

RECOMMENDATIONS FOR NWT'S HSPL: AUTHORIZED USES

I. DEFINITION

Given the unique application of language in HSPL, it may be useful to set out a definition of "use". It is recommended that a definition such as the following be adopted:

Use, in relation to personal health information in the custody or control of a custodian, means to handle or deal with the information or to apply the information for a purpose and includes reproducing the information but does not include disclosing the information.

II. BASIC ASSUMPTION

The issue of consistent uses and secondary uses is one that can cause confusion, and accordingly create misguided expectations under with HSPL. Given the various yet related uses for which health organizations use health information, it is recommended that a clear statement about secondary uses be established, for example:

Personal health information can be used for the purpose for which it was collected, or for other purposes recognized by the Act. These include "secondary purposes" such as where there is consent for the use, the use is a "directly related purpose", for management, training and research activities, for investigation and law enforcement, or where there are serious and imminent threats to individuals or the public.

In addition, it recommended that those permissible secondary uses be set out by way of an exhaustive list. The following schemes for the establishment of uses (and secondary uses) are taken from Alberta and Newfoundland.

- ***The Newfoundland Scheme***

Permitted uses

34.A custodian may use personal health information in its custody or under its control for one or more of the following purposes:

- (a) for the purpose for which the information was collected or created and for all the functions reasonably necessary for carrying out that purpose;
- (b) where an Act or an Act of Canada permits or requires a person to disclose the personal health information to the custodian, for the purpose for which the information was disclosed;
- (c) for planning or delivering health care programs or services provided or funded by the custodian, in whole or in part, allocating resources to those programs or services, evaluating or monitoring those programs or services or preventing fraud or an unauthorized receipt of services or benefits related to those programs or services;
- (d) for the purpose of risk management or error management or for the purpose of activities to improve or maintain the quality of care or to improve or maintain the quality of related programs or services of the custodian;
- (e) in a manner consistent with Part II, for the purpose of disposing of the information or modifying it in order to conceal the identity of the individual who is the subject of the personal health information;
- (f) for the purpose of seeking the consent of the individual or his or her representative, where the personal health information used by the custodian for this purpose is limited to the name and contact information of the individual or the individual's representative;
- (g) for the purpose of a proceeding or contemplated proceeding in which the custodian is or is expected to be a party or witness and where the information relates to or is a matter in issue in the proceeding or contemplated proceeding;
- (h) where the custodian is the minister or a department, for the purpose of obtaining health care cost recovery;

- (i) for the purpose of obtaining payment or processing, monitoring, verifying or reimbursing claims for payment for the provision of health care or related goods and services;
- (j) for an approved research project in accordance with section 44;
- (k) as permitted or required by law or by a treaty, agreement or arrangement made under an Act or an Act of Canada;
- (l) to prevent or reduce a risk of serious harm to
 - (i) the mental or physical health or safety of the individual the information is about or another individual, or
 - (ii) public health or public safety;
- (m) where the custodian is a custodian referred to in paragraph 4(1)(a), (b), (c), (d) or
 - (i) for the following functions within the geographic area in which the custodian has jurisdiction:
 - (i) planning and resource allocation,
 - (ii) health system management,
 - (iii) public health surveillance, and
 - (iv) health policy development;
- (n) where the custodian is a person referred to in paragraph 4(1)(n), for the performance of a function referred to in subsection 14(2) of the *Mental Health Care and Treatment Act*;
- (o) another use to which the individual who is the subject of the personal health information consents; and
- (p) to produce information that does not, either by itself or in combination with other information in the custody of or under the control of the custodian, permit an individual to be identified.

Scope of use

35.A custodian shall limit the use of personal health information in its custody or under its control to those of its employees and agents who need to know the information to carry out the purpose for which the information was collected or a purpose authorized under this Act.

- *The Alberta Scheme*

Use of individually identifying health information

27(1) A custodian may use individually identifying health information in its custody or under its control for the following purposes:

- (a) providing health services;
- (b) determining or verifying the eligibility of an individual to receive a health service;
- (c) conducting investigations, discipline proceedings, practice reviews or inspections relating to the members of a health profession or health discipline;
- (d) conducting research
 - (i) if the custodian has submitted a proposal to a research ethics board in accordance with section 49,
 - (ii) if the research ethics board is satisfied as to the matters referred to in section 50(1)(b),
 - (iii) if the custodian has complied with or undertaken to comply with the conditions, if any, suggested by the research ethics board, and
 - (iv) where the research ethics board recommends that consents should be obtained from the individuals who are the subjects of the health information to be used in the research, if those consents have been obtained;
- (e) providing for health services provider education;
- (f) carrying out any purpose authorized by an enactment of Alberta or Canada;
- (g) for internal management purposes, including planning, resource allocation, policy development, quality improvement, monitoring, audit, evaluation, reporting, obtaining or processing payment for health services and human resource management.

(2) A custodian referred to in section 1(1)(f)(iii), (iv), (vii), (xii) or (xiii) may, in addition, use individually identifying health information in its custody or under its control to carry out the following functions within the geographic area in which the custodian has jurisdiction to promote the objectives for which the custodian is responsible:

- (a) planning and resource allocation;
- (b) health system management;

- (c) public health surveillance;
- (d) health policy development.

Use of health information by affiliate

28 An affiliate of a custodian must not use health information in any manner that is not in accordance with the affiliate's duties to the custodian.

Confidentiality of non-recorded information

29 A custodian that collects information described in section 1(1)(i), (o) or (u) that is not written, photographed, recorded or stored in some manner in a record may use the information only for the purpose for which the information was provided to the custodian.

Use of personal health number by non-custodian

30 A person who is authorized to require an individual to provide a personal health number pursuant to section 21(1)(b) may use that information only for the purpose for which the information was collected.

III. SPECIAL ISSUE: USE FOR RESEARCH PURPOSES

The Northerners' Panel identified a need for further information about personal health information being used for research, and more specifically, the role of Research Ethics Boards ("REBs"). First, for context, below are some statistics about REBs and their roles in Canada:

"Since the 1970s, in accord with national policies governing ethics in research involving humans, some 300 local REBs in Canada have been established in a variety of settings including universities, government laboratories, community organizations and teaching and community hospitals. In many teaching hospitals, at least 50% of the research protocols reviewed by REBs are clinical trials that are sponsored by industry for purposes of testing new pharmaceutical interventions in human health so as to meet the regulatory licensing requirements of Health Canada and the USA Food and Drug Administration. In addition, some company-based and private for-profit REBs have developed over the last few years to allow REB review of privately sponsored research outside academic institutions, and hence without access to local REBs."

After receiving ethics approval from an REB, the survey was administered by e-mail to 664 investigators and co-investigators supported by NSERC's Discovery Grants program (formerly Research Grants) ... who stated on their application forms that they conduct research that involves human subjects:

- The types of REBs used vary by respondents' research domain, with relatively greater use of biomedical REBs among engineering and natural sciences researchers (60.6%) than among researchers in psychology or the life sciences related to human health and disease (32.7%), and relatively greater use of social science/psychological REBs among this latter group (76.0%) than among their colleagues in natural sciences and engineering (27.7%).
- Attitudes toward the ethics review process among these respondents have both positive and negative aspects. Almost 40% of respondents agreed or strongly agreed that ethics review processes are bureaucratic procedures that contribute little and slow the progress of research. Respondents indicated some dissatisfaction with the implementation of the TCPS at their institutions. However, about 60% indicated that ethics review procedures are a useful source of information and advice on ethical practice, and 75% felt that ethics review processes are necessary to ensure ethical practices.
- On average, respondents felt they were "familiar" with the TCPS, but almost one-third (31.1%) considered themselves to be "not at all" or "not very" familiar with it. A significant minority of respondents - 10% - had never heard of the TCPS before the survey. Twenty percent had never read it or used it, while 40% had read it but never used it. Researchers in psychology and the life sciences related to human health and disease rated themselves as significantly more aware of the TCPS than did researchers working in other areas of the natural sciences or engineering."

Second, we can examine how REBs can be governed under HSPL, by looking (for example) to the Alberta model:

Division 3 - Disclosure for Research Purposes

Definition

48 In this Division, "health information" means individually identifying diagnostic, treatment and care information or individually identifying registration information, or both.

Research proposal

49 A person who intends to conduct research may submit a proposal to a research ethics board for review by that board.

Role of research ethics board

50(1) The research ethics board must

- (a) consider whether the researcher should be required to obtain consents for the disclosure of the health information to be used in the research from the individuals who are the subjects of the information, and
- (b) assess whether, in the opinion of the research ethics board,
 - (i) the proposed research is of sufficient importance that the public interest in the proposed research outweighs to a substantial degree the public interest in protecting the privacy of the individuals who are the subjects of the health information to be used in the research,
 - (ii) the researcher is qualified to carry out the research,
 - (iii) adequate safeguards will be in place at the time the research will be carried out to protect the privacy of the individuals who are the subjects of the health information to be used in the research and the confidentiality of that information, and
 - (iv) obtaining the consents referred to in clause (a) is unreasonable, impractical or not feasible.

(2) In making an assessment under subsection (1)(b), the research ethics board must consider the degree to which the proposed research may contribute to

- (a) identification, prevention or treatment of illness or disease,
- (b) scientific understanding relating to health,
- (c) promotion and protection of the health of individuals and communities,
- (d) improved delivery of health services, or
- (e) improvements in health system management.

(3) The research ethics board must prepare a response setting out

- (a) its recommendation under subsection (1)(a),
- (b) its assessment of the matters set out in subsection (1)(b), and
- (c) any conditions that the research ethics board considers should be imposed on the researcher.

(4) The research ethics board must send a copy of the response required in subsection (3) to the Commissioner.

Publication of response

50.1 If the response of the research ethics board sent to the Commissioner under section 50(4) indicates that the research ethics board is satisfied as to the matters referred to in section 50(1)(b), the Commissioner may publish the response in any manner the Commissioner considers appropriate.

Bar to research

51 If the research ethics board is not satisfied as to any of the matters referred to in section 50(1)(b), the researcher may not apply to a custodian under section 52.

Application for disclosure of health information

52 If the research ethics board is satisfied as to the matters referred to in section 50(1)(b), the researcher may forward to one or more custodians

- (a) the response of the research ethics board to the researcher's proposal, and
- (b) a written application for disclosure of the health information to be used in the research.

Conditions and consents

53(1) A custodian who has received the documents referred to in section 52 may, but is not required to, disclose the health information applied for.

(2) If the custodian decides to disclose the health information,

- (a) the custodian
 - (i) must impose on the researcher any conditions suggested by the research ethics board, and
 - (ii) may impose other conditions on the researcher,and
- (b) the researcher must obtain the consents referred to in section 50(1)(a), if recommended by the research ethics board, prior to the disclosure.

Agreement between custodian and researcher

54(1) If the custodian decides to disclose health information to a researcher, the researcher must enter into an agreement with the custodian in which the researcher agrees

- (a) to comply with
 - (i) this Act and the regulations made under this Act,

- (ii) any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information, and
 - (iii) any requirement imposed by the custodian to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information,
- (b) to use the health information only for the purpose of conducting the proposed research,
 - (c) not to publish the health information in a form that could reasonably enable the identity of an individual who is the subject of the information to be readily ascertained,
 - (d) not to make any attempt to contact an individual who is the subject of the health information to obtain additional health information unless the individual has provided the custodian with the consent referred to in section 55,
 - (e) to allow the custodian to access or inspect the researcher's premises to confirm that the researcher is complying with the enactments, conditions and requirements referred to in clause (a), and
 - (f) to pay the costs referred to in subsection (3).

(2) When an agreement referred to in subsection (1) has been entered into, the custodian may disclose to the researcher the health information requested under section 52

- (a) with the consent of the individuals who are the subjects of the information, where the research ethics board recommends that consents should be obtained, or
- (b) without the consent of the individuals who are the subjects of the information, where the research ethics board does not recommend that consents be obtained.

(3) The custodian may set the costs of

- (a) preparing information for disclosure,
- (b) making copies of health information, and
- (c) obtaining the consents referred to in section 55,

which must not exceed the actual cost of providing that service.

(4) If the researcher contravenes or fails to meet the terms and conditions of an agreement under this section, the agreement is cancelled.

Consent for additional information

55 If the researcher wishes to contact the individuals who are the subjects of the information disclosed under section 54(2) to obtain additional health information, the custodian or an affiliate

of the custodian must first obtain consents from those individuals to their being contacted for that purpose.

Court order

56(1) If a researcher refuses to allow a custodian to access or inspect its premises in accordance with the agreement referred to in section 54, the custodian may apply to the Court of Queen's Bench by notice of motion for an order under subsection (2).

(2) If the Court is satisfied that there are reasonable and probable grounds to believe that access to premises or the production or removal of documents is necessary for the purpose of determining whether an agreement referred to in section 54 is being complied with, the Court may make any order it considers necessary to enforce compliance with the agreement.

(3) Where authorized to do so by an order under subsection (2), a custodian may

- (a) enter and search any premises of the researcher where the research is conducted,
- (b) operate or cause to be operated any computer system of the researcher to search any data contained in or available to the system and produce a document from the data, and
- (c) seize and make copies of any documents of the researcher that are or may be relevant to the investigation.

(4) An application for an order under this section may be made ex parte unless the Court orders otherwise.

(5) The custodian must return any documents seized pursuant to a court order within 60 days after the conclusion of the investigation that gave rise to the seizure, including any hearing or appeal.

(6) In this section, "document" includes any correspondence, memorandum, book, plan, map, drawing, diagram, pictorial or graphic work, photograph, film, microfilm, sound recording, videotape, machine readable record or other material or thing, regardless of physical form or characteristics.