RESEARCH

DEFINITIONS

RESEARCH

Research means a systematic investigation designed to develop or establish principles, facts generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research. (*PHIA* section 52(c)).

PLANNING AND MANAGEMENT OF THE HEALTH SYSTEM

Under PHIA section 3 (s), planning and management of the health system means the analysis of information with respect to:

- the management, evaluation or monitoring of,
- the allocation of resources to, or
- planning for all or part of, the health system including the delivery of services.

Only the Minister of Health and Wellness is authorized to plan and manage the health system. Section 31(l) authorizes only the Minister to indirectly collect personal health information for the purposes of planning and management of the health system, and section 38(1)(g) states that a custodian may disclose personal health information without consent only to the Minister for the purposes of planning and management of the health system.

However, under section 35(1)(a), any custodian is authorized to use personal health information in its custody or control without consent for the purposes of:

- planning or delivering programs or services that the custodian provides;
- planning or delivering programs or services that the custodian funds in whole or in part;
- allocating resources to any of them;
- evaluating any of them; or
- monitoring any of them.

EXAMPLE

Kevin, a chiropractor in private practice, wants to evaluate the effectiveness of a new technique to reduce neck pain. Kevin may use his patients' personal health information without their consent to review the outcomes of the technique.

OTHER EXCEPTIONS

Pursuant to section 5(2)(a) of *PHIA*, the legislation does not apply to statistical, aggregate or de-identified health information.

Section 3(g) of PHIA defines "de-identified information" as *"information that has had all identifiers removed that:*

> *(i) identify the individual; or*
>
> *(ii) where it is reasonably foreseeable in the circumstances, could be utilized, either alone or with other information, to identify the individual."*

PHIA does not apply to personal health information about an individual after the earlier of one hundred and twenty years after a record containing the information was created and fifty years after the death of the individual (section 5(2)(b)). This provision may be relevant to research where the personal health information being sought is outside the application period for *PHIA*.

Under section 49(2), retention schedules require that information no longer required to fulfill the purposes identified in the schedules (e.g. direct patient care) be securely destroyed, erased or de-identified. Section 49(3) allows information to be de-identified and retained for purposes other than the original purposes for which it was collected.

EXAMPLE

Ingrid wants to do a research project on Alzheimer's disease using hospital records for patients who died 60 years before the research will be initiated. In this case, *PHIA* would not apply, as the personal health information is outside of the application period for *PHIA*.

Section 51 of *PHIA* requires that the hospital ensure that its retention and destruction schedule for personal health information has been followed. However, section 49(3) permits the hospital

to retain the information in a de-identified form to be used for secondary purposes, including research.

If the hospital has retained the information in a de-identified form, Ingrid would still be able to undertake the research.

USE OF PERSONAL HEALTH INFORMATION IN THE CUSTODY OR CONTROL OF A CUSTODIAN FOR RESEARCH

PHIA has introduced rules to provide protection of personal health information in circumstances where a custodian wants to use personal health information in their custody or under their control for research.

Pursuant to section 55 of *PHIA* a custodian may use personal health information for research if, before commencing the research, the custodian:

- prepares a research plan that meets the requirements in section 59;
- submits the research plan to a research ethics board (REB);
- receives the approval of the research ethics board; and
- meets any conditions imposed by the REB.

"Use" is defined by *PHIA* as meaning to handle or deal with the information, but does not include disclosing the information.

Pursuant to section 55 of *PHIA,* a custodian may use personal health information in its custody or control if the custodian submits a research plan to a REB that meets the requirements of section 59. When developing a research plan, a custodian may reference the Research Plan Checklist to ensure they have satisfied all requirements. See Template 7-1 *Research Plan Checklist.*

In addition to submitting a research plan to a REB, the custodian must also receive approval from the REB, and meet any conditions imposed by the REB.

Unlike the *disclosure* of personal health information for research purposes, a custodian is not required to enter into a data disclosure agreement when using the personal health information in its custody or under its control.

Although the personal health information is in the custody and control of the custodian, consent of the subject individuals is still required unless a REB has determined that the consent of the subject individuals is not required, or that it is *impracticable* to obtain consent.

"IMPRACTICABLE"

PHIA section 52(b) defines "impracticable" as *"a degree of difficulty higher than inconvenience or impracticality but lower than impossibility."*

In the *Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ,[1] "impracticable" refers to *"undue hardship or onerousness that jeopardizes the conduct of the research."* This is consistent with the intent in *PHIA*, which requires that the researcher consider and attempt all available means of requesting consent.

In practice, it may be helpful to consider circumstances where it is *impracticable* to obtain consent. The Canadian Institutes for Health Research has set out circumstances where this may be the case:

- the size of the population being researched;
- the proportion of prospective participants likely to have relocated or died since the time the personal information was originally collected; or
- the lack of an existing or continuing relationship between prospective participants and the data holder who would need to contact them (e.g. a patient database that does not have a regular follow-up program to maintain a complete and accurate record of changes in registrants' contact information over time);

such that:

- there is a risk of introducing bias into the research because of the loss of data from segments of the population that cannot be contacted to seek their consent, thereby affecting the validity of results and/or defeating the purpose of the study; or

[1] *Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010* available at http://www.pre.ethics.gc.ca/eng/index/

- the additional financial, material, human, organizational and other resources needed to obtain consent could impose a hardship or burden on the researchers or organization so burdensome that the research could not be done. [2]

DISCLOSURE OF PERSONAL HEALTH INFORMATION IN THE CUSTODY OR CONTROL OF A CUSTODIAN FOR RESEARCH

Pursuant to section 56 of *PHIA* a custodian may disclose personal health information about an individual to a research if the researcher:

(a) submits to the custodian:

(i) an application in writing;

(ii) a research plan that meetings the requirements of section 59; and

(iii) a copy of the submission to and decision of a research ethics board that approves the research plan; and

(b) enters into the agreement required by section 60.

A researcher who seeks disclosure of personal health information for research must submit a research plan to a REB for approval. These conditions are clearly outlined in sections 56 - 60 of the Act and include, but are not limited to:

- a description of the research proposed to be conducted;
- a description of the personal health information required and the potential sources of the information; and
- a description of how the personal information will be used in the research.

See section 59 of *PHIA* or Template 7-1 *Research Plan Checklist* for a complete list of conditions.

Pursuant to section 57 of *PHIA*, within the research plan, the researcher must highlight if consent is being sought for subject individuals. If not, the researcher must provide an

[2] *CIHR Best Practices for Protecting Privacy in Health Research 2005*, at page 7 http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf

explanation as to why seeking consent is impracticable – and the custodian must accept this explanation.

If the custodian is satisfied under section 57 that consent is not required, the custodian is required to inform the Review Officer that personal health information is being disclosed for research without consent. See Template 7-2 *Review Office Notification* for a sample letter to submit to the Review Office.

Where a custodian discloses personal health information to a researcher, the researcher shall enter into an agreement (*see* Template 7-3 *Data Disclosure Agreement*) with the custodian to adhere to requirements including:

- to comply with any terms and conditions imposed by a research ethics board or custodian;
- to use the information only for the purposes outlined in the research plan as approved by a research ethics board; and
- to notify the custodian immediately and in writing if the personal health information is stolen, lost or subject to unauthorized access, use, disclosure, copying or modification.

See section 60 of *PHIA* for a complete list of requirements.

THE RESEARCH PLAN

The research plan referenced in the research sections of *PHIA* does not have to be a separate document from the existing research project protocol already created for other purposes, including submission to the REB, applications for funding or thesis approval provided that all the information required under section 59 is included in the existing document.

See Template 7-4 *Request for Access to Personal Health Information Held by Custodians.* This form includes all requirements under section 56(a)(i) of *PHIA* and can be used as a template application form for data held by custodians.

SUMMARY OF REQUIREMENTS

> ***Note:** For a complete list of requirements under section 59, see Template 7-1 Research Plan Checklist*

CUSTODIAN USING PERSONAL HEALTH INFORMATION FOR RESEARCH

Before commencing research using personal health information in his/her custody or control, the custodian shall:

(a) prepare a research plan that meets the requirements in section 59;

(b) submit the research plan to a research ethics board;

(c) receive the approval of the research ethics board; and

(d) meet any conditions imposed by the research ethics board.

RESEARCHER REQUESTING PERSONAL HEALTH INFORMATION FROM CUSTODIAN – WITH CONSENT OF SUBJECT INDIVIDUALS

Before commencing the research, the researcher shall:

1. submit to the custodian

   a) an application in writing;

   b) a research plan that meets the requirements of Section 59; and

   c) a copy of the submission to and decision of a research ethics board that approves the research plan; and

2. enter into the agreement required by Section 60.

RESEARCHER REQUESTING PERSONAL HEALTH INFORMATION FROM CUSTODIAN – WITHOUT CONSENT OF SUBJECT INDIVIDUALS

Before commencing the research:

1. the researcher shall submit to the custodian:

    a) an application in writing;

    b) a research plan that meets the requirements of Section 59; and

    c) a copy of the submission to and decision of a research ethics board that approves the research plan;

    d) enter into the agreement required by Section 60

2. A research ethics board has determined that the consent of the subject individuals is not required;

3. the custodian is satisfied that:

    a) the research cannot be conducted without using the personal health information;

    b) the personal health information is limited to that necessary to accomplish the purpose of the research;

    c) the personal health information is in the most de-identified form possible for the conduct of the research;

    d) the personal health information will be used in a manner that ensures its confidentiality; and

    e) it is impracticable to obtain consent; and

4. the custodian informs the Review Officer that personal health information is being disclosed without the subject individuals' consent (see Template 7-2 *Review Officer Notification letter*).