

GUIDANCE FOR RESEARCH TEAMS: INJURY DATA COLLECTION FOR CRASH RECONSTRUCTION STUDIES



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Abstract

More than thirty years ago, the Road Safety and Motor Vehicle Regulation Directorate of Transport Canada began establishing multidisciplinary accident research teams across Canada. Historically, these teams have been located in universities under the direction of one or more professors who have an interest in, and a commitment to, road traffic safety. The motivation for this data collection project is to provide the ministry with the necessary field research data that will identify important safety issues and monitor responses to government rule making.

The multidisciplinary aspect of the teams is essential, providing engineering skills for crash reconstruction, and medical knowledge to explain injury data and suggest likely injury biomechanics. Cooperation of the policing and legal communities has been most helpful in locating and obtaining access to crash sites and damaged vehicles.

Collision reconstruction studies involve inspecting and photographing damaged vehicles, and roadway and roadside evidence. One of the more challenging aspects of data collection by the teams involves obtaining injury data on the crash victims. In completing most reconstruction reports it is impractical to obtain the consent of injured individuals whose personal health information is required. This has required establishing and maintaining the trust and cooperation of the legal custodians of recorded injury data, in keeping with recognized legal safeguards.

In order to manage the tension between the need to protect confidentiality and the public's right to know, when such research contributes to public safety, federal and provincial governments have enacted legislation that recognizes the value of such research. In support of this research, these statutes spell out necessary safeguards for the protection of confidentiality. This paper outlines these developments and reviews how the multidisciplinary accident research teams have been collecting injury data while recognizing these necessary constraints.

When crash data collection involves a large urban area, or when a particular study requires statistical sampling of a broad geographical area, it is challenging for a reconstruction team to establish a working relationship with many health information custodians. In spite of the best efforts of medically trained team members, inadequate case sampling may result in such studies being curtailed or abandoned. This paper provides research teams with the background information and guidance to most effectively collect, utilize and disclose this sensitive personal injury information.

Résumé

Il y a plus de trente ans, la Direction générale de la sécurité routière de Transports Canada a entrepris de mettre sur pied des équipes multidisciplinaires en leur confiant le mandat d'effectuer de la recherche en matière d'accidents dans l'ensemble du Canada. Ces équipes sont basées dans les universités et sont sous la direction d'un ou de plusieurs professeurs qui manifestent un intérêt, ainsi qu'un engagement, envers la sécurité routière. Le projet de cette collecte de données visait à fournir au Ministère les données nécessaires de recherche sur le terrain en vue d'identifier les principales questions ayant trait à la sécurité et de surveiller la réaction aux règles établies par le gouvernement. L'aspect multidisciplinaire des équipes est essentiel, en ce sens que cela permet de regrouper des personnes ayant des compétences en génie pour la reconstitution d'un accident et possédant des connaissances médicales permettant d'expliquer les données relatives aux blessures réelles et vraisemblablement à la biomécanique des blessures. La collaboration entre le milieu des politiques et le milieu juridique s'est avérée très utile en permettant de situer les lieux de collision et d'y avoir accès ainsi qu'aux véhicules accidentés. Les études sur la reconstitution des collisions impliquent d'inspecter et de photographier les véhicules accidentés ainsi que les preuves recueillies sur la route et en bordure de la route. L'un des aspects les plus complexes de la collecte de données par les équipes consiste à obtenir les données sur les blessures des victimes de collisions. En préparant la plupart des rapports de reconstitution, il est pratiquement impossible d'obtenir le consentement des personnes blessées dont les renseignements personnels sur la santé sont requis. Cela a nécessité l'établissement et le maintien de la confiance et de la collaboration des gardiens légaux des données saisies sur les blessures, en tenant compte des garanties juridiques reconnues. Afin de gérer l'opposition entre le besoin de protéger la confidentialité et le droit de savoir du public, lorsqu'une telle recherche contribue à la sécurité publique, les gouvernements fédéral et provinciaux ont promulgué des lois qui reconnaissent la valeur de ce type de recherche. Pour l'appuyer, ces lois précisent les garanties nécessaires pour protéger la confidentialité. Cet article explique ces développements et examine la façon dont les équipes multidisciplinaires responsables de la recherche sur les accidents ont recueilli des données sur les blessures tout en tenant compte de ces contraintes nécessaires. Lorsqu'une équipe d'investigation doit recueillir des données de collisions dans une grande ville ou une grande région, il est souvent difficile d'établir des rapports de travail efficace avec tous les membres de la communauté médicale œuvrant dans la région visée. Pourtant, malgré tous les efforts des membres de l'équipe d'investigation possédant une formation médicale, le choix inapproprié des cas soumis à l'étude peut conduire à une recherche incomplète ou même abandonnée. Cette communication présente donc, aux équipes d'investigation, un guide qui leur permettra de recueillir, d'utiliser et de transférer efficacement les renseignements médicaux personnels requis par la recherche en sécurité routière.

THE KREVER COMMISSION INTO THE CONFIDENTIALITY OF HEALTH INFORMATION

Canada is only one of many jurisdictions in the western world to express increasing concern about the problems relating to the confidentiality of personal information such as health records. The rise of the information society has created anxiety about the use of information. Privacy in this sensitive area is being given increasing levels of protection by legislation. An early stimulus to develop improved legislative protection for the privacy of personal health information was the Ontario Commission of Inquiry into the Confidentiality of Health Information conducted in the late 1970's by Mr. Justice Horace Krever.

These extensive hearings lasted over three years and received widespread coverage by the print and electronic media. This project and other studies uncovered many unacceptable breaches of confidentiality. The final report of the Krever Commission was published in three volumes [1]. In Volume III, Chapter 26, the topic of "Research" was addressed in 37 pages. Justice Krever outlined the tension between an invasion of personal privacy and the need to acquire this information for research purposes leading to a public benefit. The following statements by Justice Krever outline his convictions on hearing the many submissions:

Despite my strong conviction that confidentiality is fundamental not only to the provision of proper medical care, but also to the preservation of the dignity and integrity of the individual, I am persuaded that research is one respect in which the benefit to society by researcher's access to personal health information outweighs the possible risk to the individual. This, however, resolves only the contest between an absolute and a limited right of confidentiality. The determination must still be made of the circumstances in which the balance favours society.

The questions of when and under what conditions confidential health information should be released to researchers without the consent of patients should be answered as part of the process of weighing the competing valid interests involved in the inevitable conflict between a patient's right to privacy and researchers', and thus society's, need for information. I am persuaded that in an enlightened society, most persons would agree that, in exchange for the benefits which flow to all members from medical research, some degree of individual privacy must be relinquished. In weighing the loss of privacy against the benefit to mankind, the manner in which information is handled must be considered as well as the promise of the research itself. The task at hand is to develop guidelines to regulate the access to information by researchers by reconciling, to the greatest extent possible, the right of the individual to privacy with the legitimate needs of society.

I am very sensitive to the problems faced by members of the research community. Because of the essential nature of the work they do and the benefits that accrue to society by reason of that work, it is my view that their demonstrated need for information should be accommodated as much as possible. There is no suggestion that the information acquired by them, to which I have referred, has been abused or misused in any way.

The distinction between physician and non-physician researchers is unnecessary. The confidentiality of the information acquired as part of the research project is best preserved by ensuring that those who have access to it are aware of the need for confidentiality and undertake to protect it. It is not necessary to limit access arbitrarily to a class of people. Researchers are generally sensitive to the importance of confidentiality. There is awareness that, if the public perceives that information given to the researchers is released in an identifiable form, there will be a reluctance on the part of the public to provide information, the basic tool of the researcher.

Of equal importance is the physical security of the information collected and maintained by researchers. This includes methods of storage, dissemination and destruction. Because the computer allows the data to be manipulated in several different ways there is a tendency to collect and keep more information than is necessary, so that it can be used for projects other than that for which it was collected. The longer identifiable data are maintained the more opportunity there is for abuse or misuse of the information.

Mr. Justice Krever made the following recommendations as a result of his assessment of the proper role of the research community in acquiring and using personal health information:

Recommendations:

That a health-care facility be permitted to disclose identifiable health information to a qualified researcher for the purpose of a research project without the consent of the subjects involved, provided that approval has been granted by an appropriate human experimentation committee whose members must not be confined to the principal investigator's discipline, and must include one or more representatives of the public, and provided also that the human experimentation committee has been satisfied that the principal investigator has met the following criteria:

(a) the identifiable information sought is indispensable for the purpose of the research project;

(b) the importance of the research project, in the opinion of the committee, justifies the breach of the subject's privacy; and

(c) the principal investigator undertakes:

(i) that he or she will provide adequate physical security for the information;

(ii) that he or she will remove or destroy information identifying the subjects at the earliest opportunity compatible with the requirements of the research project; and

(iii) that he or she will not further disclose the identifiable health information except to persons who must have access to it for the purpose of the project, or in an emergency situation in which there is a risk to the life or safety of a subject or another person, or when required to do so by law.

Government agencies collect extensive collision data on selected vehicle crashes subject to existing privacy legislation requiring protection of personal privacy. The Canada Privacy Act,

Chapter P-21, was proclaimed in January 2004 [3]. The purpose of this federal act is to extend the present laws of Canada that protect privacy of individuals with respect to personal information about themselves held by a government institution.

The Act provides individuals with a right of access to that information. "Personal information" means information about an identifiable individual that is recorded in any form. The Act states that no personal information shall be collected by a government institution unless it relates to an operating program or activity of the institution. This clearly identifies as acceptable the activity of the university-based research teams supported by, and reporting to, Transport Canada.

Section 8 of the Act in subsection (2) states the following:

Subject to any other act of parliament, personal information under the control of a government institution may be disclosed (i) to any person or body for research or statistical purposes if the head of the government institution is (ii) satisfied that the purpose for which the information is disclosed cannot reasonably be accomplished unless the information is provided in a form that would identify the individual.

Because of the long-established practice of coding identifiable information under the control of a government institution prior to reporting collision and injury data, this coded information received and retained by the Road Safety Directorate is unlikely to be considered "personal information" as defined in the Privacy Act. Over time, as future considerations may arise, it is open to the Directorate to further "sanitize" the retained data to be confident that disclosing the information would fail to identify any specific person as the source.

Canada's Personal Information Protection and Electronic Document Act (PIPEDA) establishes rules for how private sector institutions may collect, use or disclose personal information in commercial activities [2]. It is unlikely that collection of collision data by government agencies for research purposes, a non-commercial activity, would be subject to PIPEDA.

All Canadian provinces except Quebec have recently enacted legislation addressing the need to protect the confidentiality of personal health information, with special consideration defined for valid research studies. Quebec hospitals and clinics are generally subject to the public sector privacy law. It is instructive to review the Personal Health Information Protection Act (PHIPA) 2004, enacted by the Province of Ontario in response to the publicity surrounding the Krever Commission's findings and recommendations. Section 44 of the Ontario Act (reproduced in Appendix A) addresses the exceptions that may be granted for valid research studies. Statutes in the other nine provinces that address the protection of personal health information and disclosure for research purposes are listed in Appendix B.

PERSONAL HEALTH INFORMATION PROTECTION ACT (PHIPA)

The PHIPA generally applies to health information custodians ("HICs"), but the word "custodian" is somewhat misleading. It generally refers to an organization (such as a hospital or clinic) or to a health care professional (such as a physician), rather than to the particular individual who happens to have "custody" of health information as such. The obligations

imposed by PHIPA go far beyond the hospital and clinic records rooms. Some of the western statutes use the term "trustee" rather than "custodian".

Generally speaking, the three activities regulated by personal information laws are *collection, use and disclosure*. Under PHIPA, a health information custodian may be engaging in research itself, in which case what it does with personal health information is a use governed by clause 37(1)(j) and subsection 37(c), or it may be disclosing personal health information to an outside or an independent researcher, in which case that disclosure, and what the researcher does with the personal health information, are governed by section 44. The type of research engaged in by the Transport Canada funded university teams falls within the disclosure provisions of section 44.

The two key points articulated in section 44 are: *there must be a research plan, and this plan must be approved by a research ethics board*. Section 44 as it deals with external researchers can be summarized as follows:

Physicians, hospitals and other health care providers are defined as "health information custodians". They are permitted to disclose "personal health information" about an individual to a researcher who has submitted:

- *an application in writing;*
- *a research plan in writing that sets out:*
 - *the affiliation of each person involved in the research;*
 - *the nature and objectives of the research and the public or scientific benefits anticipated;*
 - *the other 12 items of information which are required by section 16 of the Regulations under PHIPA, (see Appendix A).*
- *a copy of an approval of the plan by a research ethics board, which is required to consider the matters that it considers relevant, including a number of factors set out in section 44(3) that approval can be subject to conditions specified in the board's decision.*

PHIPA does not require a custodian to disclose information to a researcher who has met these conditions: section 44 says only that it "may" do so. If the custodian decides to make the disclosure, then before it does so, the researcher must enter into an agreement with the custodian in which the researcher agrees to comply with the conditions and restrictions (if any) that the custodian imposes relating to the use, security, disclosure, return or disposal of the information.

A researcher is subject to a number of additional restrictions and limitations set out in subsection 44(6). In addition to complying with the research agreement and with any conditions specified by the board in its decision approving the research plan, a researcher must use the information only for the purposes set out in the approved plan, must not publish the information in a form that could reasonably enable a person to ascertain the identity of an individual, must not contact or attempt to contact an individual, directly or indirectly, unless the custodian (not the researcher) first obtains the individual's consent to being contacted, and

must notify the custodian immediately in writing if the researcher becomes aware of any breach of subsection 44(6) or of the research agreement.

To provide a transitional period for research that was already in progress, subsection 44(12) provides, in effect, that a health information custodian that lawfully disclosed personal health information to a researcher for the purpose of conducting research in the three year period before November 1, 2004 (when PHIPA came into force) may continue to disclose personal health information to the researcher for the purposes of that research until October 31, 2007.

THE EARLY YEARS OF INJURY DATA COLLECTION

Increasingly, over many decades of hospital and clinic patient care, personal information including health care records have been shared with a multitude of medical staff and care givers on a "need to know" basis to deliver optimal care to individual patients. In order to adequately monitor how effectively treatment and safety measures are performing, these patient care settings have for many years permitted access to personal health information for study by internal assessors. More recently, requests for access to health care information by external researchers have been granted, with attention to increasingly stringent confidentiality requirements as well as clear justification based on the expected community benefit.

For more than 30 years, the multidisciplinary accident research teams have been collecting, coding, storing and utilizing injury data on road traffic victims in support of research studies to promote safety benefits to the public. During this time, as outlined above, increasingly detailed statutory regulations have been introduced by federal and provincial governments to regulate the disclosure of personal health information. All of these statutes have specified the required process by which disclosure of this sensitive information is to be made available to researchers.

In the early years of injury data collection, the medical members of the university based research teams approached the appropriate health care institutions with the need for injury data in support of crash research studies. These health care institutions (generally hospitals or clinics) were already familiar with a variety of internal research studies where obtaining the consent of the individuals whose personal health information is being disclosed would be impractical. These health care institutions were already collaborating with internal and even a few external research studies promoting improved health care and safety.

An application by researchers to obtain personal health information involved the presentation of a research plan for review by the appropriate persons and committees. The plan presented by the teams outlined the nature and objectives of the study, and the expected public and scientific benefits. In the proposals, coding safeguards to limit disclosure of sensitive information to only bona fide research purposes were explained.

These institutions were generally were prepared to accept the status of the university-based teams, represented to them by medical team members, as worthy of consideration. This consideration involved initial scrutiny by clinical staff, further review and acceptance or rejection by the medical advisory committee at monthly meetings of staff. Finally, the institution's board of governors were asked to review, and either approve or deny any research requests that had been approved at the earlier stages of consideration.

DEVELOPMENT OF DATA COLLECTION PROCEDURES TO MATCH STATUTORY STANDARDS

Over the years the multidisciplinary accident research teams developed a level of communication and trust with health information custodians who cooperated with these research programs. Much of what is now coded in government privacy legislation, relating to research involving the use of personal health information, was in place early in the relationship

between the teams and the health information custodians. Research plans have always been presented for approval in a manner acceptable to the custodian. The teams' methods of data collection, use, storage and disclosure has regularly been reviewed. A recent project submitted to Transport Canada [4] demonstrated that in the close collaboration of the teams with health information custodians, the process closely followed the recently proclaimed government privacy statutes where applicable.

Throughout the years that the university-based teams have been collecting and using this personal health information, one problem that sometimes arises is difficulty establishing and maintaining a trusting, collaborative relationship with specific custodians of this sensitive personal health information. When crash data collection involves a large urban area, or when a particular study requires statistical sampling of a broad area of involvement, e.g.: a sampling mixture of urban, suburban and rural locations, it has often been challenging for a research team to establish a working relationship with many different personal health information custodians.

To meet this challenge, research teams have been prepared to expend much time, effort and patience. A successful result requires time consuming direct involvement of a medically trained team member. In spite of such dedication to the task, less than adequate sampling can result. It has been the experience of even such a large, prestigious data collector as the National Accident Sampling System (NASS) in the US, that a proposed sampling program in some very large urban centres eventually have had to be abandoned due to a lack of local cooperation.

INITIATING A HEALTH RECORDS ACCESS PROGRAM FOR RESEARCH PURPOSES IN 2007

The custodians of personal health information are presently governed by their provincial statutes. On request, they make available standard request forms for prospective human research studies. An example of an Ontario form used by the London Health Sciences Centre (Appendix C) is a one page document with a second page of instructions.

The process involves an initial presentation to a duly constituted Health Sciences Research Ethics Board (HSREB). This board provides a multipage document that is to include the names and credentials of the researchers, the nature and objectives of the research, and the public or scientific benefits anticipated. As outlined in Appendix A, section 44(3), the Board must be satisfied that confidentiality is adequately protected, and that obtaining direct consent from involved individuals would be impractical.

The great bulk of proposals reviewed by research ethics boards addresses studies on such issues as randomized clinical trials, innovative therapies, and other issues that involve manipulating the treatment of human subjects. This raises questions of inadequate consent, coercion, deception, equitable participant selection for example that involve extensive documentation.

When a research ethics board reviews a request from a multidisciplinary accident research team, the request is limited to access to a limited amount of already documented information.

Where the application before the research board requests only selective health chart reviews, allowance is generally made to expedite such limited information searches.

The research ethics board scrutiny in such limited request attends to the issues of:

1. recognition that it is not feasible to obtain the consent of the participants;
2. credentials of the researchers;
3. the expected benefits of the study;
4. adequate protection of confidentiality.

If the research ethics board is satisfied that the above considerations have been adequately addressed, submissions are made to the grants and contract office for final approval of the contract and the protocol to be followed. The researcher will be notified of the institution's decision. Acceptance of the research proposal often requires monitoring of the study by the institution.

An institutional custodian or trustee of personal injury data that has collaborated with our accident research team throughout our years of data collection has been the office of the Chief Coroner for Ontario and the Regional Deputy Coroners. The Ontario coroner's motto is "We speak for the dead to protect the living." In keeping with their commitment to public safety, the coroners of Ontario, and the coroners and medical examiners in the other nine provinces have generally been supportive of the teams in expediting the availability of personal injury data where the researcher's credentials are accepted and confidentiality is assured.

SALUS POPULI SUPREMUS LEX : THE PUBLIC GOOD IS THE GREATER LAW

Since at least the time of Imperial Rome two thousand years ago, enlightened civilizations have curtailed individual rights and freedoms on the basis that the public interest is sometimes superior to individual interest. Government agencies have depended upon this approach to collect data in support of improving public safety. This is clearly expressed in a recent policy statement by NHTSA indicating that information collected aids investigations into the causes of crashes and injury mechanisms, and makes it possible to better define safety problems, and improve motor vehicle safety. This statement is similar to recent policy decisions expressed by the Road Safety Directorate of Transport Canada.

In a recent review for Transport Canada [4], the authors of this paper explored the nature of rights when rights compete. Establishing what is just involves balancing rights claims, which is to imply that rights conflict: my right to property versus yours, your right to privacy versus the public's right to know. Rights make explicit the rival claims that must be adjudicated if a society is to be just.

In a recent article, widely read Canadian journalist André Picard outlined the problems that personal privacy laws can create in medical research on human subjects concluding, *inter alia*:

Legislators, health administrators and research ethics boards have to be careful not to be unduly swayed by a small cadre of privacy zealots. We do not need measures that protect individual privacy at the expense of research that benefits the collectivity. There are enough threats out there already: We do not need privacy legislation that is bad for our health [5].

In another recent article, Ontario Information and Privacy Commissioner Dr. Ann Cavoukian noted that there is no rigid requirement to obtain positive consent before health information may be used for research purposes in Ontario or any other jurisdiction in Canada that has privacy legislation pertaining to personal health information. She further noted that researchers that use health information without personal consent must have a detailed research plan that is approved by a duly constituted research ethics board, and where identifiable information is needed to accomplish the research objectives, and it is impractical to obtain consent [6].

From the extensive public inquiry by Justice Krever and other early reviews, federal and provincial governments have developed and updated privacy statutes including specific considerations for the use and protection of personal health information. These developments have delivered an expressed need to recognize the positive role that research provides in benefits to society. The resulting procedural guidelines have defined a responsible pattern of behaviour by custodians and researchers to facilitate research studies, while offering reasonable confidentiality of personal health information.

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- [4] *A Review of Jurisprudence Regarding Event Data Recorders* Available online at <http://www.carsp.ca>

[5] Picard, A., *It's No Secret That Privacy Laws Can be Bad for Our Health*, Globe and Mail, January 27, 2005.

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Available online at <http://www.globeandmail.ca>

Appendix A

Personal Health Information Protection Act, 2004: Ontario

44. (1) A health information custodian may disclose personal health information about an individual to a researcher if the researcher,

- (a) submits to the custodian,
 - (i) an application in writing,
 - (ii) a research plan that meets the requirements of subsection (2), and
 - (iii) a copy of the decision of a research ethics board that approves the research plan; and
- (b) enters into the agreement required by subsection (5), 2004, c. 3, Sched. A, s.44 (2).

Research Plan

- (2) A research plan must be in writing and must set out,
- (a) the affiliation of each person involved in the research;
 - (b) the nature and objectives of the research, and the public or scientific benefit of the research that the researcher anticipates; and
 - (c) all other prescribed matters related to the research, 2004, c.3, Sched. A, s. 44(2).

Consideration by board

(3) Where deciding whether to approve a research plan that a researcher submits to it, a research ethics board shall consider the matters that it considers relevant, including,

- (a) whether the objectives of the research can reasonably be accomplished without using the personal health information that is to be disclosed;
- (b) whether, at the time the research is conducted, adequate safeguards will be in place to protect the privacy of the individuals whose personal health information is being disclosed and to preserve the confidentiality of the information;
- (c) the public interest in conducting the research and the public interest in protecting the privacy of the individuals whose personal health information is being disclosed;

and

- (d) whether obtaining the consent of the individuals whose personal health information is being disclosed would be impractical. 2004, c.3, Sched. A, s.44(3).

Decision of the board

(4) After reviewing a research plan that a researcher has submitted to it, the research ethics board shall provide to the researcher a decision in writing, with reasons, setting out whether the board approves the plan, and whether the approval is subject to any conditions, which must be specified in the decision. 2004, c. 3, Sched. A, s.44(4).

Agreement respecting disclosure

(5) Before a health information custodian discloses health information to a researcher under subsection (1), the researcher shall enter into an agreement with the custodian in which the researcher agrees to comply with the conditions and restrictions, if any, that the custodian imposes relating to the use, security, disclosure, return or disposal of the information. 2004, c. 3, Sched. A, s.44(5).

Compliance by researcher

(6) A researcher who receives personal health information about an individual from a health information custodian under subsection (1) shall:

(a) comply with the conditions, if any, specified by the research ethics board in respect of the research plan;

(b) use the information only for the purposes set out in the research plan as approved by the research ethics board;

(c) not publish the information in a form that could reasonably enable a person to ascertain the identity of the individual;

(d) despite subsection 49(1), not disclose the information except as required by law and subject to the exceptions and additional requirements, if any, that are prescribed;

(e) not make contact, or attempt to make contact with the individual, directly or indirectly, unless the custodian first obtains consent to being contacted;

(f) notify the custodian immediately in writing if the researcher becomes aware of any breach of this subsection or the agreement described in subsection (5); and

(g) comply with the agreement described in subsection (5). 2004, c.3, Sched.A,s.44(6)

Mixed disclosures

(7) If a researcher submits a research plan under subsection (1) that proposes that a health information custodian that is an institution within the meaning of the Freedom of Information and Protection Privacy Act or the Municipal Freedom of Information and Protection of Privacy Act, or is acting as part of such an institution, disclose to the researcher personal health information, together with personal information within the meaning of those two Acts that is not personal health information, those two Acts do not apply to the disclosure and this section applies to the disclosure. 2004, c. 3, Sched. A, 44(7).

Transition

(8) Despite subsection (7), nothing in this section prevents a health information custodian that is an institution within the meaning of the Freedom of Information and Protection of Privacy Act or the Municipal Freedom of Information and Protection of Privacy Act or is acting as part of an institution from disclosing to a researcher personal health information, that is personal health information within the meaning of those two Acts, if, before the day this section comes into force the researcher has entered into an agreement that requires the custodian to comply etc.

Disclosure under other Acts

(9) Despite any other Act that permits a health information custodian to disclose personal health information to a researcher for the purpose of conducting research, this section applies to the disclosure as if it were a disclosure of research under this section unless the regulations made under this Act provide otherwise. 2004, c. 3, Sched. A, s.44(9).

Research approved outside Ontario

(10) Subject to subsection (11), a health information custodian may disclose personal health information to a researcher or may use the information to conduct research if,

- (a) the research involves the use of personal health information originating wholly or in part outside Ontario;
- (b) the research has received the prescribed approval from a body outside Ontario that has the function of approving research; and,
- (c) the prescribed requirements are met. 2004, C. 3, Sched. A, s.44(10).

Same

(11) Subsections (1) to (4) and clauses (6) (a) and (b) do not apply to a disclosure or use made under subsection (10) and references in the rest of this section to subsection (1) shall be read as references to this subsection with respect to that disclosure or use. 2004, c. 3, Sched. A, 44 (12).

Transition

(12) Despite anything in this section, a health information custodian that lawfully disclosed personal health information to a researcher for the purpose of conducting research in the three year period before the day this section comes into force may continue to disclose personal health information to the researcher for the purposes of that research for a period of three years after the day this section comes into force. 2004, c. 3, Sched. A, s.44(12).

PHIPA - section 16, 12 items of information required:

- (1) A description of the research proposed to be conducted and the duration of the research.
- (2) A description of the personal health information required and the potential sources.
- (3) A description of how the personal health information will be used in the research, and if it will be linked to other information, a description of the other information as well as how the linkage will be done.
- (4) An explanation as to why the research cannot reasonably be accomplished without the personal health information and, if it is to be linked to other information, an explanation as to why this linkage is required.
- (5) An explanation as to why consent to the disclosure of the personal health information is not being sought from the individuals to whom the information relates.
- (6) A description of the reasonably foreseeable harms and benefits that may arise from the use of the personal health information and how the researcher intends to address those harms.
- (7) A description of all persons who will have access to the information, why access is necessary, their roles in relation to the research, and their related qualifications.
- (8) The safeguards that the researcher will impose to protect the confidentiality and security of the personal health information, including an estimate of how long information will be retained in an identifiable form and why.
- (9) Information as to how and when the personal health information will be disposed of or returned to the health information custodian.
- (10) The funding source of the research.
- (11) Whether the researcher has applied for the approval of another research ethics board and, if so, the response or status of the application.
- (12) Whether the researcher's interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher.

Appendix B

Canadian Freedom of Information Links

British Columbia

PERSONAL INFORMATION PROTECTION ACT
<http://www.qp.gov.bc.ca/statreg/stat/p/03063%5F01.htm#section21>

Alberta

FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY REGULATION
<http://www.canlii.org/ab/laws/regu/1995r.200/20060310/whole.html>

Saskatchewan

HEALTH INFORMATION PROTECTION
<http://www.canlii.org/sk/laws/sta/h-0.021/20060310/whole.html>

Manitoba

PERSONAL HEALTH INFORMATION ACT
<http://www.canlii.org/mb/laws/sta/p-33.5/20060310/whole.html>

Ontario

PERSONAL HEALTH INFORMATION PROTECTION ACT
<http://www.canlii.org/on/laws/sta/2004c.3sch.a/20060314/whole.html>

Quebec

AN ACT RESPECTING THE PROTECTION OF PERSONAL INFORMATION IN THE PRIVATE SECTOR
<http://www.canlii.org/qc/laws/sta/p-39.1/20060310/whole.html>

New Brunswick

PROTECTION OF PERSONAL INFORMATION ACT
<http://www.canlii.org/nb/laws/sta/p-19.1/20060310/whole.html>

Nova Scotia

FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY REGULATIONS
<http://www.canlii.org/ns/laws/regu/1994r.105/20060310/whole.html>

Prince Edward Island

FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY ACT
<http://www.canlii.org/pe/laws/sta/f-15.01/20060310/whole.html>

Newfoundland and Labrador

ACCESS TO INFORMATION AND PROTECTION OF PRIVACY ACT
<http://www.canlii.org/nl/laws/sta/a-1.1/20051121/whole.html>

Yukon Territory

ACCESS TO INFORMATION AND PROTECTION OF PRIVACY ACT
<http://www.canlii.org/yk/laws/sta/1/20041124/whole.html>

Northwest Territories

ACCESS TO INFORMATION AND PROTECTION OF PRIVACY ACT
<http://www.canlii.org/nt/laws/sta/1994c.20/20060310/whole.html>

Nunavut

ACCESS TO INFORMATION AND PROTECTION OF PRIVACY ACT
<http://www.canlii.org/nu/sta/cons/index.html>

Appendix C

Example of Access to Health Records for Research Request Form

Access to Health Records for Research, Education and Quality Assurance Request Form
Health Record Services

A. Contact Information	
Date of Request: (dd/mm/yyyy) _____	Date Required: (dd/mm/yyyy) _____
*Organization: <input type="checkbox"/> SJHC <input type="checkbox"/> LHSC	
*Name: _____	Title: _____ Ext: _____ Dept: _____ Site: _____
*Purpose for Request:	
Research <input type="checkbox"/> Quality Assurance <input type="checkbox"/> Education -> If Student, ID# _____	Name of supervisor: _____
*Title/Topic of Research Project/Quality Assurance: _____	
*How will the patient information accessed be used? _____	
B. Hard-copy Health Records Retrieval/Selection Criteria – (All applicants must complete this section)	
* Type of health records information required: <input type="checkbox"/> Paper Chart <input type="checkbox"/> Other _____	
* A chart pull list is attached or will be submitted electronically at a later date.	
A database search or list of patients (i.e., PINs) that meet the following criteria is required:	
Diagnosis/procedure - please specify _____	
Date range: From (dd/mm/yyyy) _____ to (dd/mm/yyyy) _____	
Specify any other selection criteria: _____	
List details if more than PIN required: _____	
C. Research Requests (only)	
*Is there approval from UWO REB? <input type="checkbox"/> Yes <input type="checkbox"/> No * LHRI Research R # _____	
*Principal Investigator or Hospital Sponsor contact info:	
Name: _____	Title: _____ Program/Site: _____
Phone #/Ext: _____	Organization: <input type="checkbox"/> SJHC <input type="checkbox"/> LHSC
*List research team members/title accessing health records as part of this request: _____	
*Type of study: Peer review <input type="checkbox"/> Industry-sponsored research <input type="checkbox"/> Other specify _____	
*Study duration - Start date (dd/mm/yyyy): _____	End date (dd/mm/yyyy): _____
Account #/Cost Centre (if available): _____	*Invoice sent to: _____
D. Expectations and Responsibilities of Requesters (All applicants)	
I have reviewed all related hospital corporate policies and understand and agree to the following:	
1. No changes will be made to the health records and no documents will be removed from the health records.	
2. Patient information will be collected in an unidentified format.	
3. Any data taken from health records will be kept in a secure manner and individual identifiers will be destroyed at the earliest time consistent with the hospital's Waste Management Policy or the REB approved research plan.	
4. Any data reported will protect individual privacy so that no individual can be identified.	
5. Data are used only for the purpose specified in this request or UWO REB approved research plan.	
6. No attempt will be made to contact the individuals to whom the data relates unless indicated otherwise in the REB approved research plan.	
7. Researchers will accept full responsibility for any related charges levied by Health Record Services.	
8. All applicants and their delegates will complete the Corporate Privacy and Confidentiality Education prior to accessing any information as part of this request.	
I understand that all health records information that I, or those acting on my behalf, have access to, is confidential and it will be managed in a way that is in keeping with hospital policies on privacy, confidentiality, data security, and release of information.	
*Requester's Signature: _____	*Date: _____
Approved by: _____	Print Name: _____ Date: _____

* Required Fields

HOW TO COMPLETE THIS FORM

Note: If you require additional space, continue on a separate sheet of paper.

1. Individuals requesting access to hardcopy health records for the purpose of education or quality assurance must complete and sign this form. Researchers or their delegate may complete this form for research requests.
2. Sections A, B, & C must be completed by all applicants. All sections must be completed for research requests.
Ensure you provide information for all required fields flagged with an asterisk (*) for those sections that apply.
3. To complete **Section A. Contact Information:**
Fill in your contact information, the reason for your request and describe briefly how the personal health information accessed will be used.
4. To complete **Section B. Hard-copy Health Records Retrieval:**
 - Indicate the medium of the health record you wish to access e.g., chart, EPR or other e.g., sound recording, diagnostic image, etc.
 - Chart pull lists are required for all requests except those that involve accessing the EPR. A chart pull list is a listing of PIN for the health records you are wishing to access as part of the request (see Appendix A of the corporate policy – Access to Health Records for Research, Education and Quality Assurance Request Form).
 - If you require a database search to determine the PIN required for your request, indicate that a chart pull list 'will be submitted electronically at a later date' (by checking the appropriate box) and provide the criteria required for the database search.
 - Indicate how you wish to obtain the results of the search (i.e., email or pick-up).
5. To complete **Section C. Research Requests:**
 - The term hospital sponsor refers to the Administer Leader, or the LHSC/SJHC physician, dentist or midwife with active privileges at the organization, who accepts responsibility for a research project on behalf of a non LHSC/SJHC Principal Investigator.
 - Provide the names and titles of all individuals who will be accessing the health records as part of this request.
6. Submit the signed form to Health Record Services or send the form to Health Records – Attention: Research.