Office of the
Information &
Privacy Commissioner
for British Columbia

Protecting privacy. Promoting transparency.

GUIDANCE DOCUMENT

ACCESS TO DATA FOR HEALTH RESEARCH

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CONTENTS

2.0 PURPOSE OF THIS GUIDANCE DOCUMENT

This guidance document outlines the legal provisions that apply to the disclosure of personal information of British Columbians for the purpose of health research. It **does not** address policy requirements by public bodies or organizations. Privacy laws permit the disclosure of personal information for research purposes, sometimes without consent. When authorized by law, this enables research that is in the public interest while ensuring adequate privacy protection.

In the public sector, under certain terms and conditions, several different statutes expressly authorize disclosure of personal information without consent for research purposes:

- *Freedom of Information and Protection of Privacy Act* (FIPPA);
- *E-Health (Personal Health Information Access and Protection of Privacy) Act*;
- *Pharmaceutical Services Act;*
- *Medicare Protection Act*; and
- *Public Health Act*.

In the private sector, and in specific circumstances, the *Personal Information Protection Act* (PIPA) permits organizations to disclose personal information without consent for research purposes.

2.0 TERMS AND CONDITIONS OF ACCESS

Public Sector Legislation

Freedom of Information and Protection of Privacy Act (FIPPA), s. 35

Several public bodies in the health sector have custody of personal information about British Columbians. These include the Ministry of Health, regional health authorities, and the Provincial Health Services Authority and its agencies such as BC Cancer Agency and BC Centre for Disease Control.

FIPPA authorizes these and other public bodies to disclose personal information for research purposes (without the consent of the individual) if:

- 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 Information and Privacy Commissioner,
- any data linking is not harmful to the individuals that information is about and the benefits to be derived from the data linking are clearly in the public interest,
- the head of the public body concerned has approved conditions relating to the following:
    - security and confidentiality;
    - the removal or destruction of individual identifiers at the earliest reasonable time;
    - the prohibition of any subsequent use or disclosure of that information in individually identifiable form without the express authorization of that public body, and
    - the person to whom that information is disclosed has signed an agreement to comply with the approved conditions, FIPPA and the policies and procedures of the public body relating to the confidentiality of personal information.[1]

Data stewards must, at a minimum, require researchers to comply with the following statutory terms and conditions:

Identifiable data is necessary

Researchers must demonstrate to data stewards that their research can only be accomplished with identifiable information, and that aggregate or de-identified data are not sufficient. An exception may be made, however, if the Information and Privacy Commissioner approves the research purpose.

[1] FIPPA, s. 35

Data linking is in the public interest

If a researcher intends to link data in different databases, they must indicate that the linking is not harmful and that the benefits are clearly in the public interest.

Linking datasets could be harmful if it generates new personal information that is outside the scope of the research and could be used for a different purpose. However, if that new personal information is protected and linking the data is critical to conduct the health research, it would likely be in the public interest.

Comprehensive data access agreement

The public body must have a written data access agreement with the researcher. This agreement must include privacy protective measures addressing security and confidentiality, removal or destruction of identifiers, prohibitions against further use without approval or disclosure beyond research, and an undertaking to comply with the approved conditions, FIPPA, and policies and procedures.

Research Ethics Board (REB) approval

Public bodies may impose additional terms and conditions in their policies and procedures. One of the most common is REB approval. The Ministry of Health and health authorities generally require researchers to obtain approval from a REB for their study before they disclose data to researchers. This helps ensure, among other things, that individually identifiable data is necessary to conduct the research and that the research is in the public interest.

REBs generally apply the *Tri-Council Policy Statement of Ethical Conduct for Research Involving Humans*[2] by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada.

Best practices

The Canadian Institutes of Health Research has developed best practices[3] which must be followed in order to receive funding. Funding approval is usually considered prior to authorizing disclosure.

Storage and access only in Canada (FIPPA, s. 30.1)

Section 30.1 of FIPPA requires public bodies to ensure that personal information in its custody or under its control is stored only in Canada and accessed only in

[2] http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
[3] http://www.cihr-irsc.gc.ca/e/29072.html

Canada unless the individual the information is about has expressly consented to it being stored in or accessed from another jurisdiction.

Use of contact information for participant recruitment

Researchers are not generally permitted to use data to recruit participants for their studies because it violates the privacy of individuals. However, this prohibition is not absolute in British Columbia. Health researchers may seek the approval of the Information and Privacy Commissioner to use contact information for participant recruitment.[4] This approval process is intended to balance the privacy interests of individuals with the public interest in health research by ensuring that the manner of contact is not unduly invasive.

The criteria and the application process of the Office of the Information and Privacy Commissioner (OIPC) are discussed in Part 4.0.

Use of data for research within a health authority

Data transfers within a health authority (or any other public body), such as the transfer of health authority data to a researcher employed by the health authority, is normally considered to be a use and may be authorized under FIPPA[5]. Therefore, it is not a disclosure and the terms and conditions for disclosure without consent do not apply. However, where the public body wishes to use personal information for a purpose that is different than the purpose for which it was originally collected, it must seek the consent of the individual for that change in use.

For example, if personal information is collected in order to provide an individual with health care, its subsequent use for research would require consent by the individual.

FIPPA[6] requires that employees of a public body only have access to personal information necessary for the performance of their duties.

E-Health (Personal Health Information Access and Protection of Privacy) Act ss. 14, 19, and 20

The E-Health Act governs the collection, use and disclosure of personal health information in Ministry of Health or health authority databases that are designated by the Minister of Health as health information banks. The following databases are designated as health information banks:

[4] FIPPA, s. 35(1)(a.1) and (2)
[5] FIPPA, s. 32
[6] FIPPA, s. 33.2(c)

- the Provincial Laboratory Information Solution (PLIS) repository, which contains personal health information pertaining to lab services delivered by health authorities and private labs;
- the Client Registry System/Enterprise Master Patient Index, which contains demographic information for all individuals receiving publicly-funded health care services in British Columbia; and
- the Provider Registry, which contains personal information about health service providers.

The E-Health Act permits disclosure of personal information without consent for a health research purpose if it is authorized by the designation order. Furthermore, disclosures for a research purpose must be approved by the Data Stewardship Committee. The Data Stewardship Committee is an arm's length body appointed by the Minister of Health, comprised of health professionals and members of the public.

Statutory terms and conditions[7] for disclosure for research purposes are the same as those in FIPPA with two additional prohibitions:

- any subsequent use or disclosure of personal health information must be expressly authorized by the Data Stewardship Committee[8], and
- personal health information and information related to a health service provider cannot be disclosed for market research purposes.[9] Because of its commercial nature, market research is distinct from health research.

The E-Health Act requires information-sharing agreements for disclosure and prescribes the contents of such agreements.[10] Among other things, the agreement must require the researcher to comply with the policies and procedures of the Data Stewardship Committee and the conditions imposed by the Committee.

Pharmaceutical Services Act, ss. 22 and 26

The *Pharmaceutical Services Act* permits the disclosure of personal information contained in PharmaNet for the purpose of research.[11] PharmaNet is an electronic health record system for all prescriptions dispensed in the province.

The Data Stewardship Committee decides if and how personal information may be disclosed from PharmaNet for research purposes.[12] The Act requires researchers[13] to

[7] E-Health Act, s. 14
[8] E-Health Act, s. 14(2.1),(e)(iii)
[9] E-Health Act, s. 20
[10] E-Health Act, s. 19
[11] *Pharmaceutical Services Act*, ss. 22(2)(l) and 22(3)(a)
[12] *Pharmaceutical Services Act*, s. 26
[13] An employee of the Ministry of Health or a Ministry service provider is not required to submit a request [s. 26(2)]

submit a data access request to the Data Stewardship Committee. All of the statutory terms and conditions set out in the E-Health Act apply to the request.[14]
Personal information or information related to a practitioner cannot be disclosed for market research.[15]

Medicare Protection Act and the *Public Health Act*

These health statutes govern the disclosure of personal information collected for the Medical Services Plan and public health services. In both cases, the statutory terms and conditions of FIPPA apply to disclosures for research purposes.

There may be other terms and conditions that must be met before the Ministry of Health, health authorities, or the Data Stewardship Committee approve access to data for health research purposes. These are imposed in accordance with their own policies and procedures.

Private Sector Legislation

Personal Information Protection Act (PIPA), s. 21

PIPA prescribes how private sector organizations can disclose personal information for research purposes without consent of the individual. Some health sector organizations governed by PIPA include offices and clinics of health care providers, pharmacies, some long-term care facilities, and the First Nations Health Authority.

In relation to disclosure for research purposes, PIPA includes the same terms and conditions as FIPPA, with an additional condition: seeking an individual's consent must be impracticable. The threshold of what is impractical is high – mere inconvenience or financial cost would not justify disclosure without consent.[16]

Section 21 absolutely prohibits using personal information to contact individuals to recruit them for health research. Unlike FIPPA, there is no provision in PIPA where health researchers may apply to the OIPC for approval. PIPA also prohibits disclosure for market research purposes.[17]

3.0 ROLE OF POPULATION DATA BC

Researchers may have access to health data through Population Data BC (PopData), a contracted service provider to the Ministry of Health. PopData is a provincial-wide multi-university platform that provides time- and project-limited data access to university-affiliated researchers on a cost recovery basis.

[14] *Pharmaceutical Services Act*, s. 26(3)
[15] *Pharmaceutical Services Act*, s. 25
[16] PIPA, s. 21(1)
[17] PIPA, s. 21(2)

PopData's data holdings include the following health datasets:

- Medical Services Plan Payment Information File,
- PharmaCare,
- Discharge Abstract Database,
- Home and Community Care,
- Mental Health,
- BC Cancer Agency Registry Data, and
- BC Perinatal Registry Data.

PopData supports researchers by

- coordinating data access requests to the Chief Data Steward of the Ministry of Health;
- de-identifying data and linking data across various sectors; and
- providing a secure research environment for researchers to ensure the data is protected.

PopData has its own privacy principles, policies, procedures, and practices. Further information about the mandate and operations of PopData are available on its website at https://www.popdata.bc.ca/.

4.0 PARTICIPANT RECRUITMENT

Health researchers may seek the approval of the Information and Privacy Commissioner to use personal information for the purpose of recruiting participants for their study. The Information and Privacy Commissioner must approve:

1. the research purpose;

2. the use of the disclosed information for the purpose of contacting a person to participate in the research; and

3. the manner in which contact is to be made, including the information to be made available to persons contacted.[18]

Researchers must submit their data access requests to the Data Stewardship Secretariat of the Ministry of Health. Secretariat staff review the request and submits it to the Data Stewardship Committee. The Data Stewardship Committee then makes a recommendation to the Information and Privacy Commissioner as to whether it should be approved. Among other things, the committee assesses whether the research could be accomplished without contact information.

[18] FIPPA, s. 35(2) and the E-Health Act, s. 14(2.1)(c)

Requests for data not in the custody or control of the Ministry of Health or a health authority must be submitted directly to the OIPC.

The Commissioner assesses whether the public interest in the research is proportionate to the privacy risk to individuals. The Commissioner considers a number of factors including:

- the volume and sensitivity of the personal information to be disclosed;
- whether all other methods to identify and contact individuals to participate in research are exhausted or impractical; and
- whether the manner of contact would be considered to be too invasive given the public's expectation of personal privacy.

The Commissioner also reviews:

- documentation verifying research ethics board approval;
- documentation indicating approval of the research study from a funding agency (if applicable); and
- information regarding the proposed manner of contact, such as
    - a telephone script or a copy of a letter from the researcher to the prospective participants describing the study,
    - what will be asked of participants, and
    - a telephone number that may be called to consent to participation or to request no further contact.

The OIPC will contact the researcher at the earliest opportunity if further information is required. Both the researcher and the Data Stewardship Secretariat are notified in writing of the Commissioner's decision.

The form that must be completed by researchers to make a request to use personal information for participant recruitment can be found on the OIPC website.[19]

Further information regarding the process to make a request is available on the Ministry of Health website at:

http://www2.gov.bc.ca/gov/content/health/conducting-health-research-evaluation/data-access-health-data-central/academic-researchers/requests-to-contact-bc-residents

5.0 CHALLENGES TO ACCESS

Unfortunately, BC does not have a single privacy and security framework that applies to the disclosure of personal information for research purposes. Disclosure varies depending on the type of data and whether it is in the custody or control of a public body or an organization. This "patchwork" of legislation is challenging for health researchers

[19] https://www.oipc.bc.ca/media/16989/oipc-contact-form-potential-study-participants.pdf

requesting access to data. Provisions may also be misinterpreted or applied unevenly and this is sometimes misconstrued as a barrier to access.

Inadequate staff resources within public bodies and organizations can result in lengthy delays in access to data. This was identified as a problem in a roundtable on health research in BC in June 2012.[20] Participants concluded that public bodies and organizations must allocate adequate resources to facilitate the responsible management of data for health research and other valid secondary use. The report of the roundtable discussion is available at: https://www.oipc.bc.ca/special-reports/1483.

The research community has requested harmonized criteria and a consistent approval process for accessing health data. In December 2013 the OIPC and the Ministry of Health convened a health data research forum. The key long-term recommendation was to improve data access approval processes through the development of harmonized health legislation. The report of the health data research forum is available at: https://www.oipc.bc.ca/special-reports/1610.

In the 2014 report *A Prescription for Legislative Reform: Improving Privacy Protection in BC's Health Sector*,[21] Commissioner Denham recommended a single stand-alone health information statute detailing comprehensive terms and conditions for data access approvals.

6.0 FREQUENTLY ASKED QUESTIONS

General questions about access requests

1. Q: I am an academic researcher interested in gaining access to data in the custody or control of the Ministry of Health or a health authority. What is the process for making a request?

A: Visit the public body's website or contact them directly to inquire about the process. Part 7 of this guidance document has links to sources of data for health researchers, including resources for making data access requests to the Ministry of Health and a number of health authorities.

PopData is also a useful source of information and offers assistance to researchers in coordinating requests. The process for making a request generally requires information about the researcher, details of the project, data fields requested, data protection plans, and supporting documents such as research ethics board approval and funding arrangements. This information is

[20] *Report of the roundtable discussion on access to data for health research*, https://www.oipc.bc.ca/special-reports/1483

[21] *A Prescription for Legislative Reform: Improving Privacy Protection in BC's Health Sector*, https://www.oipc.bc.ca/special-reports/1634

reviewed by the data steward or by the Data Stewardship Committee and, if approved, a data access agreement is entered into between the public body and researcher.

2. **Q: My request for access to data was turned down by the public body. Is there an appeal process?**

   A: There is no appeal process. FIPPA authorizes public bodies to exercise their discretion in disclosing data which contains personal information.

   Approval of a data access request depends on a number of factors, and is generally specific to the circumstances of the request. Among other things, public bodies consider the internal resources and expertise required to prepare the requested data. They also consider whether the nature and scope of the data access request is appropriate given the research purpose.

3. **Q: Do the terms and conditions for the disclosure of data for a research purpose still have to be met when the data has been de-identified?**

   A: Because of the risk of re-identification the statutory terms and conditions should be applied to all disclosures, even when the data may have been de-identified. As it is very difficult to de-identify data such that there is zero risk of re-identification, while still retaining enough information to be useful for research, public bodies should assume that data will be re-identified.

Contacting patients for their consent to participate in a research study

4. **Q: I am an employee of a health authority and I want to contact potential participants, from the patient pool of the hospital at which I work, for their consent to participate in a research study. Do I need approval from the Commissioner to get access to patient contact information?**

   A: The answer depends on the nature of the research study. Research conducted under a program or activity of the hospital or health authority does not require Commissioner approval (s. 35 of FIPPA). In this case, individuals are essentially being contacted to seek consent to a change in the use of their personal information as described in s. 32(b). The disclosure to the employee would be authorized by s. 33.2(c) of FIPPA.

5. **Q: An external researcher wants a health authority to pre-screen patients to determine eligibility to participate in a study based on pre-defined criteria. They have requested that the contact information of eligible patients be disclosed to the researcher so the patients may be contacted and asked to participate in the study. Is this permitted under FIPPA?**

A: No. Section 35(1)(a.1) applies as this would be a disclosure of personal information for the purpose of contacting an individual to participate in research. In order to contact those patients, the researcher should seek the approval of the Commissioner to authorize the disclosure of contact information for the purpose of participating in health research, pursuant to s. 35(2).

6. Q: An external researcher wants a health authority to pre-screen patients to determine eligibility to participate in a study based on pre-defined criteria. Once eligibility has been determined, the researcher wants a health authority staff member to contact patients and provide them with information about the study and the researcher's contact information. Is this permitted under FIPPA?

A: This is considered a use of personal information by the health authority and would be permitted only if either of the following conditions apply:

- the use falls under a program or activity of the public body, and the patients were notified at the time of collection (s. 32(a)); or
- the patients have consented (in a manner prescribed by s. 11 of the FIPPA Regulation) to this change in use of their information by the public body (s. 32(b)).

Application of s. 33.1(1)(b) of FIPPA

7. Q: Do the requirements associated with s. 35 of FIPPA apply in cases where consent is obtained under s. 33.1(1)(b) for the disclosure of personal information, in accordance with s. 11 of the FIPPA Regulation?

A: No. If a study relies upon s. 33.1(1)(b) to authorize disclosure of an individual's personal information by consent then s. 35 does not apply. It is important to note here that if consent is relied upon for disclosure of personal information, it must be obtained in the manner prescribed by s. 11 of the FIPPA Regulation.

Application of s. 33.1(1(s) of FIPPA – Disclosure outside of Canada

8. Q: Do the consent provisions in s. 11(2)(d) of the FIPPA Regulation (regarding disclosure of information outside of Canada) apply in cases where a health authority is disclosing personal information for a research purpose under s. 35 of FIPPA?

A: No. Consent is not required for disclosure for research pursuant to s. 35. The authority for disclosure of personal information in accordance with s. 35 of FIPPA, inside or outside of Canada, is found under s. 33.1(1)(s). Requirements in s. 11(2)(d) of the FIPPA Regulation apply only when authority for disclosure is obtained under s. 33.1(1)(b) of the Act.

Application of s. 35 of FIPPA – "Use" versus "Disclosure"

9. Q: Do researchers who are employees of a public body need to complete a research agreement pursuant to s. 35 of FIPPA when they conduct research on personal information that is under the custody or control of the public body?

A: No, as long as the use of personal information is authorized under s. 32 and the personal information is necessary for the performance of the duties of the employee, a research agreement pursuant to s. 35 would not be required.

7.0 RESOURCES

Relevant legislation

Freedom of Information and Protection of Privacy Act

Personal Information Protection Act

E-Health (Personal Health Information Access and Protection of Privacy) Act

Previous OIPC reports addressing health research

Report of the Health Research Roundtable

Report of the Health Data Research Forum

A Prescription for Legislative Reform

Data approval process for popular sources of data

Population Data BC (PopData)

Services for Researchers

Data Available

Data Access Process

BC Ministry of Health

Requesting Access – Process for Academic Researchers

Data Stewardship Committee

Requests to Contact BC Residents

BC Health Authorities

Provincial Health Services Authority (PHSA)

Ethics & Oversight

Vancouver Island Health Authority (VIHA)

Research Approvals and Ethics

Fraser Health Authority (FHA)

Key Approval Steps: The Responsible Conduct of Research

Information for Academic Researchers who wish to conduct research in FHA

Department Agreement for Providing Research-related Services

Vancouver Coastal Health Research Institute (VCHRI)

Operational Approval of Research

Interior Health Authority

IHA Research
IHA Information requests

Northern *Health Authority*

NHA research information (including evaluation programs)

Other health organizations

BC Centre for Disease Control

Data Access Requests

BC Cancer Agency

Access to data from the cancer registry

BC Renal Agency

Information concerning PROMIS Database and access to PROMIS Database

Perinatal Services BC

Information concerning access to Perinatal Data Registry

These guidelines are for information purposes only and do not constitute a decision or finding by the Office of the Information and Privacy Commissioner for British Columbia. These guidelines do not affect the powers, duties, or functions of the Information and Privacy Commissioner regarding any complaint, investigation, or other matter under FIPPA or PIPA.