

# A Voluntary Privacy Standard for Health Services and Policy Research: Legal, Ethical and Social Policy Issues in the Canadian Context

*Karen M. Weisbaum, Pamela M. Slaughter  
& Paulette K. Collins*

In this review, the authors describe how one group of Canadian researchers has begun to address current privacy protection challenges with the end goal of developing a Canadian national standard for privacy protection specific to health services and policy research (HSPR.) They provide a concise description of some of the key messages and issues that resulted from a recent series of HSPR workshops and describe some of the workshop outcomes in terms of their legal, ethical and social/policy significance. The review ends with a brief description of some future directions for research and development in this area.

## **Introduction**

Privacy of personal information is a current hot topic across Canada and nowhere does that heat radiate more than in debates about privacy of personal health information, particularly in the area of health research.

In Canada, there are many different kinds of “health research.” The Canadian Institutes of Health Research (CIHR) generally classifies research according to four “pillars”: 1) basic biomedical; 2) applied clinical research; 3) health services research; and 4) population health.<sup>1</sup> Each category can be distinguished from the others in a variety of ways, including the manners in which data are collected,

pooled (or aggregated) and analyzed. While each category of research may involve collection and use of health information, the information is not necessarily of the same scope or depth, or used in the same way for the same research purpose.

For example, clinical trials overlap with clinical care. Data collection in clinical trials involves direct contact between research subjects and members of the research team, so individuals are always known to at least one researcher.<sup>2</sup> Researchers need to know that particular data are about a particular individual. Personal identity is likely not revealed widely within the research team, nor is it necessary for the researcher to know subjects’ direct identities, as unique study numbers are usually assigned to data from an individual. Nevertheless, the nature of the research is such that the data are either highly identifiable, or there is at least a significant potential for identification of individual research subjects if appropriate safeguards are not observed.

In stark contrast, HSPR uses health information that is external to the circle of care. It consists mainly of personal health information collected into large databases that are used primarily for administrative purposes, such as physician service claims or provincial drug benefit reimbursement. These large databases are also used for the secondary purpose of scholarly research focused on the health of entire popula-



tions,<sup>3</sup> rather than unique individuals. Use of these data for particular studies does not include personal identifiers, such as names and addresses. The data often include the elements of age-in-years and sex, as well as demographic information. The data are never used to make a decision that directly affects a specific individual.

It makes sense, therefore, that different kinds of health research reflect significantly different kinds of privacy issues. There is a corresponding need for different and appropriate privacy protection standards that are tailored to the nature of each category of health research and the personal health information that is used for that research.

Such a need is especially acute in the case of HSPR researchers who find themselves bound by guidelines that flow largely from models developed for clinical trials.<sup>4</sup> Many HSPR researchers already argue that this is inappropriate and adds an extra burden in conducting legitimate and valuable research. In addition, there is currently a patchwork of statutory and regulatory standards across Canada for privacy protection of personal health information, which create extra challenges for HSPR data collection activities that extend beyond provincial borders. As a result of all these factors, HSPR researchers have been left without clarity about what constitutes appropriate or adequate standards for privacy protection in HSPR protocols and programs of research.<sup>5</sup>

Despite this lack of clarity, the HSPR community has made efforts to delineate its own appropriate standards. At a recent national HSPR privacy workshop, a group of Canadian HSPR researchers addressed many current privacy challenges with the goal of developing a national privacy standard specific to HSPR. This paper brings together some of the key messages that resulted from the workshop, providing a concise description of some of the legal, ethical and social issues in HSPR that emerged from the workshop discussions and that suggest areas for future research about privacy of personal health information in HSPR.

## **The Workshops**

In light of the privacy-related challenges currently faced by the HSPR community and described above, the Institute for Clinical Evaluative Sciences (ICES) in Ontario and the Manitoba Centre for Health Policy (MCHP) received a grant from CIHR. The grant was made for the purpose of organizing a two-part workshop, held in October 2003 and February

2004. Participants from across Canada included HSPR researchers, as well as individuals from the provincial privacy commissions and ombudsman offices, administrative data providers, stewards and trustees, data custodians, medical record managers and members of the health law community. The goal of the total three and a half days of the workshops was to discuss and initiate development of an appropriate and harmonized draft privacy standard for Canadian HSPR. The standard would be “appropriate” in that it would reflect the nature of HSPR and associated data collection processes. It would be “harmonized” in that it would allow for differences in provincial and territorial privacy statutes and guidelines.

In this collaborative endeavour, participating experts shared privacy policies, procedures and codes, templates for staff confidentiality agreements and collaborative research agreements, held roundtable discussions of key privacy issues and incorporated the perspectives of two international experts. The workshops resulted in a report entitled *Harmonizing Research and Privacy: Standards for a Collaborative Future*.<sup>6</sup> The Report contains a summary of the workshop discussions and recommendations for continuing to develop a national HSPR privacy standard. While participants did not always agree, there were many issues on which they reached a significant degree of consensus. From this emerged a number of legal, ethical and social/policy points, some of which are described below.

## **Legal Relevance of a Harmonized Standard and Related Issues**

The HSPR community is understandably concerned about legal liability that may flow from a privacy breach. For example, in a claim for negligence, to what standard might an HSPR researcher or institution be held? Where there is an apparent infringement of a statutory standard, how will liability be determined? Statutory standards most often provide broad guidance. A harmonized standard may provide a measure of acceptable professional conduct by HSPR researchers and evidence of due diligence, especially where it is adopted across the HSPR research community and if there is input from statutory oversight authorities, such as provincial privacy commissioners.

A national standard for HSPR—provided that it at least meets the “floor” of legislation and regulations—provides assurance for researchers who apply it in their research activities that they are, at the very least, fulfilling statutory



obligations to maintain confidentiality and perhaps exceeding statutory standards to meet potentially higher ethical obligations and privacy best practices.

Once a harmonized standard is in place for Canadian HSPR, it may facilitate harmonization of standards with other international jurisdictions. For example, at the February 2004 portion of the workshop, ethicist Dr. Eric Meslin provided an overview of the “privacy rule”<sup>7</sup> in the climate of the U.S. *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*.<sup>8</sup> Referring to a recent paper coauthored with colleague Michael McDonald, Meslin described the “equivalent protection” provisions within the U.S. *Code of Federal Regulations*.<sup>9</sup> These equivalent protection provisions hold potential for harmonization of research standards across international borders: the provisions might provide a mechanism for U.S. authorities to recognize Canadian privacy protection standards that are different—in substance or process—but result in substantially equivalent privacy protections.

The Canadian health system holds potential for national HSPR, assuming that data can flow across provincial and territorial boundaries. The federal *Personal Information Protection and Electronic Documents Act*<sup>10</sup> (*PIPEDA*) presents a challenge to this potential. For example, *PIPEDA* does not provide specific guidance for health research. In addition, *PIPEDA* is based on a consent model, whereas some provincial health privacy statutes are based on authorization models. This creates uncertainty among researchers: which legislation applies to HSPR activities; who will have authority to oversee HSPR activities—the provincial/territorial oversight body or the federal privacy commissioner? A voluntary standard that promotes the common occurrence of similar kinds of processes that mitigate risk to privacy—including HSPR privacy codes and privacy impact assessments—would facilitate a harmonized approach to protecting privacy in HSPR while allowing for the flexibility that is needed to accommodate differences in local legislation. The standard might also serve to inform the process of amending *PIPEDA* in 2006.

### **Ethical Relevance of a Harmonized Standard and Related Issues**

Under the *Tri-Council Policy Statement (TCPS)* research ethics boards have responsibility for balancing risk of harm to individuals with the potential benefits of research. While many research ethics board members understand the nature

of risk to privacy in clinical trials, many do not understand that the nature of risk to privacy in HSPR is significantly different. Given this, review of HSPR studies would best occur in three phases: 1) peer review (to consider methodology and clinical importance of the research); 2) research ethics board review (to consider the ethics of the proposal, including review of risk to privacy specifically in HSPR); and 3) data steward and privacy officer review (to consider whether data protection, security, linkages, management, collection, use and disclosure are appropriate for the research proposed and that they represent minimal risk.) As part of a standardized approach to HSPR, all three types of review could be accomplished using common checklists.

As illustrated by international guest speaker and epidemiologist Dr. Fiona Stanley, the public benefits of HSPR can be dramatic: it can be used to show that an accepted treatment commonly used in the general population involving tens or hundreds of thousands of individuals carries a significant risk of harm. Rather than asking what limits should be placed on access to HSPR data, Stanley posed the question of whether or not it is morally reprehensible to fail to use available data to improve the health and well being of the population. Asking this question is especially pertinent in the Canadian context, where a publicly funded, universally accessible health system permits study of the entire population and allows for research about full spectrums of disease states, minimizing concerns about generalizability and bias.

### **Social and Policy Relevance of a Harmonized Standard and Related Issues**

Where a harmonized standard has been adopted by the research community with input from appropriate oversight authorities and is accepted as the preferred level of professional conduct, that standard may become the basis of “certification”, that is, there would be confirmation that the privacy policies, procedures and practices at that research site meet the standard and that the standard would be in agreement with local legislation.

If the standard (and the associated certification process, where this is in place) is acceptable to research ethics boards, granting agencies and statutory oversight authorities, it may reduce the need for review of data security and privacy protections for each and every HSPR protocol. All HSPR activities at a site would be conducted in accordance



with the standard, providing clarity about the risk involved. Certification would guarantee that the site has formally adopted the standard. Research ethics boards would then be able to focus on evaluation of scientific validity and the societal importance and benefit of the research, assured in light of the requirements of the standard. The burden on research ethics boards would be reduced, as liability concerns would be diminished and human resources needed to assess data and privacy protections would be lessened. Granting agencies would have confidence in the data security and privacy protection processes for grant applicants who are certified when they apply for research funding. Statutory oversight authorities, including privacy commissioners, might find that requirements for transparency and accountability in legislation would be reflected in certification.

Public support for HSPR is imperative for its continued success and relevance to the goal of improving the health of Canadians. However, people do not always know about or understand the relationship between the use of health data and the benefits of HSPR activities. For example, it is not clear the public understands that, unlike clinical trials, HSPR uses the least amount of de-identified information required for research and that the data are aggregated at the highest level possible. Improved, ongoing communication and public education will encourage support and awareness, diminish concern about the potential for harm through identification of individuals and increase public trust. A voluntary standard would include an affirming research communication strategy for public dissemination of study results and would include statements that the availability and use of the data enabled the development of a particular research conclusion.<sup>11</sup>

Different HSPR environments have different historical contexts for the use of a word. This is unlikely to change, even with a harmonized standard. Rather than try to reach consensus on the best or “correct” definition of a word, there should be a mechanism for understanding the different ways in which words are used in the HSPR context. Developing a table of “equivalencies”, made available to all HSPR organizations and researchers, would facilitate effective communication within HSPR.

Statutory oversight authorities, such as privacy commissioners and ombudsman offices, may not be in a position to create a standard or develop detailed procedures by which legislation is to be followed. Some have stated, however, that they would be willing to review evolving frameworks and offer comments where they see potential weaknesses and strengths. Where these authorities work cooperatively to provide comment on the standard, while it might not contribute to harmonization of legislation, it would certainly contribute to harmonization of practices in HSPR. As well, the standard might be strengthened as a tool for interpreting legislation.

*“Nevertheless, the nature of the research is such that the data are either highly identifiable, or there is at least a significant potential for identification of individual research subjects if appropriate safeguards are not observed.”*

## **Future Directions**

The workshop discussion began the process of developing a Canadian voluntary standard for HSPR. To continue the process, next steps must include identification of a credible and representative group or body to begin the process for developing the standard. The process might start with a review of current standards and existing local practices and legislation.

As always, securing adequate funds from an appropriate source will be essential for ongoing development.

In addition, the workshop discussions suggested related issues for possible future academic enquiry. For example:

- 1) While a voluntary standard would not have the status of law, it might come to be seen as a standard of care by which statutory oversight authorities or courts could assess the conduct of HSPR researchers and institutes. Once a standard is developed, it would need to be examined relative to legislation and regulations to ensure that activities in accordance with the standard constitute statutory due diligence.
- 2) For the purpose of review of *PIPEDA* in 2006, elements of the standard need to be identified with the goal of addressing existing holes in legislation specific to HSPR, ensuring that any amendments that might result from the review would provide a good fit with the nature of HSPR activities.
- 3) Closer examination of the “equivalent protection” provisions within the U.S. *Code of Federal Regula-*



tions would determine their potential as a model for enhancing harmonization across Canadian jurisdictions, as well as for creating better rules for sharing information between Canadian and U.S. HSPR researchers. Such endeavours would most likely facilitate the development of a standard that could continue to serve the health interests of all Canadians.

---

*Karen M. Weisbaum, Queen's University, Kingston, Ontario; Pamela M. Slaughter is a Privacy Officer at the Institute for Clinical Evaluative Services, Toronto, Ontario and Paulette Collins is the Chief Administrative Officer at the Manitoba Centre for Health Policy, Faculty of Medicine, University of Manitoba.*

1. Descriptive information about CIHR and its institutes is available online: <http://www.cihr-irsc.gc.ca/e/7263.html>.
2. This direct contact is the core of the need for informed consent to participate from the research subject. Identifiability of the research subject, or at least the significant potential for identification, is also a basis of the need for informed consent to collect personal health information from subjects for clinical trials. This is particularly true when the eventual destination of the information is a commercial entity, where responsibility for the information will exist beyond the jurisdiction of any academic research board or statutory oversight authority, such as a provincial privacy commissioner.
3. For this and other related reasons, statutory authorities for privacy across Canada, including the Office of the Privacy Commissioner of Canada, have expressed support for use of personal health information for the kinds of research purposes pursued in HSPR. See Privacy Commissioner of Canada, *Annual Report to Parliament 2000-2001, Commissioner's Overview*, online: Office of the Privacy Commissioner of Canada [http://www.privcom.gc.ca/information/ar/02\\_04\\_09\\_e.asp#000](http://www.privcom.gc.ca/information/ar/02_04_09_e.asp#000).
4. For examples of current general national standards, see the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*, online: [http://www.ncehr-cnerh.org/english/code\\_2/](http://www.ncehr-cnerh.org/english/code_2/). See also CIHR-IHSR *Draft Privacy Best Practice Guidelines* (2004), online: <http://www.cihr-irsc.gc.ca/e/22085.html>
5. This does not mean the HSPR researchers have been without guidelines and processes for protecting privacy. Even in the absence of a national standard, members of the HSPR community have worked within provincial legislation. Where no provincial legislation exists, they have (in the past) effectively fended for themselves by developing their own local standards for data security and privacy protections.
6. Pamela M. Slaughter *et al.*, *Harmonizing Research and Privacy: Standards for a Collaborative Future*, Final Workshop Summary, 17 May 2004, online: [http://www.umanitoba.ca/centres/mchp/reports/pdfs/Harmonizing\\_Research\\_Final.pdf](http://www.umanitoba.ca/centres/mchp/reports/pdfs/Harmonizing_Research_Final.pdf); <http://www.ices.on.ca/file/Harmonizing%20Research%20Final%5B1%5D%2Epdf>.
7. 45 C.F.R. Pt. 160 and Subparts A and E of Pt. 164 (2002); see <http://www.hhs.gov/ocr/hipaa>.
8. Pub L.No.104-191, 110 Stat.1936 (1996).
9. 45 C.F.R 46.101(h).
10. *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c 5.
11. One graphic example is a study reporting the root cause of overcrowding in emergency rooms was the lack of utilization of available flu vaccinations, which in turn increased the volume in emergency department visits by individuals with the flu. This led to fall influenza vaccination campaigns and corresponding decreased numbers in emergency rooms. See Alison Maclean, "Influenza's Influence: Is An Early Warning System Possible?" (1999), online: [http://www.umanitoba.ca/centres/mchp/reports/reports\\_01/flu.htm](http://www.umanitoba.ca/centres/mchp/reports/reports_01/flu.htm), based on the report by Verena H. Menec *et al.*, *Seasonal Patterns of Winnipeg Hospital Use* (1999), online: <http://www.umanitoba.ca/centres/mchp/reports/pdfs/seasonal.pdf>.

