Document 1: Introduction to the CD -

Privacy Best Practices for Secondary Data Use (SDU)

This CD contains the complete set of numbered documents for Privacy Best Practices for Secondary Data Use (SDU), which are the deliverables of the three CIHR-funded Harmonizing Research and Privacy Workshops.

At the outset of the project in late 2002 to build what became the Privacy Best Practices for SDU, the core research team (listed at the end of this document) sought to pull together a consensual “standard” of privacy protection. By the completion of the third workshop in January 2006, it was apparent that what we were actually doing was creating and sharing practical and acceptable methods for creating privacy best practices for secondary data use. For some workshop participants, the use of the term “standard” implied fixed criteria (i.e., ISO standards) that are not achievable, given the variability in provincial privacy legislation. For that reason, and acting on feedback from the three workshops involving experts in the field and from reviewers across Canada, the decision was made to adopt a more pragmatic approach; specifically, to pursue agreement on a set of privacy best practices to guide secondary data use research.

It also became apparent after reviewing the workshop transcripts, notes and reviewers’ comments, that the Tools evolving from the workshop series are:

- geared towards secondary data use organizations but include the “how to’s” for researchers interested in accessing the data that these organizations house; and,
- that any privacy best practices for secondary data use must have sufficient flexibility to be tailored to reflect/represent individual provincial legislative requirements as well as specific histories and research cultures in which the work is done.

The Tools developed through the workshops will aid organizations and researchers in defining performance expectations, structures and processes that must be in place to produce an achievable level of performance against which actual research performance can be measured.

The Tools fall into two categories:

1. Privacy Best Practices for Secondary Data Use (SDU) (including the Privacy for SDU Toolkit, Templates and Checklist)

2. Reference Materials (the encyclopedia, the translation document and the dictionary of the project)
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The Tools are organized so that the reader can go between the Privacy Best Practices for SDU and the Reference Materials to affirm that the legislative requirements are covered for their provincial jurisdiction.

The Reference Materials include Document 10: the Encyclopedia - legal scan (Statute-by-Statute Analysis), Document 9: the Translation Document (Rules in a Box), and Document 8: the Dictionary (Table of Definitions and Equivalencies). Among other functions, these documents are the foundation from which the Privacy Best Practices for SDU have been developed and provide a cross-reference to the analysis of provincial/territorial legislation. These documents allow organizations and researchers to validate and build on the Privacy Best Practices for SDU.

Document 3: The Privacy Best Practices for SDU were extracted from the Translation Document (The “Rules in a Box”) (which was derived from the Encyclopedia – Statute by Statute Analysis).

The contents of Document 4: the Privacy Toolkit and Documents 5 & 6: Templates “give life” to the requirements in the Privacy Best Practices for SDU, and provide scope for individual organizations or researchers to tailor the templates to their local jurisdictional needs. Workshop participants shared copies of their own privacy documents – administrative, technical and security privacy policies, procedures and processes – for inclusion in the workshop toolkit (in and of itself a ‘harmonizing’ activity). Privacy and data security requirements vary, depending on statutory obligations, jurisdiction and local research culture. The conditions under which the Tools were piloted accommodated these different needs.

Document 7: the Checklist is a tool which can be used to document institution/researcher-specific Privacy Best Practices for SDU and help create the inventory of privacy practices, policies and procedures. Documentation is not only an important component in 'due diligence', but is also a communication tool which promotes openness, transparency and understanding.

Similarities – and Differences
The Privacy Best Practices for SDU is complementary to the CIHR Best Practices for Protecting Privacy in Health Research, September 2005 - building on the ten elements or principles of the CIHR document to allow for comparability and inclusion. The Privacy Best Practices for SDU shows how to apply these principles to the use of secondary data without consent for research purposes.

The CIHR Best Practices document is geared to researchers and is applicable to all types of research. This core document is largely based on ethical policies and practices found in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The principles—or ‘guiding rules for best actions’ articulated in the Ten Elements of the CIHR Best Practices document — are the baseline for the Privacy Best Practices for SDU. Through the lengthy CIHR consultation process, these Elements themselves have
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been subject to rigorous national review, thereby ensuring a degree of “quality assurance”.

The Privacy Best Practices for SDU was based on multiple review processes – starting with the work at the Toronto Workshops (I & II) held in 2004 and 2005, and continued in the Winnipeg January 2006 workshop (III). This review process included feedback from provincial Privacy Commissioners and Ombudsmen, other members of the research team, voluntary reviewers of different disciplines from among the workshop participants; and from the pilot project of these tools conducted between July-October 2006 (see Appendix 10 in the Final Report for a list of pilot sites).

The significant difference between the CIHR Best Practices document and the Privacy Best Practices for SDU is that the requirements articulated in the Privacy Best Practices for SDU are grounded in provincial privacy legislation – not ethical policies and practices. The Privacy Best Practices for SDU provide an outline of what an organization should do or be doing to manage secondary data use without consent for research purposes.

SUMMARY OF WORKSHOP TOOLS

**Privacy Best Practices for Secondary Data Use (SDU)**
This document provides the foundation for ensuring respectful use of secondary data. It lays out, in plain language on the left-hand side of the page, a distillation of legislative requirements across Canada’s provinces and territories to protect the privacy of individuals whose health information is used for SDU research. The right-hand column contains titles of templates for policies, practices and procedures contained in the Privacy Toolkit. This document is founded on the Reference materials below – the Translation document Rules in a Box which originates from the Encyclopedia - Statutes-by-Statutes Analysis.

**Privacy Toolkit for SDU (secured and non-secured environments)**
The Toolkit and companion Templates provide users with a range of appropriate options - methods for actions that will meet the legislative requirements. These documents are offered as templates, by active researchers, for your use. You are invited to borrow liberally from these, or use them as a platform to develop your own policies, practices and procedures. Organizations and researchers are encouraged to create and tailor a practical application of the Privacy Best Practices for SDU that is appropriate to their local research culture and legislative requirements. You are asked to acknowledge the originating organization in any document created from or if using a template.

**Checklist for Privacy Best Practices for SDU**
The Checklist provides another tool for SDU organizations/researchers to use to create and record an inventory of SDU privacy best practices, by prompting the formalization in written form of all necessary policies and procedures. For those who want to apply the Best Practices for SDU, it's a method to record/monitor/facilitate the application and use of the Best Practices and can help construct the 'big picture' for your organization or project.
REFERENCE MATERIALS (The Building Blocks)

Encyclopedia - Statute-by-Statute Analysis of Privacy Legislation Relevant to Secondary Data Use Organizations by Jurisdiction - an analysis
This document contains an analysis of the relevant provisions of each key statute by province/territory and provides a readable interpretation of legislation and regulations specific to SDU. Each analysis follows the same categories (Elements) as the CIHR Best Practices for Protecting Privacy in Health Research, allowing for comparison with the CIHR document.

PI (Personal Information) and PHI (Personal Health Information) are acronyms used throughout the analysis. Not all statutes use the same terms or discriminate between personal information and personal health information. The language used reflects that found in the statutes.

The Translation - The Rules in a Box
This document contains the same material as in the statute-by-statute analysis, but it is organized according to the categories/elements in the CIHR Best Practices for Protecting Privacy in Health Research document. Analysis of the relevant statutory provisions for each province/territory are in the left-hand column, while the right-hand column provides non-legal language points – translating and distilling the analysis into concise policy requirements. These policy requirements form the basis of Privacy Best Practices for SDU.

The Dictionary - Table of Definitions and Equivalent Terms
This document contains the ten frequently-used concepts that have been identified and the corresponding terms/definitions from each jurisdiction. This provides readers with a basis for finding and comparing terms across statutes and helps demonstrate the comparability and similarity of obligations (rather than dissimilarities) across jurisdictions.

Benefits of using the Tools
Adherence to the Privacy Best Practices for SDU anchored in this context can provide multiple benefits:

• Organizations and researchers using the Privacy Best Practices for SDU – with the template provisions for data security and privacy protections, including balancing of risk and benefit, transparency of purpose, use, retention and accountability, both in local jurisdictions and in collaborative provincial and national frameworks—would be assured that they are meeting the legislative requirements that exist.

• These SDU best practices provide a strong foundation for ensuring respectful use of administrative data for research purposes, a goal that is important to researchers and the public.

• The set of best practices provide an authoritative source that has rigorously reviewed privacy in SDU against the background of PIPEDA’s Ten Guiding Principles and would be useful in any sort of court challenge regarding SDU; and would inform the amending process of PIPEDA, and proactively position SDU needs.
• The templates in the Toolkit are currently in use by organizations and researchers engaged in this type of research; thus reduces the need to “start from scratch” and reduces costs (in and of itself a harmonizing activity). Given concerns of researchers that privacy expertise is a scarce resource in Canada (and costly to organizations and researchers already working with tight budgets), this is a practical approach that has already worked for several of the organizations who undertook this project.
• Provides an accountability standard for the public whose data are used for these research purposes.
• Provides a tool for due diligence; demonstrates familiarity with legislative requirements.
• Facilitates review and audit by privacy oversight bodies (generally Privacy Commissioners and Ombudsmen but can be others). The Privacy Best Practices for SDU are acceptable to many provincial Privacy Commissioners, data stewards, and Research Ethics Boards (REBs). Potentially, organizations and their researchers could also potentially be “pre-certified” for submissions to granting agency competitions for funding.
• Provides a checklist for REBs to assess that adequate safeguards are in place to protect the privacy of the individual, and provides REB accountability parameters for the public for its decisions.
• Can provide an arbitration mechanism when research and privacy are at odds.

**Some additional benefits of using the Checklist:**
• brings together in a single source all of an organizations’ policies and procedures for privacy, confidentiality and security
• provides education about privacy, confidentiality and security, as the process can require consultation with many (or even all) individuals within an organization — particularly if everyone has an opportunity to review the completed Checklist
• the completed Checklist can be used to promote communication, openness and transparency, and document due diligence

This document is not:
• A legal opinion. If you have a legal dilemma, a specific legal issue or question, then you need a legal opinion and giving you that will involve looking not only at obviously relevant legislation but perhaps not so obviously relevant legislation as well as case law, as well as I this particular area findings or reports of Privacy Commissioners and Ombudsmen and so on.
• A compliance tool. In Manitoba, a privacy compliance tool check list that one can go through to ensure meeting the minimal requirements of Manitoba legislation has been drafted; we have drawn on that model for the SDU Checklist.
• A substitute for the statutes.
• A static document. It needs to be updated as legislation and regulations change.
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A summary of recommendations can be found in Document 11: Final Report.

We look forward to your comments on the Privacy Best Practices for SDU and the supporting Tools. If you have any questions about the materials, kindly contact either Pam Slaughter (pam@ices.on.ca) or Paulette Collins (paulette_collins@cpe.umanitoba.ca).

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