

Review of federal and provincial legislation relating to the use and disclosure of personal (health) information for research purposes (research: U. Ogbogu)

Draft Document Privacy and Genetic Research Project (T. Lemmens, L. Austin, U. Ogbogu, N. Menon, S. Hargreaves, R. Vale)

Summary

- Regulations on use and disclosure of personal (health) information for research purposes are fairly uniform throughout Canada
- Identifying and non-identifying personal information held by public institutions can generally be disclosed for research purposes without the consent of the person to whom the information relates, subject to prescribed statutory conditions that ensure controlled use of the disclosed information.
- With the exception of Manitoba, there is no ethics review requirement for research projects seeking disclosure from public institutions. Statutory authority to approve disclosure is commonly vested in the head of the public institution in control of the personal information.
- The federal government and a few provinces (BC, AB, QB) regulate disclosure of personal information by private organizations. AB legislation provides for ethics review prior to disclosure.
- BC, AB, SK, MB, ON also specifically regulate the disclosure of personal health information. Rules are similar to those governing disclosure of personal information, except that all provinces require review and approval of the research proposal by an ethics review committee.
- Ethics approval does not guarantee disclosure – the custodian of personal health information may still refuse to disclose.
- Forthcoming legislation in BC provides for a data stewardship committee to manage / oversee information disclosure practices. The committee's approval is required **prior to disclosure of personal health information for health research purposes**. The committee will be made up of members drawn from a wider range of interests (stakeholders) than traditional research ethics review committees, and members will receive remuneration for their services.
- Under forthcoming BC legislation, persons whose information is held in a health information bank must authorize disclosure, unless the Minister waives this requirement on the recommendation of the data stewardship committee.

Privacy legislation on the use and disclosure of personal (health) information for research purposes is fairly uniform throughout Canada. Two main regulatory mechanisms exist for the use and disclosure of health-related personal information. The first can be found in personal information and privacy protection legislation, and the second in legislation dealing specifically with personal health information. The key features of both types of legislation, as it relates to use and disclosure for research purposes, are outlined below.

1. Rules for use and disclosure of personal information for research purposes in personal information and privacy legislation

All provinces regulate personal information held by public institutions. A few provinces (BC, AB, QB) also regulate information held by private organizations. Federal legislation exists for information held by both public and private institutions.

a. Public institutions

Typical provisions:

The personal information custodian (commonly a public body or institution) can generally use and disclose personal information in its custody for research or statistical purposes without the consent of the person to whom the information relates, so long as the following general conditions exist or are met.

1. The research purpose cannot reasonably be accomplished unless that information is in identifiable form. Most provinces also require that a public official approve the research purpose.
2. Any record linkage is not harmful to the person(s) to whom the information relates and the benefits to be derived from the record linkage are clearly in the public interest.
3. The head of the public body concerned has approved conditions relating to 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.
4. The person to whom that information is disclosed signs an agreement to comply with approved conditions, the applicable legislation, and other policies and procedures relating to the confidentiality of personal information.

Additional province-specific requirements:

British Columbia:

Disclosed information must not be used for the purpose of contacting a person to participate in the research (s. 35(1)(a.1) **FIPPA, R.S.B.C. 1996, c. 165**). A proposed amendment to this section will allow exceptions for health related research where the commissioner approves the research purpose, the use of disclosed information for the purpose of contacting persons, the manner of contact, and the information made available to those contacted by the researcher.

Manitoba:

The head of the public body that receives the information request *may* refer the request to a **review committee** for its advice on whether:

- (a) the personal information is requested for a bona fide research purpose;
- (b) the research purpose cannot reasonably be accomplished unless the personal information is provided in a form that identifies individuals;
- (c) it is unreasonable or impractical for the person proposing the research to obtain consent from the individuals the personal information is about; and
- (d) disclosure of the personal information, and any information linkage, is not likely to harm the individuals the information is about and the benefits to be derived from the research and any information linkage are clearly in the public interest.

Approval by review committee does not guarantee disclosure - head of the public body may still reject request or require that other statutory conditions (listed below) be met. See generally ss. 46 – 48, **FIPPA, C.C.S.M., c. F-175**.

Statutory conditions

- (a) the protection of the personal information, including use, security and confidentiality,
- (b) the removal or destruction of individual identifiers at the earliest reasonable time, and
- (c) the prohibition of any subsequent use or disclosure of the personal information in a form that identifies individuals without the express written authorization of the public body; and
- (d) the person to whom the personal information is disclosed has entered into a written agreement to comply with the approved conditions.

Ontario:

Disclosure agreement has more formal requirements e.g. information to be kept in physically secure location, all individual identifiers to be destroyed by a date specified in the agreement, names of all persons who will have access to the information, etc.

New Brunswick:

Consent is not required when a public body collects, uses or discloses personal information for purposes of legitimate research in the interest of science, of learning or of public policy, or for archival purposes.

b. Private institutions

AB, BC, QB & the Feds regulate disclosure by private sector custodians. The rules are substantially similar to those applicable to public custodians.

BC & PIPEDA require that it must be impracticable for the organization to seek the consent of the individual to whom the information relates before disclosure.

AB requires a research agreement between custodian and person seeking disclosure and the **approval of the research by a recognized research ethics review committee**.

2. Use and disclosure requirements in Personal Health Information Legislation

Provinces with personal health information protection (PHIP) legislation (BC, AB, SK, MB, ON) commonly distinguish between non-identifying health information (NIHI) and identifying health information (IHI). Generally, custodians may use or disclose NIHI for any purpose.

Custodians may also use and disclose IHI for research purposes without the consent of the person to whom the information relates. However, review of the research proposal by an ethics committee is required in all provinces with PHIP legislation. Ethics approval does not guarantee disclosure – the custodian may still refuse to disclose. The person requesting personal health information is also required to enter into an agreement to comply with specified conditions with the trustee/custodian.

Province-specific provisions

British Columbia

Forthcoming BC legislation (the BC E-Health (Personal Health Information Access and Protection of Privacy) Act, S.B.C. 2008, c. 38) authorizes the Minister to establish or designate databases containing personal health information as “health information banks” for purposes of conducting or facilitating research into health issues, the provision of health services to individuals, and identifying those in need of and those providing health services, among other things.

The Minister’s designation order may also authorize the disclosure of personal health information for a research purpose.

The designation order must authorize the person whose personal health information is contained in the health information bank that is the subject of the order to make a disclosure directive. However, this requirement does not apply in respect of a health information bank if the data stewardship committee (DSC) recommends to the minister that disclosure directives should not be made in respect of the health information bank.

The DSC is solely responsible for managing the disclosure, for a planning or research purpose, of information contained in a health information bank or a ministry database and for making recommendations to the Minister in respect of disclosure directives.

The DSC is to be appointed by the Minister and consist of not more than 12 persons including

- (a) one person from within the ministry of the minister,
- (b) one person chosen as representative of either regional health boards or the Provincial Health Services Authority,
- (c) one person nominated by the council of the College of Physicians and Surgeons of British Columbia.

(d) one person nominated by the council of the College of Pharmacists of British Columbia, or (d) one person nominated by the board of the college established under section 15(1) of the Health Professions Act for the health profession of the practice of pharmacy,

(e) one person nominated by the board of the college established under section 15(1) of the Health Professions Act for the health profession of the practice of nursing,

(f) one person engaged in health research, and

(g) 3 persons chosen as representative of the general public.

DSC members **are to be paid a remuneration set by the Minister**, and reasonable travel and out-of-pocket expenses.

DSC approval is required for all requests for personal health information for health research purposes. DSC review criteria is similar to that contained in provincial health information legislation.

Saskatchewan

The personal information trustee is required to, where practicable, use or disclose only de-identified personal health information if it will serve the purpose. There is also a deemed consent provision, which provides that consent to disclosure can be deemed for the purpose for which the trustee collected the information or for a purpose that is consistent with that purpose.

Manitoba

Two different ethics review committees undertake approval of the research project, depending on the source of the information requested.

a) The **Health Information Privacy Committee**, for personal health information maintained by the government or a government agency.

(b) An **institutional research review committee**, for personal health information maintained by a trustee other than the government or a government agency.

If a research project will require direct contact with individuals, a trustee shall not disclose personal health information about those individuals without first obtaining their consent. However, the trustee need not obtain their consent if the information consists only of the individuals' names and addresses.

Ontario

A REB must approve any use or disclosure of personal health information by a custodian, irrespective of who is using the information.

The REB requirements, details, processes are substantially similar to other jurisdictions and involves three main steps:

- i. Application by the person seeking to use the personal health information (includes a written application and research plan);
- ii. Approval by REB; and
- iii. Person seeking information must enter into an agreement with the custodian to comply with specified conditions.

REBs must have at least five members, including,

(i) at least one member with no affiliation with the person or persons that established the research ethics board,

(ii) at least one member knowledgeable in research ethics, either as a result of formal training in research ethics, or practical or academic experience in research ethics,

(iii) at least two members with expertise in the methods or in the areas of the research being considered, and

(iv) at least one member knowledgeable in considering privacy issues.