodies must ensure their service providers follow the HIA, FOIP (as applicable), and their own policies and requirements with regards to protecting privacy and security.

5. Ensure an appropriate agreement been executed with service providers

- Consider how your service providers are classified under privacy legislation
    - HIA affiliate and/or information manager?
    - FOIP employee?
- If under HIA, agreement must meet requirements set out in HIA for information managers.
- Alberta Health has published guidance in its *HIA Guidelines and Practices Manual*
- Service Alberta and Red Tape Reduction has made recommendations for agreements under FOIP.
- Service providers are “information managers” and “affiliates” under HIA and “employees” under FOIP.
- Policies should be implemented to allow affiliates/employees to initiate QI/PE within a pre-established legal and ethical framework.
- Affiliates of custodians may only collect, use and disclose health information as authorized by their custodian.
- Employees of public bodies may only collect, use and disclose personal information as authorized by their public body.

6. Determine whether the information needed for the QI/PE project should be individually identifying or non-identifying

- Both HIA and FOIP promote the use of non-identifying information where possible. If the parties to a QI/PE project have differing views or policies as to what constitutes non-identifying information, they will need to agree on an acceptable standard for the project.

7. Determine Legal authority

- Under HIA, “quality improvement” and “evaluation” are explicitly permitted for internal management purposes.
- Under FOIP, the purpose of the QI/PE project must be consistent with the purpose for which the personal information was originally collected. QI/PE projects may be considered to be “necessary for an operating program or activity”; however, public bodies determine whether QI/PE projects fall within a consistent purpose on a case-by-case basis, so some difference in interpretation is to be expected depending on the public bodies involved and the project.

8. Consider whether the project will rely on individual consent

- In a privacy context, consent refers to the individual’s (information subject’s) consent to collect, use or disclose health/personal information to support the QI/PE project, rather than the more fulsome informed consent described in ARECCI Guideline Tool.

Collection

- Public bodies and custodians rely on legal authority to collect PI/HI, rather than consent.

Use

- Custodians rely on legal authority to use health information.
- Public bodies may rely on consent to use personal information; other authorities may be applied, including individual consent.

Disclosure

- Public bodies and custodians may rely on legal authority to disclose health/personal information; other authorities or individual consent may be applied.
- Both HIA and FOIP include mandatory elements that need to be included in consents, which may be administered on paper or electronically.

9. Decide whether a PIA is required/recommended

Health Information

- If the information needed for the QI/PE project is in the custody or under the control of a “custodian” under the HIA

and

- the activity is a new administrative practice or information system

and

- will collect, use or disclose individually identifying health information,

then

- the custodian must prepare and submit a PIA to the OIPC before implementing the activity.

Personal Information

- If the information needed is in the custody or under the control of a public body under FOIP

and

- the activity is a new administrative practice or information system

and

- will collect, use or disclose individually identifying personal information

then

- the OIPC recommends that the public body or organization prepare and submit a PIA to the OIPC before implementing the activity– whether the PIA is submitted to OIPC is the public body's decision

also

- the public body may be obliged to conduct a PIA under its own policies or may decide to conduct a PIA on an ad hoc basis – whether the PIA is submitted to OIPC is the public body's decision.

10. Follow applicable information security rules

- Follow policies/requirements of the custodian(s) or public body(ies) exercising custody or control over the information needed to support the project.
- Information security requirements must be documented in policies and procedures and, where multiple parties are involved in the QI/PE project, appropriate agreements.

Appendix: ARECCI Project Ethics Forum Case Study

The following case study is also used in ARECCI Guidelines and Screening Tools. The intent here is to apply the Privacy Considerations Checklist for QI/PE Projects to the case study (see previous sections of this paper for elaboration on the concepts and questions in the Checklist).

The case study provides alternative solutions to some privacy challenges. In following the case study, remember that this scenario is an exercise intended to provoke discussion and allow readers to consider options – the case study is not advice. Consult your organization's policies and privacy officer before embarking on similar projects.

Case study - Newcomers outreach project for pregnant women

This initiative was developed to address risk factors associated with low birth weight and postpartum depression among pregnant women. Specifically, this initiative focuses on women who are new to Canada with limited financial resources whose risk for both low birth weight and postpartum depression are elevated compared to other pregnant women. The organization hired women from different ethnic and cultural communities who are fluent in both English and their native language(s) to serve as outreach workers to those communities. The outreach workers raised awareness of free weekly prenatal classes and encouraged pregnant women to participate in these classes. The outreach workers attend the weekly prenatal classes to provide translation services and to help participants get to know each other. If women met the income eligibility criteria, the outreach workers connected the participants with local resources to support their families, for example, free English classes, food bank referrals, and low cost baby supplies or furniture. Participants receive outreach worker services until 1 month postpartum.

The organization would like to study the effects of the outreach worker services on pregnant women and their babies. Specifically, they want to find out if women in the program had lower rates of low birth weight and/or postpartum depression compared to women who did not participate in the program. It was decided to do a chart audit of these women's outcomes since the organization collects the birth weight information and screens for postpartum depression risk at the postpartum visit.

The organization also wants to know what participants think of the program and what barriers were experienced when attending the program. They decided to conduct focus groups during one of the regular weekly classes. They plan to hire an external translator to conduct these focus groups in the participants' native languages. This translator will then translate the focus group transcripts for the organization.

One of the key members of the organization recently received a notice of an upcoming conference on serving the immigrant population. This individual suggested the findings be published at this conference. As the project leader, you are asked to conduct the study and prepare the submission for the conference.

Application of Privacy Considerations Checklist for QI/PE Projects

1. Determine the status of those conducting QI/PE relative to privacy laws

- The "organization" in the case study screens for postpartum depression risk at the postpartum visit and will conduct a chart audit. As such, the organization likely employs health professionals subject to the Health Information Act (HIA) (e.g. physicians, registered nurses) who provide health services to individuals.
- In Alberta, these health professionals would be considered custodians under the HIA and would exercise custody and control over the health information needed for this QI/PE project.
- The case study does not describe the organization's structure. The organization could itself be a custodian, such as Alberta Health Services (AHS) or Covenant Health. Alternatively, the organization could be formed of a group of independent custodians in their own right (e.g., a group of independent family medicine clinics).
    - If the organization is itself a custodian, the organization could carry out the QI/PE project under the organization's policies and procedures.
    - If the organization is composed of a group of custodian-peers, they should consider establishing a formal decision-making or governance structure for this project and future projects.
- The organization could be a private sector organization or public body that employs custodians. However, in this situation, the information that the custodians collect, use and disclose to support the provision of health services is still "health information" subject to the HIA.
- Under the HIA, the outreach workers, translators and focus group leaders would be considered "affiliates" of the custodians who ultimately exercise custody and control over the health information needed for the project.

2. Determine nature of proposed project

- The project will review the effects of the outreach worker services and conduct focus groups to understand participant experiences. It looks like the project is mostly program evaluation, but could involve some quality improvement aspects. Since privacy laws don't define QI/PE, the scope and purpose of the project should be documented in relation to an authoritative definition of what constitutes QI/PE.
- Ideally, the custodians will have already established a written QI/PE policy that describes the kinds of activities that constitute QI/PE, based on an authoritative source. If there is no QI/PE policy, consider implementing one before this project begins.
- While there is a plan to share the findings of this project at a conference, it does not appear this project fits within the HIA definition of "research", which involves "academic, applied or scientific research". For example, a plan to publish results in a

peer-reviewed scientific journal is a good indicator of research. If uncertain, consult ARECCI guidance, legal counsel, and/or REB officials.

3. Identify what information is needed to support the QI/PE project

- The information needed for this project is birth weight, postpartum depression risk screening data, and patient outcome data. All of this information was originally collected and used by custodians in the context of providing health services to individuals and would be considered "health information" under the HIA.
- Further information will be collected from patients during focus groups to understand what they think of the program and what barriers they experienced when attending the program. This information is not collected to provide health services to patients; rather it appears the purpose is program evaluation.

4. Ensure service providers are following appropriate rules

- The affiliates noted above (outreach workers, translators and those hired to conduct focus groups) must have a formal relationship with the custodians, documented in written agreements or employment contracts. This applies whether the affiliates are paid or volunteers/students.
- Agreements must oblige affiliates to follow the custodians' direction and policies with regard to collecting, using, disclosing and protecting health information.
- The custodians will need to ensure their affiliates are trained on the custodians' policies regarding collection, use, disclosure and protection of health information.

5. Ensure an appropriate agreement been executed with any service providers

- It does not appear that any other service providers will be hired for this project, other than the affiliates noted above. As noted, agreements or employment contacts must be executed with these affiliates.

6. Determine whether the information needed for the QI/PE project should be individually identifying or non-identifying

- Custodians have a duty to collect, use and disclose health information at the highest degree of anonymity possible. When completing the chart review, health information should be anonymized and/or aggregated as much as possible.
- It does not seem that information collected during focus groups needs to be associated with individuals. Patient comments recorded during focus groups could be recorded without any individual identifiers.
- Any results shared at the conference must be anonymized and/or aggregated to render the results "non-identifying" according to the HIA.

7. Determine Legal authority

- If the custodians determine that this project constitutes quality improvement and/or program evaluation, sub-section 27(1)(g) of the HIA provides legal authority for each custodian to conduct this activity with regards to health information under their own custody or control.
- The HIA allows custodians to disclose health information to other custodians without individual consent for purposes authorized under section 27(1). However, sub-section 27(1)(g) of the HIA authorizes custodians to use identifying health information for "internal management purposes". Because it only speaks to the use of health information for internal management, it is difficult to rely on 27(1)(g) as a legal authority for individual custodians to share (i.e., disclose) health information with each other.
    - Each custodian participating in this project could keep chart reviews separate until health information can be combined or aggregated in non-identifying form.
    - If it is not feasible to use anonymized information for the project, custodians could ask the patients for consent under section 34 of the HIA to disclose (i.e., share) identifying health information for the purposes of the QI/PE project.
- If the organization sponsoring this project were itself a custodian, (e.g., Alberta Health Services (AHS), Covenant Health), the health services providers (e.g., physicians, registered nurses) would likely be the organization's affiliates, rather than independent custodians in their own right. In this situation, the health services providers could exchange identifying health information under section 27(1)(g) of the HIA for QI/PE purposes. Because the health services providers are all part of the same organization (i.e., the same custodian), this would be considered internal use of health information, rather than disclosure.
- With regards to the information generated at focus group sessions, it has already been recommended under consideration 6 that this could be recorded in non-identifying format. As such, non-identifying information may be collected, used and disclosed for any purpose.

8. Consider whether the project will rely on individual consent

- Note this consent consideration applies only to what is strictly required by privacy legislation. Other ethical considerations may apply which could determine a requirement to gather consent from patients to participate in the project.
- As noted above under consideration 7, if the project is conducted by multiple custodians and health information needs to be shared among them in identifying format, the HIA requires individual consent to disclose the health information.
    - Consent to disclose health information must include all of the requirements listed section 34 of the HIA.

- If the project is conducted entirely within an organization that is itself a custodian (e.g., AHS, Covenant Health), consent to disclose health information under section 34 of the HIA is not required – rather, this would be considered an internal use of health information. However, the organization may still choose to administer a consent to comply with its own policies or to meet ethics norms.

9. Decide whether a PIA is required/recommended

- Deciding whether a PIA is required can be challenging. Under the HIA, PIAs must be prepared and submitted to the Information and Privacy Commissioner for review before the custodian implements proposed (i.e., new) administrative practices and information systems that relate to collection, use and disclosure of identifying health information.
- The project described in the case study appears to be a new administrative process that will use and potentially disclose identifying health information. This triggers the PIA requirement under section 64 of the HIA.
    - If the custodians are able to rely on non-identifying information to carry out the QI/PE project, a PIA may not be necessary.
    - Even if not strictly required by the HIA, custodians may choose to prepare a PIA to comply with their own policies or to manage risk.

10. Follow applicable information security rules

- If multiple custodians are sharing health information, they will need to agree on information security policies and safeguards to transmit, store and eventually dispose the data needed for the project.
- If the project is organized under a single custodian, all affiliates of that custodian must follow the custodian's information security polices and safeguards.
- All service providers (e.g., outreach workers, translators and focus group leaders) must follow the custodian's information security polices and safeguards.

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