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Data Stewardship in Electronic Medical Records and the Policy Challenges for Research Programs: A Canadian Perspective

Dong, Allen

UNIVERSITY OF CALGARY

Data Stewardship in Electronic Medical Records and the Policy Challenges for Research Programs: A Canadian Perspective

by

Allen Richard Dong

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Abstract

Research access to personal health information presents a challenge to policy makers and researchers alike. It is usually framed as a conflict between data access for the benefit of society and the protection of privacy. This thesis examines the policy challenge by studying the data access policies of several organizations that are affiliated with academic institutions and provide research access to personal health information. By applying a policy ethics framework that combines the Veatch matrix and the Accountability for Reasonableness conditions of Daniels and Sabin the data access policies reveal an ethically justifiable resolution of the policy challenge. A case study conducted on one of the organizations yields a policy model that interviewees report, worked well in practice in the years 1996 to 2002. The policy options that emerged from the model could be adapted for use in any jurisdiction whose legal regime is similar to that of Canada's provinces and territories.

KEYWORDS: Policy ethics, Secondary Data Use, Health Services Research, Electronic Health Records, Personal Health Information, Privacy, Population Health Research

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A literature review always benefits from the assistance of professional librarians and I was fortunate to be able to call upon Diane Lorenzetti at the Health Sciences Library and Nadine Hoffman at the Law Library. Thank you both for sharing your expertise.

My heartfelt appreciation goes to the members of Population Data BC who participated in the case study. Your comments brought policy to life and gave it a depth beyond the written word.

To my sponsor the Calgary Rural Primary Care Network: Thank you so much for seeing the potential of this work and giving me the latitude to realize it.

Finally and most importantly I wish to thank my wife Elaine and daughter Natalie for keeping me sane and providing a loving sanctuary, especially during that first year when we all had to make adjustments. My family is my rock.

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Chapter One: **INTRODUCTION**

1.1 Introduction

Whenever personal information is stored, there is an inherent tension between resultant calls for personal privacy of that information and calls for access by third parties to that information.[12] Nowhere is this better illustrated than in the context of electronic databases such as those that routinely capture administrative personal health information. Libertarians urge non-disclosure without individual consent as a matter of personal control and autonomy whereas health policy advocates urge data liberation as a matter in the public interest. In many ways the debate and tension parallels that around the abandonment of Canada's mandatory long form census.[3] Some see the collection of the long form census information as an invasion of privacy; others see it as core to needs assessment and good planning. The present thesis examines the requirements of ethical policy making for the governance of electronic medical records as a database repository that collectively constitutes a rich source of information amenable to data-mining and analysis for health research purposes.

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[1] Sara Rosenbaum, "Data governance and stewardship: designing data stewardship entities and advancing data access," *Health Services Research* 45, no. 5 pt 2 (2010), p.1443.

[2] The reader is alerted to the fact that the citation system used throughout this thesis is the Chicago Manual of Style for humanities. Reasons for this choice are that the preliminary literature search revealed a paucity of standard MeSH (Medical Subject Heading) terms relevant to secondary use of electronic health records and hence the first literature search was insufficient. As a result this research defaulted to ancillary literature sources better suited to the use of Chicago Manual of Style for humanities.

[3] *Order in Council regarding Statistics Canada*, P.C. 2010-1077, 12 August, 2010, *Canada Gazette,* Part I, vol 144*,* no. 34.

1.2 Context

1.2.1 Privacy and Confidentiality

As a starting place it is important to recognize the distinctions between privacy and confidentiality. The terms are often confounded thus leading to misunderstandings of the scope of problems and best ways to approach solutions. Privacy in this thesis is understood to be the relationship an individual has to his or her own personal information before any disclosure to anyone else. In this way it involves only one party.

Confidentiality by contrast is the relationship to that personal information following its disclosure to an outsider. Thus confidentiality essentially involves at least two people, the original owner and the party to whom the information is disclosed; furthermore confidentiality is the imposition and acceptance of restrictions on further disclosure by the recipient of that personal information. Those restrictions may impose security requirements on databases holding confidential information. These security requirements may be operationalized through technological means and/or through standard operation policies that prescribe standards for disclosure and access.

Another characteristic of confidentiality is that it creates a privileged status towards the personal information that one would not otherwise have; in turn this privileged status creates a *prima facie* duty to protect against further disclosure or access by others. This is evident in the etymology of the word "confidentiality" deriving as it does from *fido* meaning "to trust."

1.2.2 Conflicts and tension between Data Liberation and Privacy

Modern information management technology such as Internet products Facebook and Twitter has expanded the societal norm of free data exchange but has also inflamed

the longstanding conflict with protection of information privacy. For example, while it is widely known that Facebook's privacy policy has evolved to allow users greater control over what other users can see, Facebook retains all information added to a profile even if it is subsequently deleted, and more troublesome than that, "Facebook has uncontrolled access to everybody's data, regardless of the so-called privacy settings".[4] Yet this form of information sharing appears to be normative on the Internet. In health care the management of the conflict between data disclosure for research and protection of privacy has been an ongoing struggle exacerbated by the widespread adoption of electronic medical records.

Policy makers and population and public health researchers are not the only parties that recognize the value of electronic databases. In addition to researchers and indeed the patients themselves there are for example third parties including the public media, health-condition lobby groups, and kinship groups stand to benefit from being able to access the information housed in databases. All of these aspects may be described as secondary use or forms of data liberation that can be enabled or thwarted by data stewardship policy. Closer examination identifies different kinds of secondary use such as: Administrative Purposes; Research Purposes; Program Evaluation, Quality Assurance; Kinship and family histories; Other Purposes.

1.3 Rationale – Why this study now?

At the time of writing I worked with two Primary Care Networks in Alberta. It is through my work at these two organizations that I recognized the research potential of

[4] "Facebook & your privacy", *Consumer Reports 77*, no. 6 (June 2012), 24-31.

electronic health records that were held by data stewards of varying size. For example stewards such as Alberta Health Services and the Health Quality Council of Alberta are responsible for the health information of millions of people while primary care physicians keep health records for clinic patients in the order of several hundreds. Researchers who need to do secondary data collection from the electronic medical databases of primary care physicians would encounter an onerous task due to the lack of both government policy and research-based infrastructure.

When I did an initial scan of operating data stewardship frameworks in Canada I looked for mentions of research in statutes governing health information. The results revealed a lack of support for researchers and little evidence of an effort to put research at the forefront of health information governance. This dearth has presented an opportunity to probe data access policy for those who seek personal health information for research purposes.

Taking the provision of good clinical care as a given matrix, a primary objective of electronic record-keeping in health care is to ensure good custodial administrative practice and sound data stewardship.[5] Another objective is to provide a population-based image of access and use of health services in any given region or institution. Electronic databases thus have become rich sources of data for research as well as convenient virtual forms of the traditional charts. Parallel to this growth there has been emergence of stringent privacy law with varying provisions across Canada. In Alberta for example the

[5] I am not making a distinction between custodian and steward. The legislation across the country and policy documents refers to both custodians and stewards indifferently. Therefore these terms will be used interchangeably.

Health Information Act (hereinafter referred to as "HIA") creates the legal concepts of personal health information (PHI), electronic health record (EHR), and custodians and provides a set of rules (not just policy or guidelines) governing the collection, use and disclosure of PHI gathered in a therapeutic setting.[6] Key terms from the HIA that are central to this thesis set out verbatim in Appendix A. Under the HIA rules consent is the default setting for all use and disclosure other than for immediate therapeutic purposes.[7] However, the addition of part 5.1 to the HIA addressing as it does electronic health records is so recent that its interpretation remains largely undetermined and is as yet untested in the courts.[8] It is the interplay of the various provisions that informs much of the substance of the thesis. So the starting place will be to consider the Alberta legislation, with a view to correlating later with legislation elsewhere.

1.4 Policy ethics versus Research ethics

Those who are familiar with the research process that involves human subjects will have encountered the term "ethics". Its application in this research area very often is associated with the work of research ethics boards, research ethics committees and institutional review boards. To a lesser extent the principles of bioethics as articulated in the Belmont Report are also associated with medical research (see section 3.3.7).[9] In

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[6] *Health Information Act*, R.S.A. 2000, c. H-5, as amended 2010 Nov 1, part 1 sections 1, 2, 3 and part 5.1 *passim*.
[7] *Health Information Act*, section 2
[8] *Health Information Act* part 5.1 was brought into effect in November 2010.
[9] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington DC: DHEW Publication OS 78-0012, 1978), accessed at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

Canada the oversight of research with human subjects is conducted by research ethics boards and guided by a document called the Tri-Council Policy Statement.[10]

Ethics as it relates to policy is suggested by the following general definition: "Ethics is the theoretical reflection on the nature of the good and on what we ought to do."[11,12] Therefore this thesis is concerned with policy that ought to be created for researchers who wish to use Canadian personal health information in their studies. Manifestations of ethical policy include the aforementioned research ethics boards and the Tri-Council Policy Statement. Personal health information occupies a small area in the scope of these two policy manifestations but the policy options within it deserve scrutiny and, as will be shown in this thesis, suggestions for improvement.

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[10] 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* (Ottawa: Interagency Secretariat on Research Ethics, 2010), Chapter 5.
[11] Carlo Petrini, "Ethics-based Public Health Policy?" *American Journal of Public Health* 100, no. 2, 2010, 197.
[12] Roger Crisp, "Ethics," in *The Shorter Routledge Encyclopedia of Philosophy*, ed. Edward Craig (New York, NY: Routledge, 2005), 242–245.

Chapter Two: **LITERATURE REVIEW**

2.1 Introduction

2.1.1 Approach to Literature Review

The longstanding tension and conflict between data liberation and protection of privacy play out not only in the academic literature but also more explicitly in legislation, regulations, policy, and guidelines pertaining to personal health information. The objective of the thesis is to inform ethical policy development for organizations that make personal health information available for researchers. Legal, medical and ethical considerations will play roles in the development of policy so each of these areas was explored in the literature review process.

2.1.2 Canadian Legislative Frameworks

Legislation from all Canadian jurisdictions was reviewed that had stewardship of health information as a field of competence. The online reference from the Canadian Legal Information Institute (Canlii) was used to collect this legislation.[13] Legislation and regulations were searched using the terms "health information", "privacy", "research" and "secondary use."

There are fourteen jurisdictions in Canada that have the constitutional authority to create health information legislation – One federal government, ten provincial governments, and three territorial governments. As seen in section 2.3 each of these jurisdictions has legislation in force that governs the collection, use and disclosure of personal health information.

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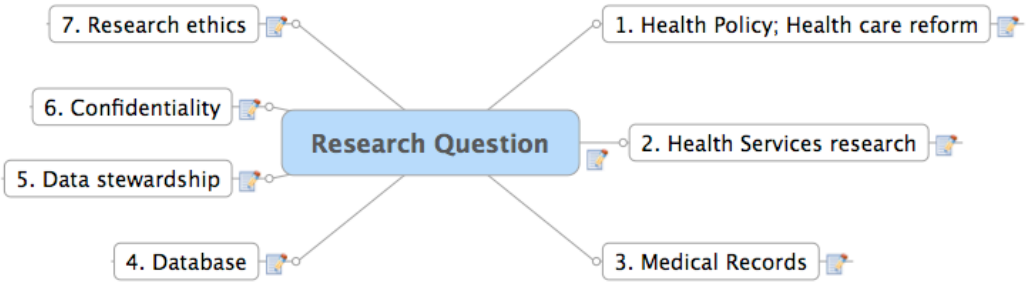
[13] http://canlii.org/en/index.html

2.1.3 Databases of Medical Literature

The OVID Medline database was used for the search of relevant articles in the medical literature.[14] This database is searchable using conventional Medical Subject Heading (MeSH) terms.[15] In consultation with a professional research librarian at the University of Calgary a search strategy using MeSH terms was constructed and deployed in conjunction with a mind map is shown in Figure 1.[16]

gure 1 – Mind Map of Terms for Literature Search



MeSH terms were attached to one of seven categories:

- Group 1, Policy
- Group 2, Research[17]
- Group 3, Electronic Medical Records
- Group 4, Databases
- Group 5, Data Stewardship
- Group 6, Confidentiality
- Group 7, Ethics

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[14] http://ovidsp.tx.ovid.com.ezproxy.lib.ucalgary.ca
[15] http://www.nlm.nih.gov/mesh/2011/mesh_browser/MBrowser.html
[16] ACKNOWLEDGEMENT: Diane Lorenzetti, Librarian University of Calgary, with assignment to the Department of Community Health Sciences.
[17] Research using health information collected for another primary purpose. That is, data collection for the research was a secondary use of the health information.

The complete list of MeSH search terms is listed in Appendix B.[18]

The search yielded 2081 articles. Based on reading of titles and abstracts, each article was scored on a scale of 1 to 5, where 1 was very irrelevant, 2 was somewhat irrelevant, 3 was not sure, 4 was somewhat relevant, and 5 was very relevant. Articles considered relevant were those that at a minimum dealt with secondary use of personal health information collected primarily for clinical purposes. Furthermore, articles that considered research as a primary purpose for collection of personal health information were considered irrelevant. Articles considered very relevant included 3 or more of the categories listed above. Articles considered somewhat relevant included at least 2 of the categories listed above.[19] 185 articles were identified as either somewhat relevant or very relevant and then examined more closely.

2.1.4 Databases of Public Policy Literature

The Canadian Public Policy Collection was used to identify publications that contained a Canadian perspective on data stewardship of personal health information. The author recognizes that the literature on secondary use of personal health information is rapidly growing; thus the literature found during the search phase of this thesis may have been augmented over the intervening period. That search was undertaken with the assistance and professional advice of health research and law librarians at the Faculty of

[18] None of the terms "secondary use" and "data stewardship" is a MeSH term so other terms had to be used as a proxy. I used the MeSH terms from the Rosenbaum article as a starting place, however given the lack of more appropriate MeSH terms the inclusion/exclusion criteria with a scoring scale of 1 to 5 was chosen as a way of reducing 2081 articles to a meaningful core.

[19] Some subjective discretion was exercised when selecting articles that bordered on being relevant.

Medicine and the Faculty of Law in the University of Calgary.[20] The material cited in this chapter reflects the state of the found literature as at June 1st 2011.

2.2 Preliminary Findings

Privacy is broadly defined in a modern western democratic society. Indeed, "privacy is a notoriously vague, ambiguous, and controversial term that embraces a confusing knot of problems, tensions, rights, and duties."[21] This thesis concerns itself exclusively with the collection, use and disclosure of personal health information. In that spirit the following definition of privacy, suggested by Westin, brings the term into sharper focus: "[p]rivacy is the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others."[22]

Much of the literature on the use of health information for research purposes did not explicitly distinguish primary collection and secondary collection of data. An example of the former is a clinical trial which will involve asking subjects for personally identifying information, ordering diagnostic tests, prescribing medication and taking clinical notes. All of these activities generate data whose primary purpose is to support the research activity of the trial. Articles that pertained to primary data collection of this sort were excluded from the literature review.

The landscape for Canadian legislative frameworks for personal health information is consistent on placing research activities under the rubric of protection of

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[20] ACKNOWLEDGEMENTS: Diane Lorenzetti, Health Sciences Library and Nadine Hoffman, Law Library, University of Calgary.
[21] Colin J. Bennett, *Regulating Privacy: Data Protection and Public Policy in Europe and the United States* (Ithaca: Cornell University Press; 1992): 11-12.
[22] Alan Westin, *Privacy and Freedom* (New York, Athenum, 1967): p.7.

privacy; that is, where policy exists or is being considered, protection of privacy necessarily plays a dominant legislative role in secondary use of personal health information for research purposes.

2.3 Canadian legislative frameworks and Data Stewardship of Personal Health Information

2.3.1 Constitutional authority to create legislation

Canada is a loosely bound federation of ten provincial governments, three territorial governments and one national government. Each of these jurisdictions has legislation in force to control the collection, use, and disclosure of personal health information. These acts can generally be called health information acts.

Curiously, the Canadian Constitution is silent on the word "health"; there is not a single mention of it anywhere in the foundational constitutional statutes.[23,24,25] The closest assimilation is the express power of the provinces to establish and maintain hospitals, asylums, charitable and eleemosynary institutions.[26] But there is no mention of health care or medical systems outside the setting of a hospital.

On the other hand the federal government has the express power to ensure peace, order and good government and to make laws about quarantine, marine hospitals, commerce, patents and business.[27] Through the jurisdictional interpretations found in case law and through evolved conventions, the provinces may create their own health legislation as if falling under the express powers provisions found in section 92(7) of the

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[23] *Constitution Act, 1867*, 30 & 31 Vict, c. 3.
[24] *Constitution Act, 1982*, Schedule B to the Canada Act 1982 (UK), 1982, c. 11.
[25] Marlisa Tiedemann, *The Federal Role in Health and Health Care* (Ottawa: Library of Parliament, 2008), p.1.
[26] *Constitution Act 1867*, S.92 (7).
[27] Marlisa Tiedemann, *Health and Health Care*, p.1.

Constitution Act, 1867[28] while the authority of the territories is granted through the respective Acts of the national parliament.[29,30,31] Furthermore, by convention, while the territorial governments have powers that are similar to the provinces they in fact are under the jurisdiction of the national government. This is why in Canada there are fourteen legislative acts and not just one act governing personal health information.

2.3.2 Legislative and Judicial Functions Related to Personal Health Information

The following section (2.3.3) describes the breadth of legislation that governs the handling of personal health information within each jurisdiction in Canada. They are constituents in a body of public law called administrative law. Terms in administrative law that pertain to stewardship of health information require definition to clarify relationships among them. These terms are described below:

- Statute – An act of the legislature; in Canada an act of a provincial legislature or the Federal Parliament adopted pursuant to constitutional authority. Statutes constitute a primary source of law and are enacted, for example, to prescribe conduct, define crimes, create inferior government bodies, appropriate public monies, and in general promote the public good and welfare.[32]
- Regulation – A regulation, order, rule, form, tariff of costs or fees, proclamation, by-law, or resolution enacted (i) in the execution of a power conferred by or under the authority of an act [or statute]; or (ii) by or under the authority of the

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[28] *Constitution Act, 1867*, S 92(7).
[29] *Nunavut Act*, S.C. 1993, c 28.
[30] *Northwest Territories Act*, R.S.C. 1985, c N-27.
[31] *Yukon Act*, S.C. 2002, c 7.
[32] John Yogis and Catharine Cotter, *Canadian Law Dictionary*, 6th Ed. (Hauppauge: Barron's Educational Services, 2009): 265.

Lieutenant Governor in Council, but does not include an order of a court or an order made by a public officer or administrative tribunal in a dispute between 2 or more persons. Regulations are legislation that have the same force of law as a statute but are decreed by an Order in Council rather than passed by the legislative assembly. [33]

- Policy – "Policy making is the application of informed, rational thinking, influenced by public circumstances and political considerations, to the condition of the State to devise plans of action for government." [34]
- Guidelines – Form of administrative directive which cannot confer enforceable rights, but can be written to be mandatory.[35]

Each of the fourteen legislative jurisdictions in Canada has enacted statutes that control the collection, use and disclosure of health information within its respective jurisdiction. Additionally some jurisdictions promulgate regulations that flow from the statutes. All of this legislation must respect the Canadian Charter of Rights and Freedoms.

It is important to note that the reach of each legislative authority is confined to its legal and constitutional boundaries; thus no province can pass a statute or regulation that is binding on any other province. This means in effect that there cannot be provincial legislation about interprovincial (as distinct from intra-provincial) collection, use or disclosure of PHI. The interprovincial nature of much secondary use of PHI and EHR

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[33] Daphne A. Dukelow, *The Dictionary of Canadian Law*, 4th Ed. (Scarborough: Thomson Carswell, 2011): 1098.
[34] Gregory Tardi, *The Legal Framework of Government: A Canadian Guide* (Aurora: Canada Law Book, 1992): 141.
[35] Daphne A. Dukelow, *Dictionary of Canadian Law*, 570.

highlights the need for interprovincial accords and/or federal legislation. Whereas the Personal Information Protection and Electronic Documents Act, or PIPEDA (see section 2.3.3), is federal legislation that purports to be national in scope, it is not clear that it is or can be for personal health information, coming as it does explicitly under the empowering federal jurisdiction over commerce.[36]

The legal question of inter-jurisdictional transfer of health information has not yet been tested in the courts, but it is conceivable that disputes in law relating to personal health information that arise from provincial statutes could result in judicial rulings that are binding in all jurisdictions in Canada. This scenario is possible because the Canadian court system is unitary as well as hierarchical with the Supreme Court of Canada occupying the position of the court of last resort for the entire country. Its rulings can cross the "watertight compartments" of the 14 jurisdictions.[37]

That said, within each province there is an internal court hierarchy with the provincial court of appeal occupying the apex within the province. No decision from the appeal court of a particular province is binding on any other province. But as illustrated through the shaded boxes in Figure 2, the ruling on a case heard in a S.92 provincial or territorial court can be appealed to the S.96 provincial superior court; in turn the S.96 ruling can be appealed to the S.101 Supreme Court where a ruling made there is binding across all 14 jurisdictions.

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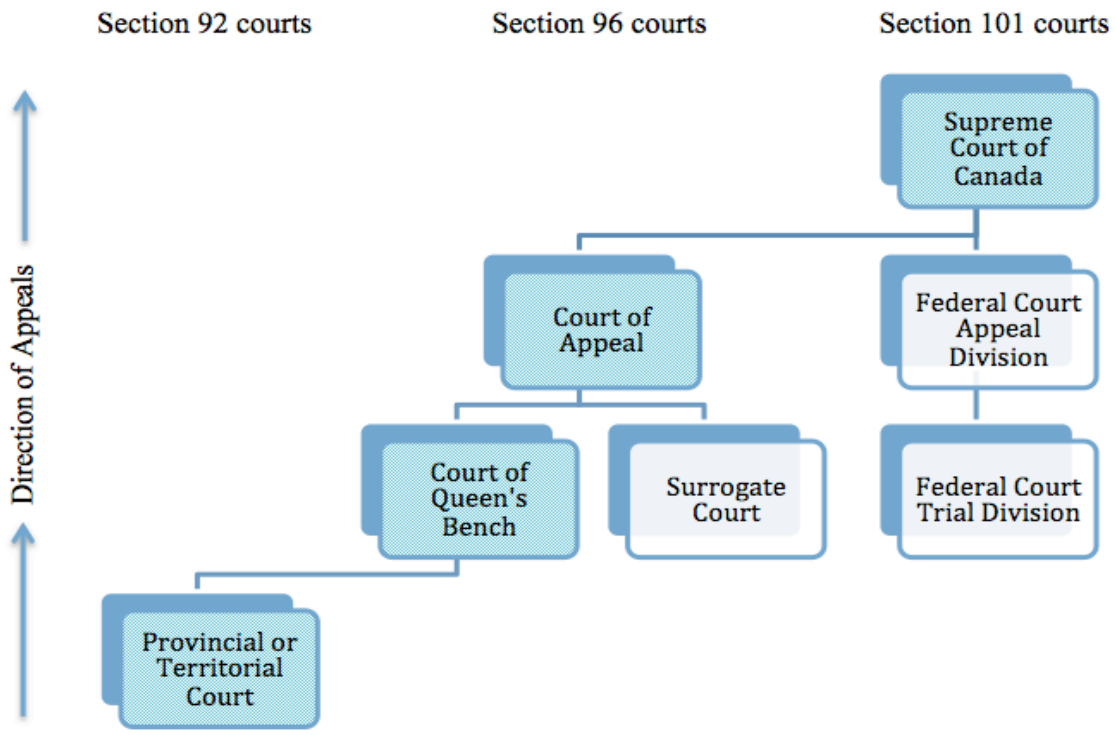
[36] Constitution Act 1867, S.91 (2).
[37] Frederick L. Morton, *Law, Politics, and the Judicial Process in Canada*, 3rd Edition (Calgary: University of Calgary Press, 2002): 427.

Figure 2 – Court Hierarchy in Canada[38]



2.3.3 Stewardship frameworks

The term stewardship is directly associated with a certain type of information holder defined in the various statutes governing personal health information. Examples of the name given to this type of information holder are "custodian", "data steward", "health information custodian", or "trustee". Whenever "data steward" appears in this thesis it is meant to represent these various named legal entities.

Stewardship of personal information has been characterized as a fiduciary duty owed to subjects of the information.[39] In the case of health care, typically patients are the

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[38] Adapted from Figure 1 in Frederick L. Morton, *Law, Politics, and the Judicial Process in Canada*, 3rd Edition (Calgary: University of Calgary Press, 2002): 111.

subjects of health information and those who provide health care services to them are the stewards of that health information. When viewed through the lens of the health information acts in Canada the imperative is clear – stewards are obliged to protect the identity of those whose health information is under their keep. This imperative extends (by operation of health information privacy legislation such as the Health Information Act of Alberta) to those who are not stewards but wish to use health information, like researchers.

Privacy through the protection of identity is presumably a constitutional right in Canada guaranteed by the Charter of Rights and Freedoms under the provision against unreasonable search and seizure.[40] The province of Quebec has rights legislation called the Charter of Human Rights and Freedoms that somewhat mirrors the Canadian Charter and contains an explicit privacy clause.[41] The effect of this privacy provision, as it applies to secondary use of personal health information, has not yet been tested in the courts but should be borne in mind as potentially yielding an alternative model of privacy rights within that province.

Notwithstanding the imperative to protect the identity of individuals some forms of secondary data use are explicitly permitted in health information legislation. One such permitted use is research as outlined in Table 1.[42] When examining the various laws in

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[39] Gordon Brackstone and Pamela White, "Data stewardship at Statistics Canada," *Proceedings of the Social Statistics Section, American Statistical Association* (2002), 284.
[40] *The Constitution Act, 1982,* Schedule B to the Canada Act 1982 (UK), 1982, c. 11, S.8. The privacy right is not explicitly stated here but follows from case law interpretation of Section 8: "Everyone has a right to be secure against unreasonable search and seizure."
[41] *Charter of human rights and freedoms*, R.S.Q., c. C-12, S.5 and S.9.
[42] Karen Weisbaum and Marie Hirtle, *The Encyclopedia: Statute-by-Statute Analysis of Privacy Legislation by Jurisdiction (as of June, 2006) for Privacy Best Practices for Research Involving Secondary Data*

Canada governing the research use of health information a decisive pattern emerges. All Canadian jurisdictions situate research use within the rubric of privacy protection. However, disclosures of health information by data stewards in identifiable form have been considered problematic and will be discussed in section 2.4 of this thesis.

Table 1 - Health Information Legislation and Research

Jurisdiction	**Name(s) of legislation and / or regulations**	**Personal health information (PHI) for Research uses**
British Columbia	Freedom of Information and Protection of Privacy Act, RSBC 1996, c 165 Health Care Consent Regulation, BC Reg 20/2000	Release of PHI for research is permitted under restrictive conditions. Consent is the default but a waiver of consent can be granted by a research ethics board (REB).
Alberta	Health Information Act, RSA 2000, c H-5 Designation Regulation, Alta Reg 69/2001	Release of PHI for research is permitted under restrictive conditions. Consent is the default but waiver of consent can be granted by a REB.
Saskatchewan	Health Information Protection Act, SS 1999, c H-0.021 REBs receive authority from minister of health	Use of de-identified personal health information is preferred; otherwise release of PHI is permitted under restrictive conditions. Consent is the default but waiver of consent can be granted by a REB.
Manitoba	Personal Health Information Act, CCSM c P33.5 Personal Health Information Regulation, Man Reg 245/97 Mental Health Act, CCSM c M110 Freedom of Information and Protection of Privacy Act, CCSM c F175	The Act explicitly states that it does not apply to de-identified information. PHI can be released to researchers without consent if approved by a REB or HIPC and a written agreement is executed between the researcher and the trustee disclosing the PHI.

Use (SDU) (Ottawa: Canadian Institutes for Health Research, 2006). Updates to the table have been made to reflect current legislation and regulation in force.

Jurisdiction	Name(s) of legislation and / or regulations	Personal health information (PHI) for Research uses
Ontario	Personal Health Information Protection Act, 2004, SO 2004, c 3, Sch A General, O Reg 329/04	Consent is the default but PHI can be released to researchers without consent if the research and the research plan are approved by a REB.
Québec	An Act respecting access to documents held by public bodies and the Protection of personal information, RSQ, c A-2.1 An Act respecting health services and social services, RSQ, c S-4.2 Health Insurance Act, RSQ, c A-29	Disclosure of PHI for research is permitted under restrictive conditions. Consent is the default but PHI can be disclosed to researchers without consent if the disclosure is approved by a REB.[43]
New Brunswick	Personal Health Information Privacy and Access Act, SNB 2009, c P-7.05 General Regulation, NB Reg 2010-112	Disclosure of PHI for research is permitted under restrictive conditions. Consent is the default but PHI can be disclosed to researchers without consent if the disclosure is approved by a REB.
Nova Scotia	Freedom of Information and Protection of Privacy Act, SNS 1993, c 5 Freedom of Information and Protection of Privacy Regulations, NS Reg 105/94	Disclosure of PHI for research is permitted under restrictive conditions. Disclosure without consent is also permitted.[44]
Prince Edward Island	Freedom of Information and Protection of Privacy Act, RSPEI 1988, c F-15.01	Disclosure of PHI for research is permitted under restrictive conditions. Disclosure without consent is also permitted.[45]

[43] McGill University, *Ethical And Legal Aspects Of Research Involving Human Subjects Conducted In The Faculty Of Medicine And Affiliated Hospitals: Policies and Procedures 2007*, downloaded 2012 Nov 23 from http://www.mcgill.ca/medresearch/sites/mcgill.ca.medresearch/files/PandP2007_FINAL.pdf.
[44] *Freedom of Information and Protection of Privacy Act*, S.N.S. 1993, c 5, S.29.
[45] *Freedom of Information and Protection of Privacy Act*, R.S.P.E.I. 1988, c F-15.01, S.39.

Jurisdiction	Name(s) of legislation and / or regulations	Personal health information (PHI) for Research uses
Newfoundland and Labrador	Access to Information and Protection of Privacy Act, SNL 2002, c A-1.1	Disclosure of PHI for research is permitted under restrictive conditions. Consent is the default but PHI can be disclosed to researchers without consent if the disclosure is approved by a REB.[46]
Yukon	Access to Information and Protection of Privacy Act, RSY 2002, c 1	Disclosure of PHI for research is permitted under restrictive conditions. Disclosure without consent is also permitted.[47]
Northwest Territories	Access to Information and Protection of Privacy Act, SNWT 1994, c 20 Access to Information and Protection of Privacy Regulations, NWT Reg 206-96	Disclosure of PHI for research is permitted under restrictive conditions Disclosure without consent is also permitted.[48]
Nunavut	Access to Information and Protection of Privacy Act, SNWT (Nu) 1994, c 20 Access to Information and Protection of Privacy Regulations, NWT Reg (Nu) 206-96	Disclosure of PHI for research is permitted under restrictive conditions. Disclosure without consent is also permitted.[49]

When personal health information moves outside the control of one province or territory then the stewardship and privacy frameworks are less clear than when the information remains within the province or territory. Although there is a common acquiescence to the federal legislation PIPEDA, it has yet to be decided by the courts firstly whether that law, coming as it does expressly under the commerce head of

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[46] Health Research Ethics Authority, "Application for Ethics Review of Secondary Use of Data/Chart Audit", accessed 2012 Nov 23, http://www.hrea.ca/getdoc/0f805d7f-a934-4a5a-95d8-29345cd1efd6/Data-Chart-Audit-Application.aspx

[47] *Access to Information and Protection of Privacy Act*, R.S.Y. 2002, c. 1, S.38.

[48] *Access to Information and Protection of Privacy Act*, S.N.W.T. 1994, c. 20, S.49.

[49] *Access to Information and Protection of Privacy Act*, S.N.W.T. (Nu) 1994, c. 20, S.49.

power[50], can legitimately occupy the field for non-commercial transfer of personal health information and secondly whether its scope reaches to non-governmental institutions holding health information. Of clearer national application would be the Charter of Rights and Freedoms which all legislation in Canada must conform with; but here again the courts have yet to decide on the Charter issues related to inter-jurisdictional transfers of health information. Relevant sections of the Charter could include the following: 1 (Guarantee of rights and freedoms subject only to reasonable limits), 2 (Freedom of association), 7 (Life, liberty and security of the person), 8 (Security from unreasonable search or seizure), 12 (Freedom from cruel and unusual treatment), 15 (Equality rights and affirmative action), 25 (Aboriginal rights) and 36 (Regional disparities equalization rights).[51] In summary of the situation thus far: the position is one of practical agreements and conventions rather than clear law.

2.3.4 Office of the Privacy Commissioner

Each of the provinces, territories and national government has a privacy commissioner who administers the provisions of the respective health information act that govern privacy. These privacy commissioners have a quasi-judicial function as agencies of parliament and legislature, not of government. Unlike the agencies of statutory ministries that collect health information such as Alberta Health Services, the various cancer agencies of the provinces and the First Nations and Inuit Health Branch, the office of the privacy commissioner is accountable directly to the parliament or legislature, not to the minister of health. Stated differently, the commissioner's office

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[50] *Constitution Act, 1867*, S.91(2).
[51] Appendix C contains excerpts of the Charter sections mentioned.

resides in the judicial function of the political systems of the provinces, territories and national government. Whereas the police are agencies of the executive branch and do not pass judgement, the privacy commissioner has the authority to pass judgements in the form of rulings binding on the government and executive branch, as well as private citizens.

2.4 Privacy arguments and objections

A key argument favouring protection of privacy over secondary use of health information is that the potential consequences in betraying patient-provider trust are too harmful to risk. This argument is different from the libertarian claim and argument that it is an individual's right to control collection, disclosure and use of his or her own personal health information. This potential harm argument is a consequentialist position as compared with the rights-based (autonomy) position taken by the libertarians. This distinction will be explored in greater detail in section 3.3.2.

Betrayal of trust can occur when disclosed health information is used in a way that harms the interests of the individual who is the subject of that information. Representative of the camp that places protection of privacy over secondary use, Woodward not only describes the threats to privacy and confidentiality that can arise during secondary collection of personal health information but she also argues that these threats and the breaches that result "undermine … trust in the profession."[52] Woodward is also concerned about the possibility of re-identification of individual patients in de-

[52] Beverly Woodward, "Medical record confidentiality and data collection: current dilemmas," *Journal of Law, Medicine, & Ethics* 25, 2-3 (1997), 94.

identified records.[53] Her argument for non-disclosure of information is based on the premise that the harm that can come from threat of identification outweighs the benefit accrued through the research that would use this information. Alpert shares the Woodward concern about undermining trust and posits a possible consequence, specifically that lack of confidence in the ability of the medical profession to protect the confidentiality of private health information will lead to patients withholding relevant clinical information from providers and thwart the ability of the latter to properly care for the former.[54] While Alpert and Woodward's comments are borne out of concern for the privacy of health records in the United States they are compatible with the Canadian context.

On the other hand, Alpert's and Woodward's argument about affecting front line care can also be applied to the argument for restricting research access to personal health information. Providers sometimes rely on research to inform their clinical care decisions.[55] The data required for certain fields of research, such as population health, are sometimes derived from personal health information that is used without consent. If a researcher does not have access to this kind of identifiable information for the study then its validity is at the very least called into question and at worst it is compromised. If studies are compromised in this way then providers who use the results of such studies may unknowingly recommend inappropriate care to patients.

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[53] Ibid, 94.
[54] Sheri A. Alpert, "Protecting Medical Privacy: Challenges in the Age of Genetic Information," *Journal of Social Issues* 59, no. 2 (2003), 318.
[55] David L. Sackett, William M.C. Rosenberg, J.A. Muir Gray, R. Brian Haynes and W. Scott Richardson, "Evidence based medicine: what it is and what it isn't: It's about integrating individual clinical expertise and the best external evidence", *British Medical Journal* 312, no. 7023 (1996), 71-72.

An argument to counter libertarian protection of privacy exists in public health research ethics and is articulated for example by Miller who disputes the argument that privacy should trump release of health information.[56] He argues that just as there are limits to property rights, so too there are limits to privacy rights. He describes the limitation on property rights and suggests an analogous limit on the right to privacy in medical records: "Owing to the public purposes served by medical records research, and the potential to conduct this research with minimal intrusion on individual privacy, it is reasonable to restrict the scope of the right of privacy such that consent is not necessarily required for this research."[57] Indeed, Miller points out that a limitation on the right to privacy already exists in practice with the legal requirement for physicians to report diagnoses of certain communicable diseases to public health authorities or to report abuse to the appropriate legal authorities.[58]

2.5 Data liberation arguments

2.5.1 Arguments

Of special interest to this study are the perspectives that place secondary use at the forefront. Berglund examines research on AIDS in Australia to illustrate the attempt to strike a balance in the tension between secondary use of health information and

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[56] Franklin G. Miller, "Research on Medical Records Without Informed Consent," *Journal of Law, Medicine & Ethics* 36, no. 3 (2008), 560-6.
[57] Ibid, 563.
[58] With the Miller-style approach that combines its focus on "public" and the empirical fact that communicable diseases and population health are no respecters of or bound within political boundaries that make up each province, there is an implicit pull to construe "health" as falling under the federal constitutional legislative domain under a "national dimension" test rather than something of a "merely local or private Nature in the Province." The "national dimension" test is case law derived where the courts stipulated an interpretation of federal powers under the peace, order and good government clause of *Constitution Act, 1867*, section 91 whereas the statement "merely local or private Nature in the Province" comes directly from section 92.

protection of privacy.[59] Goodman examines this tension through an ethical lens in separate articles on genomics data and public health.[60,61] Black et al conduct a literature review "to identify practical issues faced by researchers and data custodians around use of Canadian population-based health and health services data for research."[62] Black's review is a good starting point for this thesis because they explicitly stop short of exploring theoretical arguments for protecting privacy or favouring research. Benbassat and Levy point out that many epidemiological studies would not be possible if informed consent were required before access to personal health information was permitted.[63] Lowrance takes on the issue of secondary use of health information for research purposes from a stewardship perspective, suggesting that the balance with protection of privacy can be struck through anonymization, in essence circumventing the need to obtain consent.[64,65] Rosenbaum points out the fiduciary responsibility of data stewards in her argument to liberate health information for research purposes while also pointing out that

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[59] Catherine A. Berglund, "Australian standards for privacy and confidentiality of health records in research: implications of the Commonwealth Privacy Act," *Medical Journal of Australia* 152, no. 12 (1990): 664.
[60] Kenneth W. Goodman, "Ethics, genomics, and information retrieval," *Computers in Biology & Medicine* 26 no. 3 (1996), 223.
[61] Kenneth W. Goodman, "Ethics, information technology, and public health: new challenges for the clinician-patient relationship," *Journal of Law, Medicine & Ethics* 38, no. 1 (2010), 58.
[62] Charlyn Black, Kimberlyn McGrail, and Cathy Fooks, *Data data everywhere: Improving access to population health and health services research data in Canada. Final report* (Vancouver, Canada: Centre for Health Services and Policy Research, University of British Columbia, 2005), 48.
[63] Jochanan Benbassat and Micha Levy, "Researchers' access to stored medical data: the Israeli experience," *IRB: a Review of Human Subjects Research* 10, no.3 (1988), 1-3.
[64] William Lowrance, "Learning from Experience: Privacy and the Secondary use of Data in Health Research," *Journal of Health Services Research & Policy* 8 Suppl 1, (2003), S1.
[65] The very possibility of full anonymization is now questionable given cross-data linkage and DNA information. As an example the human remains of the tomb of the unknown soldier, although anonymous until the 1990s and the advent of advanced DNA tracking, are now known to be those of a particular individual. That soldier's family and descendants are aware of this fact.

"privacy considerations slow the march toward data access".[66] Safran, advocating for American researchers, calls for a national discussion leading to a framework for secondary use of health data.[67] Finally, the British Medical Research Council speaks of an overriding duty to use health information for the general good when it can be done without detriment to the individuals concerned, ranking protection of privacy lower than research in the public interest.[68]

Miller attempts to make an ethical argument to allow release of medical records without consent for research.[69] In jurisdictions where public money is used to deliver health care services it can be implied that there is duty to decide how best to use that money based on a sound body of research. Some of that research can only be conducted with the use of the identifiable information in medical records. To allow individuals a veto on access to their identifiable information for research would impose a barrier on society's ability to fulfill the duty to decide how best to use public money for health care. While his argument does not reach the point of data liberation it does play out in the health information legislation in Canada as we see in section 2.3.[70]

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[66] Rosenbaum, "Data Governance and Stewardship," 1450.
[67] Charles Safran, Meryl Bloomrosen, W. Edward Hammond, Steven Labkoff, Suzanne Markel-Fox, Paul C. Tang, Don E. Detmer, with input from an expert panel, "Toward a national framework for the secondary use of health data: an American Medical Informatics Association White Paper," *Journal of the American Medical Informatics Association* 14, no. 1 (2007), 1.
[68] Medical Research Council, "Responsibility in the use of Personal Medical Information for Research: Principles and Guide to Practice. Statement by the Medical Research Council," *British Medical Journal (Clinical Research Ed.)* 290, no. 6475 (1985), 1120-4.
[69] Miller, "Research on Medical Records," p. 563-4.
[70] Alberta's *Health Information Act* attempts, in Section 50, to apply a proportionality test that allows a designated research ethics board to dispense with the requirement of consent where the researcher establishes that it would be unreasonable, not feasible or not practical to obtain individual consent in matters of sufficient public importance.

2.5.2 Case studies of real world situations

The literature also contains articles that point out real world situations in which the tension between secondary use for research purposes and protection of privacy is played out. The Canadian Institutes of Health Research performed an analysis of nineteen such situations and concluded that they "provide concrete illustrations of the importance for interpreting and applying privacy laws and policies in a flexible, feasible and workable manner in order to permit the valuable social benefits of health research to continue."[71] While Bauer's case study about the re-use of a Danish cardiovascular database for breast cancer research does not directly address ethical principles[72], there is a tacit acknowledgement that in epidemiology the public interest of secondary use of health information overrides the protection of privacy. Westrin et al suggest a model of ethical analysis in epidemiology that aims to identify the principles at play but leave the hard work of deciding which principles are more important to the decision makers.[73]

2.6 Data stewardship argument – Data liberation constrained by ethical principles

The arguments above are played out in a struggle between seemingly opposed and mutually exclusive principles of data liberation and protection of privacy. However it is the position of the author that the ethical principles underpinning these positions can co-exist within a coherent policy of data access for researchers. Furthermore, an example of policy of data stewardship for the express purpose of data liberation already exists at

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[71] Canadian Institutes of Health Research, *Secondary use of Personal Information in Health Research: Case Studies* (Ottawa: Public Works and Government Services Canada, 2002).
[72] Susanne Bauer, "Mining Data, Gathering Variables and Recombining Information: The Flexible Architecture of Epidemiological Studies." *Studies in History and Philosophy of Biological and Biomedical Sciences* 39, no. 4 (2008): 415.
[73] Claes-Goran Westrin, Tore Nilstun, Bjorn Smedby, and Bengt Haglund, "Epidemiology and Moral Philosophy," *Journal of Medical Ethics* 18, no. 4 (1992): 193.

Statistics Canada and provides researchers with a rich and robust repository for their research programs while being constrained by the provisions of the *Privacy Act*.[74] In effect, Statistics Canada is constantly reminded about its stewardship obligations and states as much: "*Stewardship* … admirably captures the sense of being entrusted with the care of something of value, belonging to someone else, and using it wisely while guarding its value and respecting its owners' rights."[75] By contrast this thesis on data liberation is construed not through the lens of privacy rights as has been done in the literature but is an examination of policy through ethical principles which may include respect for privacy.

2.7 Research Questions

2.7.1 Preamble

The literature review has identified an opportunity for the development of ethics-based public policy in the area of secondary access to personal health information for research purposes. As stated in the introduction chapter the author works in Alberta, a Canadian province whose legislative framework for research use of personal health information is not dissimilar to that of the other provinces and territories in Canada. At the time of writing there is active discussion within Alberta about research access to personal health information that is collected by various data stewards. However, an explicit and positive manifestation of policy in this area is yet to be seen. Therefore the author conducted this study as if to make recommendations to an Alberta audience and the research questions will be framed in that context. Due to similarities in legislative

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[74] Brackstone and White, "Data Stewardship," 284.
[75] Brackstone and White, "Data Stewardship," 284.

frameworks across the country it is expected that recommendations from this study can inform any Canadian province or territory where policy makers wish to be clearer on policy regarding research access to personal health information.

2.7.2 Research Question 1

What policy regimes elsewhere have elements that can be connected to Alberta's data stewardship structure or can serve as potential exemplars to provide data stewardship policy options to effectively enable secondary use of health information for research purposes in Alberta?

2.7.3 Research Question 2

Do any exemplars identified in question 1 serve as ethically and structurally sound paradigms?[76]

2.7.4 Research Question 3

Abstracting general characterizations from the paradigm policy case(s) what options would allow for secondary use and appropriate protection of privacy and confidentiality?

[76] By "paradigm" I am referring to the lay meaning, i.e. good example, rather than to some specialized theory-laden meaning such as a Kuhnian paradigm.

Chapter Three: **METHODS**

3.1 Introduction

3.1.1 Outline of Approach

This thesis adopted the following research approach:

1. Performed a scoping review to identify potential policy exemplars of data stewardship policy (see section 3.2);
2. Filtered policies identified in the previous step using a ground level ethics filter[77] to identify ethics characteristics of policy then applying higher level meta filter[78] to identify a match with accountability and transparency in public policy (see section 3.3);
3. Identified the characteristics leading to the formation of the chosen policy exemplar(s) using Yin's descriptive case study methodology (see section 3.4)[79]; and
4. Reported on the implications of the case study for the development of legally and ethically satisfactory data stewardship policy and practice (see sections 5.2 to 5.4).

The overall research design is summarized in Figure 3.

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[77] Robert M. Veatch, "Resolving Conflicts among Principles: Ranking, Balancing, Specifying", *Kennedy Institute of Ethics Journal* 5, no. 3 (1995): 199-218.
[78] Norm Daniels and James Sabin, *Setting limits fairly: learning to share resources for health*, 2nd Ed. (New York: Oxford University Press, 2008): 45-66.
[79] Robert K. Yin, *Case Study Research: Design and Methods*, 4th Edition (Thousand Oaks: Sage, 2009).

Figure 3 – Research Design

Research Question	Method(s)	Data to be Collected	Analysis
1. What policy regimes elsewhere have elements that can be connected to Alberta's data stewardship structure or can serve as potential exemplars to provide data stewardship policy options to effectively enable secondary use of health information for research purposes in Alberta?	Search for data stewardship policies in Canada using a scoping review technique.[80] Key informant interviews to identify policy exemplars.	Inventory of policies and regulation that directly affect data stewardship in Alberta. Paradigm policies or regimes. Legislation, regulations and policies that affect data stewardship in Alberta.	Determine which policies or portions thereof could exist within Alberta's data stewardship regime.
2. Do any exemplars identified in question 1 serve as ethically and structurally sound paradigms?	Scoring of potential cases through the Veatch matrix and the Accountability for Reasonableness criterion.	Scores of exemplars on a gradient of acceptability as candidates for a case study.	Use the Veatch ethics matrix and Daniels A4R framework to sort and filter potential exemplars.[81,82]
3. Abstracting general characterizations from the paradigm policy case what options would allow for secondary use and appropriate protection of privacy and confidentiality?	Case study methodology following Yin's descriptive method[83]	The ethical policy options that emerge from the case study.	Identify policy options that are relevant in Alberta.
4. Synthesis of 1 through 3.	Comparative conceptual analysis	Results of 1 to 3	Thesis writing methodologies

[80] Hillary Arksey and Lisa O'Malley, "Scoping Studies: towards a methodological framework," *International Journal of Social Research Methodology* 8, no. 1 (2005): 19-32.
[81] Daniels and Sabin, *Setting Limits* Fairly, 45-66.
[82] Veatch, "Resolving Conflicts," 212.
[83] Yin, *Case Study* Research, 5-23.

3.1.2 Approval from Research Ethics Board

This thesis received approval from the Conjoint Health Research Ethics Board (CHREB) at the University of Calgary on December 19, 2011. The approval was renewed on the anniversary date of December 19, 2012.

3.2 Research Question 1 – Identify potential policy exemplars

3.2.1 Method – Scoping review and use of Key Informants

The scoping review is not to be confused with a systematic review.[84] The former is meant to expose the breadth of the literature on data stewardship whereas the latter would attempt to uncover the depth of the literature based on narrow research questions. Furthermore the former type of review is more suited to "broader topics where many different study designs might be applicable."[85]

As described in section 4.2 this research question generated a list of organizations and the data access policy of each. Before the search began there was no sense of the number of organizations operating in Canada. It was possible that numerous non-academic sources would have to be mined to discover the organizations. A scoping review methodology, which is an academically valid technique, would allow for exploring a broader set of publications with a greater tolerance for variation in the quality of the publications.[86]

It was believed that the academic literature is a logical starting point. However if that source failed to produce policy exemplars then the next step would be to look in non-

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[84] Arksey and O'Malley, "Scoping Studies," 20.
[85] Ibid.
[86] Rebecca Armstrong, Belinda J. Hall, Jodie Doyle and Elizabeth Waters, "Cochrane Update: 'Scoping the scope' of a Cochrane review'", *Journal of Public Health* 33, no. 1 (2011), 148.

academic sources such as government websites. Finally, another option to find policy examples was to contact key informants who know of organizations that make health information available to researchers.

The list of organizations that would proceed to the next research step, whose method is described in section 3.3, were those that met all of the following criteria:

- The policy came from an organization whose primary purpose is to provide researchers with access to personal health information.
- The organization operated within the legislative regime of one or more of the fourteen Canadian jurisdictions.
- The policy was readily accessible. For example, the policy that was posted on the organization's website was considered to be readily accessible.
- The organization was a going concern and actively processed data access requests.

3.3 Research Question 2 – Evaluation of Potential Policy Exemplars

3.3.1 Method

The policies identified in the first research question were subjected to an evaluation for ethical soundness. The ethical framework used in this evaluation is a combination of two structures. One is a matrix created by Veatch to sort by types of ethical principles (see section 3.3.9).[87] The other is a rubric tool created by Daniels and Sabin to evaluate the accountability and reasonableness of health care policy (see section

[87] Veatch, "Resolving Conflicts," 212.

3.3.10).[88] Subsections 3.3.2 to 3.3.10 contain a brief overview of ethics and ethical frameworks to place the choice of the Veatch and Daniels frameworks into the ethics context.

The broad stroke character was to evaluate and assign each of the possible exemplars using the Veatch matrix with the output being a description of the type of ethical parameters and theories reflected in the policy. Together these partially determined the nature of the ethical content of the possible exemplar. Then each exemplar was run through the Daniels meta-sieve to examine it for its reasonableness as gauged by the four accountability conditions. The result was two reduced charts that for each policy identified its substantive and meta characteristics to which ranking could then be assigned. The output was thus a finite subset of model policies, and possibly only one or two that met the twin goals of success and sustainability.

Information for the evaluation was derived from the written policy only. Communication with the research organizations was intentionally avoided in light of the concern of bias that could result from making direct contact before doing the case study in research question 3.

When the Veatch Matrix was used for evaluation, the policy was filtered for underlying ethical principles identified by reading the policy. When the Daniels rubric tool was used, the same policy was filtered for the four elements in the rubric tool, namely relevance, publicity, revisability, and enforceability. These are known as the

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[88] Daniels and Sabin, *Setting Limits Fairly*, 45.

A4R conditions. Generally a policy was deemed to satisfy a condition when evidence for it was found in the written policy.

The viability of a policy on data access for researchers depends on its compliance with the legislation that governs the collection, use and disclosure of personal health information. A policy that explicitly mentioned its compliance with health information legislation was considered to satisfy the relevance condition of Daniels.

For a policy to satisfy the publicity condition it had to be publicly available and its implementation must have been transparent. For example, an organization that posted its data access policy online and disclosed the decision process for ongoing data access applications would satisfy the publicity condition.

The revisability condition pertains to the ability for applicants to appeal decisions made according to the data access policy. Evidence within the written policy of an appeals mechanism satisfied the revisability condition.

The enforceability condition pertains to the ability of organizations to enforce its decisions and the ability of oversight bodies to examine the decisions and decision processes. For example, an organization that fell within the legislative purview of the information and privacy commissioner for the province would satisfy the enforceability condition.

Each policy was scored to assist in considering its suitability as a policy exemplar. For the Daniels framework, the more A4R conditions the policy satisfied the higher its score. However, organizations that had no written data access policy were immediately eliminated from further consideration as an exemplar. For the Veatch framework, the policies that recognized an ethical tension in allowing researchers access to personal

health information were given a score of 1 and those that did not recognize the tension were given a score of 0.

3.3.2 Moral Values and Prescriptions[89]

Moral judgements are not straightforward. The assertions they involve are not like physical facts about objects, such as size, shape, or colour. Determining the rightness or wrongness of actions is not amenable to laboratory techniques for collecting data, measuring, recording and running analysis programs. It is a judgement that depends on the interpretation of the facts relative to values and the values can come in many forms. That divergence is a rich one that has been explored by many moral philosophers. But "common to the philosophical approaches is a recognition that the very existence of moral dilemmas and moral disagreements is sufficient to establish that morals are not just something personal, or something particular to one group of people."[90]

The following is a sketch of the three main approaches to thinking about ethical issues and how they relate to health services. Much of the literature on moral theories, while instructive, did not address directly the issue of secondary use of personal health information. However, it was important to have a good working grasp of the theories and how they interplay in order be able to assess the ethical concerns in secondary use. By

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[89] The material in subsections 3.3.2 to 3.3.7 is substantially derived from Glenys Godlovitch, "Ethics," in *Health Care and the Law*, 4th Ed., ed. Rebecca Keenan (Wellington: Thomson Reuters, 2010), 487-511.

[90] Philosophers argue whether moral claims are objectively true. Those who are persuaded that matters of value are objective are called realists. Those who hold that matters of value are social constructs and conventions, are called anti-realists or conventionalists. Anti-realists do not hold that there is no truth about morals, rather they hold that morals are conventions in much the same way that the following are conventions: money, the organization of the letters on a keyboard or the ascent of notes on a piano from left to right.

using the Veatch Matrix and the Daniels A4R methods of analysis, the author could show how the secondary use context builds on a background of traditional theories.

3.3.3 Three traditional types of moral theory

There are three main types of moral theory:

Consequentialism, associated with utilitarians[91] and cost-benefit analysis. This kind of approach is causal in nature and focuses on means-ends and the outcomes of actions.

Deontological approaches focussed on "rational moral duties" or alternatively rights theories as the counterpart to duties. The duties view is associated with Kant[92] and others. The rights view is associated primarily with Ronald Dworkin[93] as well as others.

Virtue theories, or "moral character" theories, primarily associated with Aristotle. This approach has been revived in the last forty years especially in the area of clinical ethics where leading proponents include Edmund Pellegrino. It focuses on the character of the person as moral agent.

All three approaches assert that there are objective moral truths.

3.3.4 Consequentialism

As the word consequentialism implies, these moral theories are outcomes based. As the author of "Ethics" puts it, "Consequentialist moral theories hold that the moral worth of an action is gauged in terms of the consequences. So consequentialist theories

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[91] Key figures in the development of utilitarianism are Jeremy Bentham (1748-1832) and John Stuart Mill (1806-73).

[92] Immanuel Kant (1724-1804). Theories based on Kant's approach are called "Kantian". Among those who owe Kant an intellectual debt of gratitude are the present day "rights" theorists. Kant's own model was grounded on the notion of moral duties, but many later thinkers have reinterpreted duties in terms of rights, where one person has a right, another person has a duty.

[93] Ronald Dworkin, *Taking Rights Seriously* (London: Duckworth, 1977).

are causal theories. Broadly speaking, they hold that an action is morally right if its good consequences outweigh its bad consequences relative to some value."[94] In this respect, they are risk/benefit analyses and have a strong resemblance to the fundamental ideas in evidence-based medicine.

Again, as the author of "Ethics" says, "on its face, [utilitarianism] seems to say that what a person should do is make the world a better place for everyone… Values are said to be either intrinsic (needing no further justification) or instrumental (justified in terms of an intrinsic value)."[95] That is, values are intrinsic when they are ends in themselves or instrumental when they are means to an end. To highlight the difference between intrinsic and instrumental, health can be seen as intrinsic while exercise and diet can be seen as instrumental.

Paraphrasing "Ethics"[96], there are some significant shortcomings to a utilitarian approach. Below are some of them.

1. The causal means-ends approach appears to mandate (not just accept) the use of an individual when the overall beneficial results for others outnumber the harmful results for the individual. While it is easy to come up with examples like mandatory quarantine of a person with a dangerous communicable disease, other cases are disconcerting. For example, imagine some derelict with no relatives. No one who cares about him. He could disappear and nobody would miss him. There he is: a potential organ donor, a walking research subject. Others would benefit

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[94] Glenys Godlovitch, "Ethics", 495.
[95] Ibid, 495.
[96] Ibid, 496.

enormously from his participation in their health service, even his involuntary participation, even from his death. On the simplest version of utilitarianism, the greater good of the greater number requires it as the morally right course of action. The good of the many would definitely outweigh the harm to the one. However, many would find a calculation of this sort to be morally reprehensible in this situation.[97]

2. The free-rider problem: Provided the overall gain is maximized, it should not matter that some individuals are taking advantage of others: as long as everybody else pays the correct bus fare, it is right for one person not to pay, especially if they otherwise would not be able to travel.
3. Because the underpinning is the causal chain and harmful/beneficial calculus, autonomy and voluntary consent are at best incidental considerations, as a contributing instrumental factor in bringing about outcomes;
4. The assignment of comparative value and issues of commensurability: this problem relates directly to surgery waiting lists and prioritisation within them;
5. The scope of consideration of effects is not defined: Whose interests are to be considered? Do we need to consider future (possible) generations, only living people, or all sentient creatures?

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[97] The classic reprehensible examples are of the experiments done on concentration camp inmates by German clinicians during the Nazi period. Finding out how long a person could survive if thrown into ice-cold water was extremely relevant to downed German air force personnel. Maybe on a purely numerical basis, the good of the aircrews would and did outweigh the harm done to the victims. However, many argue that that does not justify the practice and is counted by some as a refutation of simplistic consequentialist theories.

6. Finally, there is a logical flaw: Maximizing for two disparate factors (greatest number/greatest happiness) is logically flawed where the factors are not inherently coextensive.

Nevertheless, even given counter-examples and problems like these, we still want to make moral space for the ideas of preventing harm and increasing wellbeing. That notion still has a strong influence as a moral factor.

3.3.5 Deontological theories

The deontological approach takes a completely different tack by ignoring the risk/benefit analysis. It addresses rational self-determination and looks at people as free agents making rational choices for conduct. Ethical conduct for deontologists is either about rational imperatives (moral duties) or rights claims. In health care autonomy and respect for autonomy exemplify the deontological approaches.

While the deontological approach started out with Kant in the 18th century as a theory of moral duties, the rights theory version, typified in the writings of Ronald Dworkin, is much more prevalent these days. Rights claims are often used as the underpinning of claims for access to specific sorts of health service that a health organization would not otherwise offer or for a right to privacy of personal health information. The rationality requirement common to both the moral duties and the rights versions removes from the consideration all personal preferences, inclinations, personal favourites, and even consideration of whether one's actions result in an increase in wellbeing over harm.

The major drawbacks that critics raise include the following:

1. Rights often conflict. But there is no built in way of determining deontologically which of competing claims should prevail. Any decision procedure is not itself a rights-based deontological theory, but will impact peoples' rights and freedoms.
2. Rights based theories downplay if not disregard the potential consequences – if harm results, that is regrettable, but not a matter to be factored into one's preliminary decision-making. From a medical perspective, it allows for less than optimal use of resources and for patients to make silly choices so long as they are not mentally incompetent.
3. The claim that everyone is an autonomous rational agent is an empirical claim that seems to be false: new-born infants, people who are comatose, in a vegetative state are obvious counter-examples.

The positive aspect of deontological theories is the demand for recognition of autonomy and the respect for the rights of others.

Each of consequentialist and deontological theories is represented in an ethics matrix created by Robert Veatch that was used as a methodological tool in this thesis. The Veatch matrix and its application in the thesis are described in more detail in section 3.3.9.

3.3.6 Virtue Ethics

In comparison with the two preceding approaches, virtue theory focuses on not on actions and events (consequentialism) or one duties and rights (deontological), but on the nature of the agent such as the physician, the database manager and the researcher. The aim in virtue theory "is to foster the development of virtuous people. It is safe to think of this as the good social role model approach, where a person is encouraged to analyse and

emulate the behaviour of a good person."[98] But as an approach it is thin on theoretical details. It calls for the promotion of virtuous characteristics but does not tell us what the litmus test is for anything being a virtue. Its role in relation to secondary use of personal health information is possibly limited to the essential characteristics for those administering the data warehouse.

As Godlovitch says, the difficulties with virtue theory approaches include the following: [99]

1. There are no inclusion and exclusion criteria for identifying virtues;
2. There is no method for determining excess or shortage;
3. There is no prescribed method for acquiring the virtues;
4. It is open to charges of medical paternalism;
5. It fails to address misplaced esteem, the fallen hero syndrome where someone who was admired lets one down — the loss of confidence could be calamitous;
6. When confronted with a situation for which one has no suitable role model, one is left adrift.

In relation to secondary use of personal health information, the immediate impact of the three approaches can be summarized like this: consequentialism says that secondary use is warranted when the overall good will be served, that privacy is not an intrinsic value to be protected and that consent is not an integral factor; deontological approaches put personal choices and preferences front and centre, accord right to privacy the main role and downplay the consequences; and virtue theory is largely under-

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[98] Ibid, 497.
[99] Ibid, 498.

informative on secondary use because it focuses on the character of the individual practitioner rather than the institution and systemic features.

3.3.7 Principlism and the Belmont Report

Efforts have been made to reconcile the tensions among the above three listed theories. The best-known effort is the emergence in North America of an inclusivist approach called Principlism. It was expressed in the Belmont Report of 1978 as the official response in the United States to some egregious research.[100] This report presented an amalgam of the consequentialist approaches and the deontological approaches, but it left open the question about how one should decide what weight to give to one approach over the other in any given circumstances. The Belmont Principles, as they came to be called, are the following:

- Beneficence and non-malfeasance are to be promoted,
- Autonomy is to be respected, and
- Justice is to be instantiated.

There is extensive literature devoted to these terms, so what follows is only a brief overview. Obviously the first two (beneficence and non-malfeasance) are causally oriented ethical contexts; the third (autonomy or "respect for autonomy") is a rights-based deontological approach. The key addition to be made is discussion of how the first three (beneficence/non-malfeasance and autonomy) fit in a framework of social justice.

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[100] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, (Washington DC: DHEW Publication OS 78-0012, 1978). The unethical research in question was a study on syphilis patients (the Tuskegee syphilis study) where life-saving treatment was intentionally withheld without the knowledge or consent of the patients.

3.3.7.1 Autonomy, Beneficence, Non-malfeasance

Autonomy, beneficence, and non-malfeasance are already well known through the deontological and consequentialist material and there will not be further elaboration on them in this thesis. However, the reader is referred to the extensive bioethics literature as cited in the bibliography. As noted in "Ethics,"[101] the focus on autonomy in particular has been significantly undermined more recently by arguments from feminist writers such as Sherwin[102,103], Gilligan[104] and by global collectivist writers such as Dwyer[105], Chadwick and ten Have[106] and others.

3.3.7.2 Justice

Health care professionals and policy makers frequently face the question of justice in deciding who gets access to what – be that health services or health information. Secondary access to personal health information imports questions about justice by posing questions such as: Who, when and for what purposes should a person be able to access and use personal health information and then disseminate the results? According to traditional literature going as far back as Aristotle, readers need to distinguish between distributive justice (prospective) and corrective justice (remedial, retrospective). In health care distributive justice is usually exemplified by resource

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[101] Glenys Godlovitch, "Ethics," 502.
[102] Susan Sherwin, "A Relational Approach to Autonomy in Health Care," in *The Politics of Women's Health: Exploring Agency and Autonomy*, ed. Susan Sherwin (Philadelphia: Temple University Press, 1998), 19-47.
[103] Susan Sherwin, *No Longer Patient: Feminist Ethics and Health Care* (Philadelphia: Temple University Press, 1992), 35-57.
[104] Carol Gilligan, *In a Different Voice* (Cambridge: Harvard University Press, 1982).
[105] James Dwyer, "Global Health and Justice", *Bioethics* 19, no. 5-6 (2005): 460-75.
[106] Ruth Chadwick, Henk ten Have and Eric Meslin, "Health Care Ethics in an Era of Globalisation", in *The Sage Handbook of Health Care Ethics*, ed. Ruth Chadwick, Henk ten Have and Eric Meslin (London: Sage Press, 2009), 1-9.

allocation questions and corrective justice is exemplified by population health concerns.[107]

The approach to justice taken by consequentialists says roughly organize your health care services and resources so that it will result in the greatest overall good to the greatest number of affected parties. The deontological approach says something like allocate your resources in keeping with valid rights claims. But according to Godlovitch, "fair, equitable distribution does not tell us how far afield we should set the boundaries."[108] There are many different theories of distributive justice, including the six identified by Beauchamp and Childress:

1. To each person an equal share;
2. To each person according to need;
3. To each person according to effort;
4. To each person according to contribution;
5. To each person according to merit; and
6. To each person according to free-market exchange.[109]

3.3.8 Ethics and the Rationale for using Veatch and Daniels

An alternative model of justice has been developed by health theorists such as Norman Daniels, James Sabin and Dan Wikler who follow Rawls' line of political philosophy: a just health system – hence one that justifies secondary use of health information – is one which promotes fair equality of opportunity in the population

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[107] Population health as corrective justice addresses the needs of traditionally underprivileged and/or underserved communities that demonstrate lower health status.
[108] Glenys Godlovitch, "Ethics", 501.
[109] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 5th Ed. (New York: Oxford University Press, 2001), 228.

however broadly construed.[110] It calls for an open society and an informed constructive dialogue that generates a system that is accepted, decisive and public. Secondary use of personal health information for research purposes takes on public and societal dimensions in Canada for the following reasons:

1. Health services research in Canada is partly funded by taxpayer dollars through arms length agencies such as the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council. Canadian society, through its tax contributions to the agencies, has an indirect interest in the research.
2. These agencies perform a public oversight role to ensure that the health services research they fund is scientifically sound. If a research study exposes human participants to risk then there must be an assurance that the science of the study is methodologically sound. A study that fails to meet this condition would essentially put participants at risk with at worst no benefit to the individuals or to society; therefore it would be unethical to allow such studies to proceed.
3. The personal health information that is collected in the course of delivering publicly funded health services can be used in research studies that are unrelated to original purpose for collecting the information. Despite this disconnect in purposes researchers are legally accountable to society when they ask data stewards to disclose personal health information for use in their studies. This legal accountability is imposed by the various statutes in Canada governing the

[110] John Rawls, *A Theory of Justice* (Boston: Harvard University Press, 1971), 73; 83-90.

research use of personal health information and is enforced by the privacy commissioners of the various jurisdictions.

4. In Canada, research on human subjects is examined for compliance with ethics guidelines by research ethics boards whose oversight mandate comes from legislation passed by a democratically elected legislative assembly. Research governance is another dimension of public accountability separate from the funding dimension behind reasons 1 and 2.

These public and societal dimensions of secondary use of personal health information require ethical analysis of policy to include considerations for justice. At the time of writing there was no widespread policy framework in place to analyze ethically sound secondary use. Canada's Tri-Council Policy Statement provided strong guidelines which ethics boards and publicly funded institutions are obliged to follow[111], but it was not mandatory for non-publicly funded institutions. Those guidelines are the following:

Article 5.5 from the Tri-Council Policy Statement[112]

> Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:
>
> (a) identifiable information is essential to the research;
> (b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
> (c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
> (d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
> (e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and

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[111] 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* (Ottawa: Interagency Secretariat on Research Ethics, 2010), Chapter 5.
[112] Ibid, 62.

(f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

The Veatch framework outlined in section 3.3.9 was the only tool in common ethics literature that provided a way of recognizing and characterizing any action or policy. It did this by succinctly summarizing the current theories as outlined above and then attaching lexical ordering to the found attributes. However that alone did not carry forward with it any sense of public transparency and accountability and hence was neutral as to public acceptability. This gap was filled by the other common tool in policy ethics, namely the Daniels accountability for reasonableness (A4R) criteria.

As a result of combining the Veatch matrix with the A4R conditions of Daniels and Sabin it appeared that justice would be met in ways that otherwise were unaddressed without such tools. Thus, in order to conduct ethical evidence-based practice in the development of policy it was important to use ethics frameworks such as those of Veatch and Daniels that accounted for societal aspects of the use of personal health information by researchers.

3.3.9 Veatch Ethics Matrix

This part of the research design required the use of the matrix in Figure 4 below.

Figure 4 – Veatch Ethics Matrix[113]

	Consequentialist Principles (what are the likely effects)	**Duty and Rights based Principles (what are the duties or rights)**
INDIVIDUAL	Hippocratic Utility Beneficence/Non-malfeasance (Patient's best interests, Medical Paternalism)	Respect for Persons Autonomy, Fidelity,Veracity (Patient's preferences)
SOCIAL	Social utility Greatest happiness/greatest number (Public health programmes, preventive medicine)	Justice Fairness (Affirmative actions for rare conditions, redress historical wronged groups, Special needs support services & research)

The Veatch Matrix reflects in its columns approaches to ethics and in its rows the individual and the social levels. Thus, something like greatest good of the greatest number falls in the bottom box under the consequentialist column whereas personal preference falls in the top box in the rights column.

A few moments of reflection however draws attention to the need for resolving conflict where for example the greatest good of the greatest number might support a course of action that is incompatible with protecting or facilitating an individual's preference. It is at this point that Veatch provides another key concept, namely lexical

[113] Veatch, "Resolving Conflicts," 212

ordering.[114] Lexical ordering is not part of the matrix as such but is a meta-principle for conflict resolution. Anticipating details further on, in brief, lexical ordering according to Veatch requires assigning priority to deontological over consequentialist evaluation, other things being equal.

The Veatch Matrix, when supplemented by an appeal to Veatch's other key concept of lexical ordering[115], allows both for ante facto prescription of what a future policy should cover and post facto analysis of decisions and policy. It assists with future policy determination by having policy-makers characterize the implications and ethical structure of any prospective possible policy, then by prioritizing among the various squares in the matrix it allows for determination of a range of acceptable policies. It thus moves one from "possible" policies to "acceptable" policies.[116] Ordering is done on a theoretical pragmatist basis by appeal to currently held or identified societal ranking of values. Currently it is believed that all other things being equal, the deontological duty and rights-oriented values (right hand column) of respect for autonomy and of justice outweigh the consequentialist values (left hand column).[117] The Veatch approach operates at a lower level logically than does the Daniels' Accountability for Reasonableness test discussed in the next section. As such it is much closer to the ground and to the ethical evaluation of specific policies.

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[114] Veatch, "Resolving Conflicts," 210.
[115] Robert M. Veatch, *A Theory of Medical Ethics* (New York: Basic Books, 1981), 298-303.
[116] Ibid.
[117] James F. Childress, "The Normative Principles of Medical Ethics," in *Medical Ethics*, 2nd Edition, ed. Robert M. Veatch (Sudbury: Jones and Bartlett, 1997), 37.

3.3.10 Accountability for Reasonableness

The ethics evaluation through the Veatch matrix had to be supplemented by a tool that evaluated the structural soundness of potential policy exemplars. The Daniels' tool is a meta-tool for gauging the fairness, applicability and adaptiveness of any public policy. It is therefore not a direct screening tool and will not determine ethical acceptability of any policy, but is a rubric tool. In that way it is consistent with policies that are substantially abhorrent, but this is less of a concern in light of the use of the Veatch ethics matrix.[118] In essence the Daniel's tool consists of four tests that a policy must meet as necessary conditions in order to hold decision makers accountable for their decisions. The conditions are:

1. Relevance condition: the policy must establish a procedure whereby decisions are to be made on relevant reasons;
2. Publicity condition: the policy and the implementation must be fully transparent;
3. Revision and Appeals condition, i.e. revisability: decisions under the policy must be open to review and revision for fit with evidence; and
4. Regulative condition, i.e. enforceability: the decisions made under 1-3 above must be both enforceable and auditable.[119,120]

In order to gain traction in the ethical world and to close out unethical or repugnant policies, the Daniels' model requires a supplementary political position. The position that Daniels appeals to is John Rawls's quasi-Kantian approach of Justice as

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[118] An example of abhorrent policy is Nero's solution to making his rules public by posting them at the top of columns. Another egregious example is Nazi government policies that retroactively made formerly legal behaviour like associating with communists illegal and punishable.
[119] Norman Daniels and James E. Sabin, "Accountability for reasonableness: an update," *British Medical Journal* 337 (2008), 904-5.
[120] Daniels and Sabin, *Setting Limits Fairly*, 45. "Enforceability" is a term that is synonymous with the regulative condition described by Daniels and Sabin.

Fairness in his major work, *A Theory of Justice*.[121] However in this thesis it was the Veatch matrix that provided the ethical content to supplement the Daniels model.

It should be noted that in Canada the usual mechanism for instantiating A4R's transparency and accountability model was the formal function of the research ethics board acting under authority of health information privacy legislation.

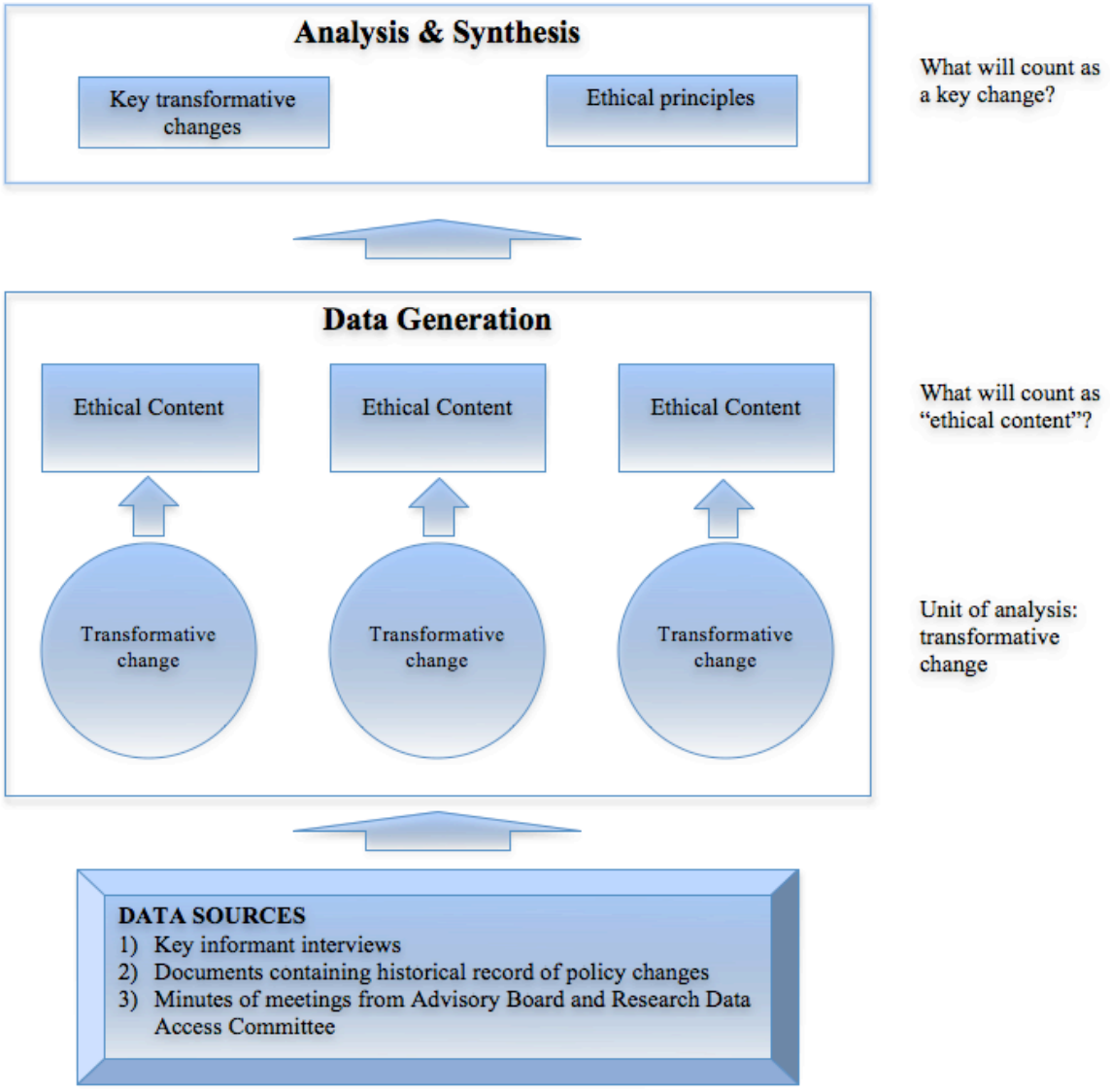
3.4 Research Question 3 – Policy Options from Paradigm Case(s)

3.4.1 Method – Case study

The paradigm case(s) were determined using the sort and filter method described in section 3.3.1. The objective of the third research question was to identify ethical policy options from the paradigm case(s). A descriptive case study design was used to identify these policy options. See Figure 5 for the study approach.

[121] Rawls, *A Theory of Justice*, 221-228.

Figure 5 – Case Study Approach



The case study approach had two goals: 1) Identify the ethical content brought to bear in the evolution of the paradigm policy and 2) Synthesize this content so that policy makers can look to this organization's experience to inform ethics-based development of data release policy for research.

Data collection consisted of seeking transformative changes to data release policy by examining documents related to changes in data release policy, interviewing key informants regarding data release decisions and recollections of those decisions or other events that led to changes in policy. Thematic analysis techniques were employed to generate higher order data by coding interview transcripts, relevant document passages, and researcher field notes. Coded elements were then analyzed for their ethical content as informed by frameworks created by each of Veatch[122] and Daniels.[123]

3.4.2 Case study unit of analysis

The selection of a unit of analysis in part determines the data collection strategy. In the Yin methodology data collection is synonymous with gathering case study evidence.[124] Several options emerged as a possible unit of analysis for this case study. They were:

1. The data release policy.
2. The timeline of the changes to the data release policy.
3. A transformative change to the data release policy.

Policy is usually not static in nature; it develops over time in response to events that are either internal to an organization or external to it. A data release policy represented a certain snapshot in time and would contain an accumulation of ethical considerations but the policy itself was always an end product of development. Identifying ethical considerations contained in a static policy document may omit ethical

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[122] Veatch, "Resolving Conflicts," 212.
[123] Daniels and Sabin, *Setting Limits Fairly*, 2008, Chapter 4.
[124] Yin, *Case Study Design*, 2009, 99-126. Arguably there is a distinction to be made between "data" and "evidence" in that data is thought to be theory-neutral, presupposing no specific theoretical framework, whereas "evidence" is inevitably theory-laden and thus not neutral.

considerations that may have been brought up during policy development but are not obvious in the policy itself.

A timeline of changes to policy was contemplated as the unit of analysis in the case study. This choice was an improvement over using only the policy itself because potentially multiple documents and events that covered the evolution of the policy could be examined. This expanded scope of examination could reveal ethical considerations that could be tied to changes in policy. However it was possible the changes with ethical content were few in comparison to the totality of changes, leading to an inefficient search for ethical content.

Looking at events that transformed policy was the next candidate for the unit of analysis. Those who were part of the organization at the time may recall the discussions taking place in the wake of these transformative events. They may recall ethical considerations that could have informed the process for changing the policy. This recall is testimony that could guide the search for ethical content among the changes that a policy could undergo over its lifetime. The case study was designed with the idea that testimony was an important component of the evidence gathered. Therefore transformative events were chosen as the most appropriate case study unit of analysis.

3.4.3 Case Study Propositions

In order to clarify the collection of data in the case study, Yin recommends creating study propositions that serve as overall guidelines throughout the case study

process.[125] Furthermore, the ethical frameworks of Veatch and Daniels provided theoretical content that assisted in the formulation of these propositions and sharpened the focus of data collection.[126] The propositions outlined in Table 2 reflected the goal of identifying ethical content in the development of the paradigm policy.

Table 2 - Case Study Propositions

Proposition	Comment
1. There are ethics-based principles to discover and describe in the evolution of the data stewardship policy.	
a) These principles will be suggested by key informants and through the examination of decisions that transform policy.	
b) The principles can be sorted into the ethical frameworks of Veatch (1995) and Daniels (2008).	
2. What role, if any, did ethical considerations play whenever the organization was faced with a change to data release policy?	
a) Were decision makers aware that ethical considerations weighed in on their decisions?	
b) If they were aware then where did decision makers get the ethical content that describes the "ought"?	This might become a question for the interviews.
3. Did ethical principles mainly guide the trajectory of the policy changes examined or were they a secondary factor?	

[125] Yin, *Case Study Design*, 2009, 28.
[126] Yin, *Case Study Design*, 2009, 130.

3.4.4 Data collection

The major sources of evidence were found in policy documents, the interviews of key informants to policy changes and field notes taken by the author.[127] The interviews were conducted in a semi-structured format using the script set out in Appendix D.

[127] Lyn Richards and Janice M. Morse, *Readme First for a User's Guide to Qualitative Methods*, 2nd Ed (Thousand Oaks: Sage, 2008), 115-116. In qualitative methodologies the field notes taken by researchers during and after a key informant interview are a valid source of data.

Chapter Four: **RESULTS**

4.1 Introduction

The search for policy exemplars occurred from October 2011 to January 2012 and began with a search of the academic literature. As indicated previously in section 3.3.1, in order to avoid bias, direct contact with individuals at the organizations was not made until progress was made independently on the first two research questions and policy exemplars were found to be satisfactory candidates for the third research question, i.e. the case study.

To be considered for the ethical analysis of the second research question a policy exemplar had to have the following characteristics:

- The policy came from an organization whose primary purpose is to provide researchers with access to personal health information.
- The organization operated within the legislative regime of one or more of the fourteen Canadian jurisdictions.
- The policy was readily and publicly accessible. For example, a policy document that is posted on the organization's website is considered to be readily and publicly accessible.
- The organization was a going concern and actively processing data access requests.

4.2 Question 1 – Identify Potential Policy Exemplars

4.2.1 Identify Organizations

A search of mandatory reports filed to the privacy commissioners of Canadian jurisdictions produced the following organizations with publicly available privacy

policies: Ontario Institute for Clinical and Evaluative Sciences (ICES), Cancer Care Ontario, Inscyte.

A key informant suggested the following organizations as potential exemplars: Manitoba Centre for Health Policy (MCHP) and Population Data BC (PopDataBC, formerly the Centre for Health Services and Policy Research or CHSPR), Veteran's Health Administration and Kaiser Permanente Division of Research.[128]

The following four Canadian research-based organizations are mentioned in a paper commissioned by the Information and Privacy Commissioner of Canada: MCHP, PopDataBC, ICES, and The Population Health Research Unit of Dalhousie University (PHRU).[129] Each of these organizations is a research institute affiliated with universities in Canada.

4.2.2 Initial Evaluation as Policy Exemplars

The criteria listed in Section 4.1 were used in the initial evaluation of the organizations listed above (see section 4.2.1). Evaluation consisted simply of checking for the existence of the each of the four criteria as seen in Table 3.

Table 3 - Initial Evaluation of Organizations

Site	Primarily Research?	Canadian?	Policy accessible?	Active?
Manitoba Centre for Health Policy (MCHP)	Y	Y	Y[130]	Y
Ontario Institute for Clinical and	Y	Y	Y[131]	Y

[128] ACKNOWLEDGEMENT: Dr. Tom Noseworthy, Professor, Department of Community Health Sciences, Faculty of Medicine, University of Calgary.
[129] Donald J. Willison, *Use of Data from the Electronic Health Record for Health Research – current governance challenges and potential approaches* (Ottawa: Information and Privacy Commissioner of Canada, 2009), 22-23.
[130] Manitoba Centre for Health Policy, *Privacy Code*.
[131] Institute for Clinical and Evaluative Sciences, *Privacy Code: Protecting Personal Health Information at ICES*, accessed 2011 Oct 25, http://www.ices.on.ca/file/ICES_Privacy_Code_July_2011_v9new.pdf.

Site	Primarily Research?	Canadian?	Policy accessible?	Active?
Evaluative Sciences (ICES)				
Population Data BC (formerly CHSPR)	Y	Y	Y[132]	Y
Population Health Research Unit (Dalhousie University)	Y	Y	Y[133]	N[134]
Cancer Care Ontario	N	Y	See ICES above	Y
Ontario Stroke Network (formerly the Registry of the Canadian Stroke Network)	Y	Y	See ICES above	Y
Inscyte	N	Y	Y	Y
Veteran's Health Administration Office of Research and Development	Y	N	Y	
Kaiser Permanente Research Centers	Y	N	See below	See below
- Northern California	Y	N		
- Northwest Center of Research	Y	N	Y	Y

Of the organizations that were evaluated three fully satisfied the initial screening criteria: Manitoba Centre for Health Policy (MCHP), Ontario Institute for Clinical and Evaluative Sciences (ICES), and Population Data BC (PopDataBC). They proceeded to further analysis.

The three candidates differ in procedures and in functions. However, it is important to note that while the three organizations facilitate data access they do not have the mandate to approve data access requests. That function is the mandate of a different body, typically the custodian or data steward. This has implications for policy options discussed later in the thesis.

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[132] Population Data BC, *Privacy Policies and Procedures*, accessed 2011 Nov 22, http://www.popdata.bc.ca/adminpanel/files/documents/privacy/PrivacyPolicy2009%20FINAL.pdf.
[133] Population Health Research Unit, *Data Access Guidelines and Procedures*, accessed 2011 Nov 22, http://www.phru.dal.ca/data_access/Data%20Access%20Request%20Guidelines%20and%20Procedures.doc.
[134] Based on reports published to the website the most recent publication activity occurred in Nov 16, 2010.

4.2.3 Post Hoc Observations

It appears that each of the three selected organizations operate in comparable legislative regimes. In the policy document of each organization, the relevant provincial legislation governing the collection, use and disclosure of personal health information is specified as seen in Table 4.

Table 4 - Legislation Governing Selected Organizations

Organization	Governing Legislation
MCHP	Personal Health Information Act, CCSM c P33.5 Freedom of Information and Protection of Privacy Act, CCSM c F175[135]
ICES	Personal Health Information Protection Act, 2004, SO 2004, c 3, Sch A General, O Reg 329/04
PopDataBC	Freedom of Information and Protection of Privacy Act, RSBC 1996, c 165

The respective policy document of each of three organizations also mentions the Personal Information Protection and Electronic Documents Act (PIPEDA), the federal legislation that asserts jurisdiction over personal information collected by commercial organizations that crosses provincial boundaries. All three organizations adopted the *Model Code for the Protection of Personal Information* in their respective policies.[136,137,138] This code is a set of principles known as the fair information principles and can be found in Schedule 1 of PIPEDA.[139]

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[135] Manitoba Centre for Health Policy, *Privacy Code*, 1.
[136] Manitoba Centre for Health Policy, *Privacy Code*, 3-8.
[137] Institute for Clinical and Evaluative Sciences, 1-7.
[138] Population Data BC, 24-25.
[139] *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5.

As pointed out in section 2.3.3 however, the effect of PIPEDA has yet to be tested in the courts when it is applied to personal health information collected by provincial data stewards such as a health authority or a family physician. In addition PIPEDA contains a provision that allows recognition of provincial legislation that is "substantially similar" to it. This means that organizations subject to provincial legislation deemed substantially similar are exempt from PIPEDA. At the time of writing the only legislation in Table 4 that had been declared substantially similar was Ontario's Personal Health Information Protection Act.[140] Other jurisdictions have been held to be substantially similar to PIPEDA – for example Alberta's *Personal Information Protection Act* but not Alberta's *Health Information Act*[141] – but they have not been included in further discussion in this section because they did not provide potential exemplar organizations for consideration.

4.3 Question 2

4.3.1 Scoring of Organizations – Veatch Matrix

Table 5 presents a summary of the scoring for the three organizations. All three achieved the same score.

Table 5 - Scoring of Organizations on Veatch Matrix

Veatch principle	MCHP	ICES	PopDataBC
Individual consequentialism	1	1	1
Individual deontology	1	1	1
Social consequentialism	1	1	1
Social deontology	0	0	0
TOTAL	**3**	**3**	**3**

[140] Office of the Privacy Commissioner of Canada, "Substantially Similar Provincial Legislation", accessed 2012 Jan 06, http://www.priv.gc.ca/leg_c/legislation/ss_index_e.asp.
[141] It is under the *Health Information Act* that personal health information is governed, and not the *Personal Information Protection Act*.

4.3.2 Scoring of Organizations – Accountability for Reasonableness (A4R)

Table 6 presents a summary of the scoring for the three organizations. All three achieved the same score.

Table 6 - Scoring of Organizations on A4R Conditions

A4R Condition	MCHP	ICES	PopDataBC
Relevance	1	1	1
Publicity	1	1	1
Revisability	1	1	1
Enforceability	1	1	1
TOTAL	**4**	**4**	**4**

4.3.3 Privacy Policy and Data Access Policy

In two of three organizations the data access policy was contained substantially within the privacy policy and to a lesser extent the data access forms available on the public website. Furthermore the examination of privacy policy provided relevant examples of the ethical principles at play in the tension between secondary use of health information and protection of privacy. The regulation of research activities was situated within privacy legislation in all three provinces, which in turn compelled these organizations to make protection of privacy the paramount consideration in its policies.

4.3.4 Manitoba Centre for Health Policy (MCHP)

As seen in Table 7 the MCHP privacy policy[142] referred to ethical principles that cover three of the four quadrants in the Veatch matrix. That is, all but the social deontological quadrant was represented in the privacy policy. This policy made clear that MCHP discloses health information to researchers: "Access to data are allowed for

[142] Manitoba Centre for Health Policy, *Privacy Code*.

approved research projects;"[143] "Each project that requires access to the Population Health Research Data Repository will be granted access by MCHP to only those data that are required for the specific project."[144]

Table 7 - Ethical Principles of MCHP policy situated in the Veatch Matrix

Veatch quadrant	Excerpts from policy[145]	Page
Social Consequentialist	Public benefit - the results of the linkage are expected to contribute to: The identification, prevention or treatment of illness, disease or injury; scientific understanding relating to health; The promotion and protection of the health of individuals and communities; or Improvements in health system policy and management.	9
	MCHP policy limits data access to researchers, programmers, and graduate students who meet these strict protocols in order to protect the security and confidentiality of the data and to ensure research undertaken is credible and contributes to the expansion of knowledge for the public good.	2

[143] Ibid, 5.
[144] Ibid, 4.
[145] Ibid.

Veatch quadrant	Excerpts from policy	Page
Individual Consequentialist	[Non-malfeasance] Anonymity is typically maintained by ensuring that any table cell does not contain less than five individuals (patients or physicians) on which data is presented.	5
	[Non-malfeasance] Even though the data are anonymized MCHP continues to apply the same standards that would be required if the data contained accessible personal identifiers under PHIA or FIPPA.	1
	[Non-malfeasance] Principles and procedures for ensuring confidentiality and security of anonymized data are strictly enforced in order to respect the privacy of users and providers of the health care system, and to protect data against loss, destruction or unauthorized use.	3
	Security safeguards protect information against loss or theft, as well as unauthorized access, disclosure, copying, use, or modification. MCHP will protect anonymized health information regardless of the format in which it is held.	7
Individual deontological	Principle 3 – Consent When researchers seek to link prospectively collected survey data with administrative data, informed consent of the individual is required prior to the link.	5

Table 8 illustrates places in the policy where ethical principles were in conflict and how the conflict appeared to be resolved. Veatch refers to the method of resolution as lexical ordering. Of particular note is the row in which individual consequentialist, i.e. non-malfeasance when disclosing health information, was ranked above individual deontological, i.e. autonomy requires informed consent by the subject of the information. It is here that confusion can develop because it appears that "public benefit" (social consequentialist) and "consent" (individual deontological) are in conflict.

In actual fact, "non-malfeasance" is a hidden principle in this statement because the research ethics board (REB) is a vehicle that can grant of waiver of consent. In the waiver process the REB first determines if obtaining consent is feasible or practical. If

the board finds that obtaining consent is neither feasible nor practical they then evaluate potential harms that could come to the subjects whose information is disclosed to the researcher. This latter activity clearly falls into the principle of non-malfeasance which is an individual consequentialist principle. At the REB it is therefore the individual consequentialist principle that is in conflict with the individual deontological principle. Through REB review this conflict is resolved by lexically ranking the former over the latter, paving the way for data release to the researcher.

Table 8 - Lexical ordering of MCHP ethical principles

Principles ranked	**Excerpts from policy**[146]	Page
Social consequentialist is ranked above all other principles.	Access to data are allowed for all approved research projects.	5
Social consequentialist is ranked above all other principles.	Each project that requires access to the Population Health Research Data Repository will be granted access by MCHP to only those data that are required for the specific project.	4
Social consequentialist ranked above individual consequentialist	As part of the approval process, it must be determined that the [data] linkage is not detrimental to the individual concerned [non-malfeasance] and the benefits to be derived must clearly provide public benefit.	6
Individual consequentialist is ranked above individual deontological	As such, in accordance with FIPPA - section 47 and PHIA - sections 22 and 24, researchers do not seek individual consent for use of these data for research and statistical purposes.	4

[146] Ibid.

Table 9 shows the places in the policy where the conditions of Daniels' Accountability for Reasonableness are satisfied. All A4R conditions were satisfied when the website as well as the privacy policy of MCHP were examined.

Table 9 - A4R conditions from MCHP policy

A4R Condition	Excerpts from policy	Place
Relevance	The basic model for providing access is based on the principle that the database is owned by the parent Manitoba organization that contributed the specific data.[147] Proposed research using Repository data must therefore be approved through a process which includes writing and submitting a proposal for the study.	Website[148]
Publicity	MCHP will make information about its policies and practices relating to the management and protection of anonymized information readily available upon request. Information regarding policies and practices will be available in printed form and/or on its Web site — www.umanitoba.ca/centres/mchp/ This information will be made available in a form that is generally understandable.	Privacy Code[149]
Revisability	MCHP will investigate all complaints within appropriate timelines. If a complaint is found to be justified, MCHP will take appropriate measures including, if necessary, amending its policies and practices and/or disciplining staff.	Privacy Code[150]
Enforceability	MCHP will inform individuals who make inquiries or lodge complaints of the existence of relevant complaint procedures, including utilization of the Provincial Ombudsman, if they are not satisfied with the University of Manitoba outcome.	Privacy Code[151]

[147] Approval for access comes not from MCHP but from the providers of the health information, e.g. Manitoba Health. MCHP is a facilitator for data access.
[148] Manitoba Centre for Health Policy, "Applying for Access", accessed 2011 Nov 15, http://umanitoba.ca/faculties/medicine/units/community_health_sciences/departmental_units/mchp/resources/access.html.
[149] Manitoba Centre for Health Policy, *Privacy Code*, 8.
[150] Ibid, 8.
[151] Ibid, 8.

4.3.5 Institute for Clinical and Evaluative Sciences (ICES)

As seen in Table 10 the ethical principles in the ICES data access policy can be placed in three of the four Veatch quadrants. As was the case in the MCHP policy the quadrants are social consequentialism, individual consequentialism, and individual deontology. The ICES privacy policy is clear about its use of personal health information: "ICES is an independent, non-profit organization that uses population-based, de-identified health information to produce knowledge on a broad range of health care issues."[152]

However, unlike MCHP or PopDataBC there is no data access request form that is publicly available on the ICES website. The website mentions that one way to obtain access to ICES data is to become an ICES scientist.[153] That is, only accredited ICES scientists have direct access to the individual-level personal health information. This type of data access is characterized by Willison as an enclave model.[154]

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[152] Institute for Clinical and Evaluative Sciences, *Privacy Code*, 8.
[153] http://www.ices.on.ca/webpage.cfm?site_id=1&org_id=26&morg_id=0&gsec_id=5314&item_id=5382, accessed 2011 Nov 22.
[154] Willison, *Use of Data*, 22-23.

Table 10 - Ethical Principles of ICES policy situated in the Veatch Matrix

Veatch quadrant	Excerpts from policy[155]	Page
Social Consequentialist	As a prescribed entity, ICES uses health information for the following purposes: To conduct studies that contribute to the effectiveness, quality, equity and efficiency of health care in the province of Ontario; To carry out population-based health services research that is relevant to clinical practice and health policy development; To document province-wide patterns and trends in health care delivery; To develop and share evidence to inform decision-making by policy makers, managers, clinicians, planners and consumers; To engage and promote collaborative discussion among Health Services Research Scientists and decision-makers; To train health research scientists and promote a wider understanding of clinical epidemiology and health services research.	1
	Our unbiased evidence provides… a stimulus for discussion of practical solutions to optimize [scarce] resources.	8
Individual Consequentialist	[Non-malfeasance] As a first use, all personal health information will be de-identified and health card numbers will be encrypted prior to use for all statistical and evaluative purposes.	2
	[Non-malfeasance] If a new purpose is subsequently identified for the use of anonymous administrative data for which ICES has custodial responsibility, the new purpose will be identified prior to use and will be articulated in a written and ethically–approved proposal.	3
	[Non-malfeasance] The onus, in this case, is on the REB to agree there are high standards in place for privacy and security of the information collected, and that the purpose of the collection serves the public interest.	3
	ICES will not collect PHI indiscriminately. Both the amount and type of information collected will be limited to that which is necessary to fulfill the identified purposes.	4

[155] Institute for Clinical and Evaluative Sciences, *Privacy Code*.

	ICES scientists and staff review all de-identified and/or aggregate information prior to its disclosure in order to ensure that it is not reasonably foreseeable in the circumstances that the information could be utilized, either alone or with other information, to identify an individual.	4
	ICES' agents/scientists and staff are prohibited from re-identifying any individual.	6
Individual deontological	ICES rarely engages in clinical trials. In such circumstances, the knowledge and informed consent of the individual is required for the collection, use or disclosure of primary clinical information.	3

Unlike MCHP, the ICES privacy policy does not explicitly appeal to the public benefit of research as a way to rank this social consequentialist principle above all others. The statement that comes closest is the following: "This section of the law permits health information custodians (HICs) to disclose personal health information (PHI) to a prescribed entity without consent for purposes of analysis or compiling statistical information relating to the management, evaluation, monitoring, allocation of resources to, or planning for the health care system."[156] However, as seen in Table 11 two other conflicts are lexically ordered: A social consequentialist principle trumps an individual deontological principle and individual consequentialist principle trumps an individual deontological principle.

Table 11 - Lexical ordering of ICES ethical principles

Principles ranked	**Excerpts from policy**[157]	Page
Social consequentialist is ranked above individual deontological.	This section of the law permits health information custodians (HICs) to disclose personal health information (PHI) to a prescribed entity without consent for purposes of analysis or compiling statistical information relating to the management, evaluation, monitoring, allocation of	1

[156] Ibid, 1.
[157] Ibid.

Principles ranked	Excerpts from policy[157]	Page
	resources to, or planning for the health care system.	
Individual consequentialist is ranked above individual deontological.	The onus, in this case, is on the REB to agree there are high standards in place for privacy and security of the information collected, and that the purpose of the collection serves the public interest. [Consent is not sought before the information is collected].	3

Table 12 shows the places in the policy where the conditions of Daniels' Accountability for Reasonableness were satisfied. All A4R conditions were satisfied when the website as well as the privacy policy of ICES were examined. As is the case with both MCHP and PopDataBC, external institutions serve oversight and appeals roles corresponding respectively to the A4R conditions of enforceability and revisability.

Table 12 - A4R conditions from ICES policy

A4R Condition	Excerpts from policy	Place
Relevance	ICES uses and/or collects only the information necessary to meet the pre-identified written and ethically-approved purposes. [That is, ICES will decide to collect information for research studies only after approval from its internal committees as well as external research ethics committees]	Privacy Code[158]
Publicity	Information about ICES' policies and practices, as related to the management and protection of personal health information, is available on ICES website – www.ices.on.ca. Descriptions of data holdings and statements of purpose are available on the ICES' website. Descriptions of studies in progress and publications from completed projects are also available on the ICES website. Additional information on the website includes: a) The name or title and address of the person accountable for ICES' policies and practices and to whom inquiries or complaints can be	Privacy Code[159]

[158] Ibid, 1.
[159] Ibid, 6.

A4R Condition	Excerpts from policy	Place
	forwarded; b) A description of the type of information held by ICES, including a general account of its use; and, c) A copy of any public information brochures (or other general information that explains ICES policies, standards or codes of practice.	
Revisability	ICES will investigate all inquiries and complaints in a timely fashion. If a complaint is found to be justified, ICES CPO/LPO will notify the President & CEO, Deputy CEO and such Directors of the organization as is appropriate. ICES will also take appropriate measures, including reviewing and amending its policies, practices and procedures as necessary.	Privacy Code[160]
Enforceability	We also have policies, practices, and procedures in place that have been audited and approved by the Information and Privacy Commissioner of Ontario. The Privacy Commissioner is mandated by law to review how we do things every three years.	Privacy Q&A[161]

4.3.6 Population Data BC (PopDataBC)

As seen in Table 13 the ethical principles in the Population Data BC data access policy can be placed in three of the four Veatch quadrants. As was the case in both the MCHP and ICES policies the quadrants are social consequentialism, individual consequentialism, and individual deontology. PopDataBC is explicit in its policy about the research use of health information and other types of personal information: "Facilitating access to such data for public-interest research purposes, while at the same time ensuring the protection of privacy and confidentiality of individuals about whom the

[160] Ibid, 7.
[161] Institute for Clinical and Evaluative Sciences, *Questions and Answers about Information Privacy Protection at ICES*, accessed 2012 Nov 22, http://www.ices.on.ca/file/Questions_Answers_Privacy_Feb2008.pdf, 3.

data pertain, is the mandate of Population Data BC;" [162] and "Population Data BC holds population-wide individual-level data to develop linkages among these data, and to support access to these data for approved research purposes." [163]

Table 13 - Ethical Principles of PopDataBC policy situated in the Veatch Matrix

Veatch quadrant	Excerpts from policy[164]	Page
Social Consequentialist	[beneficence] Policy 2.2 Population Data BC houses and protects Data to support research in human health, well-being, and development that is in the public interest.	12
Individual consequentialist	[non-malfeasance] Population Data BC treats *all* Data it holds and discloses as "Personal Information" and applies the same privacy protection standards required under FIPPA to all the Data, regardless of whether the Data contain personal identifiers or not.	9
	[non-malfeasance] Procedure 2.4 1. Identifiers are stored separately from Content Data. 2. Identifiers are used only for linkage. After linkage is complete, the identifiers are archived in a physically secure location. 3. Identifiers such as names or Personal Health Numbers (PHNs) are replaced with study-specific ID numbers for all research Data extracted for purposes of an approved research project. Only the study-specific ID numbers are disclosed to Researchers along with the approved Content Data.	12
	[non-malfeasance] Cell sizes may not be less than five as per standard guidelines for aggregation of data.	16

[162] Population Data BC, *Privacy Policies and Procedures*, 3.
[163] Population Data BC, *Research Data Access Framework*, accessed 2011 Nov 22, http://www.popdata.bc.ca/files/documents/RDAF.pdf, 1.
[164] Population Data BC, *Privacy Policies and Procedures*.

Veatch quadrant	Excerpts from policy	Page
Individual consequentialist	[non-malfeasance] Population Data BC and Data Stewards not only detail the uses and conditions under which Data are provided to Population Data BC, they also detail the conditions and requirements for Population Data BC's storage, retention, and destruction of Data.	17
	[non-malfeasance] Policy 5.4 Only a limited number of authorised personnel with restricted access are permitted to work with the Data.	15
	[non-malfeasance] Policy 7.1/7.2/7.3 Population Data BC will utilize stringent physical/technological/organizational safeguards to protect against loss, theft, unauthorized access, disclosure, copying, use, or modification of Data.	18 to 20
Individual deontological	[autonomy] Research ethics board review will confirm whether the consent(s) is/are appropriate for the requested uses of the Data.	13

The PopDataBC privacy policy, like that of MCHP, makes an explicit expression about its mandate to disclose health information to researchers and that it does so in the public interest: "Facilitating access to such data for public-interest research purposes… is the mandate of Population Data BC."[165] Research for this reason is connected to the ethical principle of social beneficence and as such falls into the social consequentialist quadrant of the Veatch matrix. Furthermore PopDataBC policy asserts the authority to disclose data for research and by doing so ranks the social consequentialist principle as paramount while other principles seen in Table 14 are lexically ranked lower than it.

Table 14 - Lexical ordering of PopDataBC ethical principles

Principles ranked	Excerpts from policy[166]	Page
Social consequentialist is ranked above all	[social beneficence] Procedure 2.2 Population Data BC has the authority pursuant to FIPPA and related Information Sharing Agreements to engage in	12

[165] Ibid, 3.
[166] Ibid.

Principles ranked	Excerpts from policy[166]	Page
other principles	Data linkage for research and statistical purposes, and to disclose Data in the form of Research Extracts to Researchers in accordance with signed Research Agreements between Researchers and Data Steward(s).	
Social consequentialist is ranked above individual consequentialist.	[social beneficence over individual non-malfeasance] (b) any record linkage is not harmful to the individuals that information is about and the benefits to be derived from the record linkage are clearly in the public interest,	7
Social consequentialist is ranked about individual deontological	[social beneficence over autonomy]Population Data BC and Researchers with approved access to Data collected by the designated public bodies are not required to seek individual consent for the use of those Data for research and statistical purposes.	13
	[social beneficence over autonomy] Facilitating access to such data for public-interest research purposes, while at the same time ensuring the protection of privacy and confidentiality of individuals about whom the data pertain, is the mandate of Population Data BC	3

Table 15 shows the places in the policy where the conditions of Daniels' Accountability for Reasonableness are satisfied. All A4R conditions were satisfied when the data access and privacy policies of PopDataBC were examined. As is the case with both MCHP and ICES, external institutions serve oversight and appeals roles corresponding respectively to the A4R conditions of enforceability and revisability.

However, of the three organizations PopDataBC has the most comprehensively and publicly expressed data access policy. Anyone who wishes to know the conditions under which personal health information will be disclosed to researchers can find them on the website and in particular by reading two documents: *Privacy Policy and Procedures* and *Research Data Access Framework*.

In light of the above, PopDataBC became the focus of attention in later stages of the data collection.

Table 15 - A4R conditions from PopDataBC policy

A4R Condition	Excerpts from policy	Place
Relevance	Policy 5.5 Population Data BC will only disclose Data to Researchers where such disclosure has been authorized by the relevant Data Steward(s) in accordance with a Research Agreement signed between the Data Steward(s) and Researcher	Privacy Policy[167]
Publicity	Policy 8.1 Population Data BC makes information about its policies and procedures relating to the management and protection of Personal Information readily available on its website or upon request.	Privacy Policy[168]
	The purpose of this framework is to provide a transparent mechanism for enabling access to data for research purposes while preserving the integrity and confidentiality of the data and retaining the integrity of data stewardship of the Public Bodies. This framework outlines general considerations in the adjudication of Data Access Requests.	Research Data Access Framework[169]
Revisability	Where challenges [to policy] are found to be justified, they will be addressed directly. This may include changing practices if needed.	Privacy Policy[170]
Enforceability	If Population Data BC learns of or suspects noncompliance with a Research Agreement, Population Data BC will immediately notify all relevant public bodies that are responsible for the response.[171]	Research Data Access Framework[172]

[167] Ibid, 15.
[168] Ibid, 21.
[169] Population Data BC, *Research Data Access Framework*, 2.
[170] Population Data BC, *Privacy Policies and Procedures*, 23.
[171] Public bodies include the Office of the Information and Privacy Commissioner. This office has the power to make binding rulings on matters falling within the legislation (in particular FIPPA) that governs the activities of Population Data BC.
[172] Population Data BC, *Research Data Access Framework*, 7.

4.3.7 Selection of case study exemplar

All three organizations achieved the same score on both the Veatch matrix and A4R conditions. However, upon closer examination of the policies PopDataBC had the most liberal data access position because its default stance was to give researchers direct access to individual-level data while the default stance of each of ICES and MCHP was to provide indirect access through accredited individuals only. Furthermore, PopDataBC was the only organization to post a document on its website containing the data access policy in addition to posting its privacy policy. The other organizations embedded its data access policy within the privacy policy. Therefore the data access policy of PopDataBC was selected as the policy exemplar. PopDataBC accepted an invitation to participate in the case study portion of the thesis.

4.4 Question 3

4.4.1 Preamble

Population Data BC describes itself as a "multi-university, data and education resource facilitating interdisciplinary research on the determinants of human health, well-being and development."[173] Their data holdings come from such provincial data stewards as the Ministry of Health Services, the BC Vital Statistics Agency and WorkSafe BC.

4.4.2 Data Collection and Analysis

Evidence collected from PopDataBC came from the following sources: Documents downloaded from the public website, semi-structured interviews with key informants at PopDataBC and documents provided by key informants.

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[173] Population Data BC, homepage at http://www.popdata.bc.ca, accessed 2011 Dec 7.

I contacted two board members some time in January 2012 who had historical knowledge of the organization spanning 23 years. They agreed to participate as key informants and recommended other key informants who worked within the operational framework of the organization.

Five key informant interviews were conducted from February 22 to February 29, 2012. One of the interviews was facilitated through a teleconference while the remainder was done in person. One of the interviews was conducted with two informants while each of the rest was done with one informant.[174] The informants either serve on the advisory board of PopDataBC, are heavily involved in its operations or do both.

The interviews were transcribed and the coded using the methods suggested by Richards and Morse.[175] The software package NVivo was used to assist with the coding process.

4.4.3 Chronological development of organization

The data holdings at PopDataBC evolved from a predecessor called the BC Linked Health Database. The latter had been accessible to researchers since 1996 and was managed by the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia. Table 16 contains a chronological summary of the development of PopDataBC.

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[174] ACKNOWLEDGEMENT: I would like to acknowledge with gratitude the individuals at Population Data BC who agreed to participate in the case study interviews.
[175] Lyn Richards and Janice Morse, *Readme First*, 133-151.

Table 16 - Chronological development of Population Data BC

Time Period	Event or Milestone
1989	Initial discussions about creating a linked health database at CHSPR
1989 to 1996	Negotiations with data stewards for creation of linked health database; formation of data access policy
1996	BC Linked Health Database is available for access requests by researchers
2003	Flow of linking data elements is suspended
2009	Control and management of BC Linked Health Database passes from CHSPR to Population Data BC

4.4.4 Transformative events to be examined

As mentioned in section 3.4.2 the case study unit of analysis was an event that transformed data access policy. The following three events produced transformative changes to policy and were analyzed within the ethical frameworks of Veatch and Daniels.

1. Data Access policy of the BC Linked Health Database
2. The end of collegial review of data access requests with one data steward
3. Population-based cohorts

The above three events stood out during interviews as going to the heart of Accountability for Reasonableness (A4R). They were illustrative of openness and accountability matters.

4.4.5 Data Access policy of the BC Linked Health Database

The first data access policy associated with the data holdings of PopDataBC can be traced back to 1996 when the data repository was known as the BC Linked Health Database. Several informants recalled the collegiality of the policy development process between CHSPR and the data steward:

[Interviewee 3]: It was awfully collegial and collaborative, I mean everybody was on the same page...

[Interviewee 2]: It was not like, any kind of fraught process.

A significant result of this collaboration was the inclusion of a guideline that the data steward agreed to use for reviewing data access applications.[176] The guideline contained a summary table that is reproduced in Table 17.

Table 17 - Levels of Ethical Challenge

	Person-specific information released	Personal identifiers released	Individuals affected	Individuals or families contacted
a	no	no	no	no
b	YES	no	no	no
c	YES	YES	no	no
d	YES	YES	YES - indirectly	no
e	YES	YES	YES - directly	YES

The letters represent an escalating scale of disclosure of identifiable health information to the researcher as follows:

a) No person-specific information is included in the data provided to the applicant.

b) Person-specific information is included in the data provided to the applicant, but all individual identifiers are first removed.

c) Person-specific information and identifiers are included in the data provided to the applicant, but no subsequent contact with individuals will occur and individuals are not expected to be directly affected in any way by the research.

[176] British Columbia Ministry of Health and Centre for Health Services and Policy Research (UBC), *Access Policy for Research Uses of Linked Health Data*, 1996, provided in electronic format by Population Data BC, 7-10.

d) Person-specific information and personal identifiers are included in the data provided to the applicant, and there is a possibility or likelihood that the information could indirectly affect future patient management for those individuals.

e) Person-specific information and personal identifiers are included in the data provided to the applicant, who intends to use the information for subsequent contact with subjects or their families.

The guideline satisfies the A4R condition of relevance. The risk of and need for identifying individuals guided the level of scrutiny required by the data steward when reviewing disclosure requests. It was understood that a) type requests were minimal risk and e) type requests required the most scrutiny because the researcher intended to use the disclosed information to contact individuals. This guideline led to data disclosure decisions made on relevant reasons because protection of privacy is a legislated responsibility of researchers, PopDataBC and the data steward. According to the recollection of key informants who were part of the development this policy outcome was intentional:

> [Interviewee 3]: So the whole idea was that you create something with which all parties are comfortable.
>
> [Interviewee 4]: It was a common language. And you see in an environment of good faith it makes sense because people will go right…
>
> [Interviewee 4]: It was never formally signed off but [the access policy] was the document that we shared with the core stewards back then. So it was recognized as being the policy insofar as it was formal. It wasn't anything like as formal as things are now but it was the policy.
>
> [Interviewee 2]: It's probably also worth saying that one of the big and internationally recognized things that was included in the original policy, the access policy, was an ethical framework, was what was called the levels of ethical challenge.

> [Interviewee 4]: That being done, though, things worked really well. Between 1996 and 2002 about 150 linkages occurred according to that policy that we got there, so it was based on that hierarchy of ethical challenge that seemed to work fine.

The access policy document was a precursor to the policy documents in place at PopDataBC and mentioned earlier in the thesis.

4.4.6 The end of a collegial review process with one data steward

In 2003 there was a deterioration of the collegiality that existed in 1996 between PopDataBC and a key data steward. Several informants mention a period that started in 2003 when the data steward suspended both the delivery of updated linking files and the approval of data access requests:

> [Interviewee 3]: But around 2003, this was the return of the ice age I think would be best way to describe it.
>
> [Interviewee 2]: So there was a time when we were not able to do linkage because we were not provided that data by the ministry. That was part of… the slowdown in the approval of projects but there was also this complete stoppage of some of the transfers of data to us.
>
> [Interviewee 5]: They had ceased the transmission feeling that you shouldn't be having identifier data anymore ...
>
> [Interviewee 5]: 2003 is when things slowed down by the Ministry. [They] sort of, I think, had some internal privacy event that caused some response and what had previously been 25 to 35, up to 40 projects a year that were going in and about that same amount getting approved in a given year with about 2 or 3 month response times, all of a sudden it stopped and almost nothing got approved in 2003 and then since then we haven't fully recovered.
>
> [Interviewee 5]: It ended up being we kept getting blockages.

The data steward abandoned the guidelines for approval for a reason that appeared to have nothing to do with the BC Linked Health Database. The data steward did not return to the guidelines at time of the informant interviews, as inferred by the following statement:

> [Interviewee 2]: And we tried to get them to … embrace the idea and modify the wording. And the … data steward was not on with that. I think that relates to the black box because the levels of ethical challenge really made things very transparent.

By abandoning the level of ethical challenge guideline by the data steward violated not only the relevance condition of A4R but also the publicity condition because when the data steward resumed review of data access requests they did so without being transparent about the review process:

> [Interviewee 2]: We have never been able to force upon the ministry, that they open the black box and let us see what's inside it.[177]

Also, after abandoning level of ethical challenge guideline, the data steward had allegedly expanded its scope of review beyond the privacy considerations of the guideline. Since the data steward no longer shared its review policy with Population Data BC informants could only point to clues to support this allegation:

> [Interviewee 5]: And that's part of the problem we're in is that … the Ministry is mainly trying to do the jobs of the other bodies.

> [Interviewee 5]: And they say it just takes a long time, they have to do their due diligence and review carefully, etc., etc. But you find they're reviewing Research Ethics Board's applications, they're reviewing the comments and the comments back and they're reviewing the grant applications and what the peer review comments were and what were the responses to the peer review comments. They're just going so far out of scope it's not funny.

> [Interviewee 3]: I think that's only one example of a more general tendency, again over the past 4 [or] 5 years or maybe even three years to want to dig into, to creep into methods. So getting involved in the process of "do the methods make sense", which is from our perspective completely out of scope [for the data steward].

> [Interviewee 3]: And again, as far as we're concerned that is out of scope, and if [the data steward's] preoccupation is, at it should be, privacy, then why are they asking questions about [research] methods?

Exceeding scope meant two things: 1) encroaching into areas of oversight that were already covered by others, e.g research ethics boards and scientific review by granting agencies, resulting in 2) increased time to an approval decision:

> [Interviewee 3]: So you gotta be careful that that six months isn't counted as ministry delay time, because it's not, except, and here what we would argue is that really depends on the nature of the questions going back to the researcher, because again if the questions are questions about

[177] The "black box" refers to the data steward's process for reviewing data access requests.

> [research] methods then our argument would be that those questions should never have gone to the researcher.
>
> [Interviewee 4]: There is something happening in [this one data steward], because all of our other data stewards approve quickly, that is preventing access.

Informants believed that data steward review should go no further than its statutory responsibility, i.e. ensuring that privacy is protected when they disclose data to researchers. The desire to see agreement on scope of review was shared by several informants and is best represented by this single passage:

> [Interviewee 4]: I think the biggest thing that ought to be done is that everybody come to agreement and get clarity on their roles…

Informants went on to say that delay time in approval is a form of data suppression, something they feel is unethical behaviour:

> [Interviewee 2]: The ethical thing to do is to use the data to inform public policy and … we're at least foolish and I think unethical not to be using them.
>
> [Interviewee 4]: That's why it's like those who don't want the data to be collected and used are engaging in what is fundamentally an unethical antisocial set of acts.
>
> [Interviewee 5]: I actually think it is completely unethical, unconscionable that there are blocks put into place for research access to data.

The outcome of data suppression is missed opportunities for public interest research. Data suppression, informants argue, denies benefit to society which falls into the social consequentialist quadrant of the Veatch matrix. Several informants stated that on the ethics of data suppression their position was influenced by the scholarship of Fiona Stanley, who argues that not using health and other types of personal information for research is a failure of duty.[178]

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[178] Fiona Stanley, "Privacy or public good? Why not obtaining consent may be best practice", *Significance* 7, no. 2 (2010): 72-75.

4.4.7 Population-based cohorts

In 2010 a data steward made a change to its review process for data access requests, specifically about study cohorts. For example a researcher requested disclosure of certain data fields for the entire population, regarded within PopDataBC as a population-based cohort or population-based study population. The data steward asked that the researcher justify the request for data on the entire population:

> [Interviewee 1]: So it's a change in policy because in the past the data stewards never asked for, never particularly asked for rationales for this kind of population-based study. It just happened in 2010, early 2010.
>
> [Interviewee 2]: The ministry right now is really reluctant to approve anything that is a population-based cohort so anytime somebody asks for a population-based cohort they [the researchers] need to provide a strong rationale for why that's required.
>
> [Interviewee 4]: A year ago or so I had some interchange with people in the [data] steward's office, right, suggesting that they weren't comfortable with the idea of population based linkage, that they thought everything should be done a sample basis and that somehow or another if we were doing population wide linkage that we were somehow violating a minimum disclosure rule.

Informants saw this requirement for rationales as another example of the data steward going out of scope in its approval process, moving beyond protection of privacy and into research methods:

> [Interviewee 3]: Why would you introduce potential sources of bias [by using a sample] when [the researcher could have] the population?
>
> [Interviewee 3]: The cohort thing, this sort of population-based cohort is one example of, something that's being scrutinized that actually takes time that you could argue they shouldn't be paying any attention to. So if [a researcher] comes in with ethics review and … with peer review, why is the ministry even looking at a question about cohorts?

Furthermore, since the data steward did not share its reason for requiring rationales with PopDataBC it violated the A4R condition of publicity.

Despite its objections Population Data BC acquiesced to this change in policy at the data steward by creating a review role for population-based cohorts. So, if a researcher wanted to use a population-based cohort then this reviewer at Population Data

BC would help the researcher write up the rationale in anticipation of the additional scrutiny by the data steward during its approval process:

> [Interviewee 1]: So the result was, going forward, if there's any project [involving] population-based study, before we submit the application to the data stewards we will do a very in-depth review of the project or the application.
>
> [Interviewee 2]: When I'm writing the rationales... I always put in things like "we are only asking for year of birth, not year and month", as to try to mitigate any potential risk for re-identification, and of course we always say that we have no intent of trying to re-identify people in any case.

The additional scrutiny increased the time taken to approve data access requests. A delay in approval that is caused by a data steward reviewing more about a data access request than required is a form of data suppression. As seen in section 4.4.6 the informants considered data suppression to be unethical because it puts up barriers to public-interest research which results in delayed or unrealized benefit to society. In the Veatch matrix data suppression violates the principle of social beneficence that falls into the social consequentialist quadrant.

4.5 Summary

Three Canadian organizations were considered as exemplars for further study because the data access policy of each satisfied all four A4R conditions and each had a similar score from the Veatch matrix evaluation. One of the three organizations was probed further through a case study in which events that transformed policy were examined. The case study revealed that over the course of time there was an ebb and flow of ethical behaviour by organizations involved with the data access approval process. In the next chapter recommendations for policy options regarding the secondary use of personal health information for research purposes will be informed by the

PopDataBC experience as well as the analysis of the data access policies of ICES and MCHP.

Chapter Five: **DISCUSSION**

5.1 Introduction

The main policy challenge for researchers who wish to use Canadian personal health information for their studies is to realize that Canada presents constitutional barriers to the free flow of personal health information across jurisdictional boundaries. Canada is a confederation of 14 jurisdictions that presents challenges for any policy that is intended to be national in scope. By constitutional convention and case law only the federal government and the 10 provincial governments have significant and independent constitutional and fiscal responsibility for health care. Each of the 10 provinces and 3 territories has almost exclusive jurisdiction over delivery of health care within its geographic territory and is the primary collector of personal health information for its inhabitants[179]. Therefore, due to the reality of Canadian Confederation the starting point to create a viable policy of secondary use of personal health information for research purposes appears to be within the provincial jurisdiction of health.

As was seen in Chapter two some guidance for policy makers was offered through the Canadian legal framework, Canadian policy literature and worldwide medical literature. Some of the literature provided clues as to what would be the most ethical policy to create in Canada. However examples of policy that can provide viable options in Canada were difficult to identify within the literature.

There were three research questions to be answered in this thesis as described in section 2.7. The outcome of the first question was a list of potential policy models that

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[179] Family physicians, dentists, and other health care professionals also collect personal health information within their clinics. However most of this information is beyond the reach of provincial governments.

could be subjected to the second question which evaluated the model for ethical soundness. The outcome of the second question was a list of three organizations operating in Canada facilitating research use of provincially collected personal health information. All three made its data access policy publicly available through its website. In examining the policies one organization stood out as having the most liberal data release policy: Population Data BC. It was development of the data release policy Population Data BC that was analyzed in more detail in the third research question.

From a policy perspective, ethics is concerned about the creation of good policy. This is not to be confused with medical bioethics which is concerned about doing right by the patient or research ethics which is concerned about doing right by the research participant. The predecessor to Population Data BC had a policy in place starting in 1996 that did right by public-interest research. It enjoyed a time period where its goal of data release for research was supported by all data stewards and reinforced through mutual agreement on a review guideline, namely the level of ethical challenge. Each party to the data approval process had a mutually exclusive scope of review and under such a collegial and transparent arrangement the review process was not beset by unjustified delays.

In this chapter policy options are explored based upon a synthesis of the evidence gathered to this point. Legal, literature and ethical perspectives set the stage for the policy options while the results of Chapter Four will inform those options from a Canadian context. Directions for future research will be proposed. Finally, a dissemination plan for the results and policy options will be presented.

5.2 Legal perspectives on Data Stewardship

The Canadian legal landscape for secondary use of personal health information can be characterized as 13 variations on a theme. As was seen in section 2.3 during the examination of Canadian legislation, the research use of personal health information was governed by privacy legislation in each of the 10 provinces and 3 territories. Each jurisdiction used an information and privacy commissioner or an ombudsman to regulate organizations that collected, used or disclosed personal health information. Furthermore the legislation of each of the 13 jurisdictions was clear about the treatment of personal health information that originated and stayed within its borders but less clear about the treatment of personal health information that was exported from or imported into its jurisdiction. In most of the jurisdictions consent for research *uses* of personal health information could be waived by a research ethics board. However, the decision to *disclose* that personal health information ultimately rested with the data steward who was under no legal obligation to honour a disclosure request for research purposes despite the approval from a research ethics board.

The legal landscape of Canada suggests the following oversight roles applicable to disclosure of personal health information for research:

1. The information and privacy commissioner to regulate disclosure and use of health information according to the statutes in force;
2. The research ethics boards to evaluate potential harms of proposed research to the subjects of the personal health information; and
3. The data stewards to ensure that privacy of the subjects of the personal health information is respected.

PopDataBC ran into difficulty with one of its data stewards about the interpretation of minimum disclosure of health information.[180] It is implied in the governing Act that a data steward release only the minimum amount of health information required to fulfill the research purpose.[181] Informants stated that whereas the data steward interpreted minimum disclosure as number of individuals for whom information was released, PopDataBC interpreted it as the number of data fields released to the researcher:

> [Interviewee 2]: We tended to take a, if you will, a column look at that. So [researchers] don't get fields that aren't required.

> [Interviewee 2]: And it seems to have shifted where there is as much concern about the rows as there is about the [fields]. And that's, that's where a lot of the complication comes in. Because when you're putting a cohort together, dropping off fields is quite easy, but being specific about what people you're including is lot more difficult.

The dispute over interpretation had caused an overlap in oversight roles. The construction of cohorts was usually overseen exclusively by a research ethics board because this activity falls under the rubric of research methods. When the data steward changed its approval policy to ask researcher to justify requests for cohorts that included the entire population it was intruding into the oversight role of the research ethics board. Furthermore, Population Data BC changed its policy to assist researchers with justifications whenever the latter asked for data disclosure of an entire population. So PopDataBC also intruded into the oversight role of the research ethics board. The outcome of such overlaps in oversight was longer approval times for data access requests.

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[180] Minimum disclosure refers to the amount of personal health information that a researcher is given to carry out the study.
[181] *Freedom of Information and Protection of Privacy Act*, RSBC 1996, c 165, S.35(1).

This policy outcome does not seem to have a sound ethical justification and was considered in section 4.4.7.

5.3 Ethics perspective on data stewardship policy

5.3.1 The lexical ordering of ethical principles in data stewardship

The ethics of policy for data stewardship start with the premise that research using personal health information provides benefit to society. However, that societal benefit is not risk-free in two ways. The first happens through inappropriate disclosure. If harm comes to individual members of that society by inappropriate disclosure of health information then data stewards may become reluctant to release information, thereby depriving society of the potential benefit of research based on this information. Another risk to society comes from the study based upon poor research design. Such a study may produce untrue or misleading results. Societal action that follows from these results may have detrimental effects to society.

Table 18 - Ethical principles of data access policy situated in Veatch matrix

	Consequentialist Principles	**Duty and Rights based Principles**
INDIVIDUAL	Waiver of consent (individual non-malfeasance)	Free and Informed Consent (autonomy)
SOCIAL	Research using personal health information (social beneficence)	

In Canada the legislative regime for research use of health information covers three quadrants of the Veatch matrix (see Table 18). Research is justified through social consequentialism in the sense that it brings benefits to society and is done in the public interest. Obtaining free and informed consent from research participants is justified

through the individual deontological principle of autonomy. Finally, the ability of research ethics boards to grant waiver of consent to use personal health information is justified through a proportionality test balancing the individual consequentialist principle of non-malfeasance with the social consequentialist principle of public interest research. As was seen in section 4.3 the data access policy of each of the three organizations provided examples of conflict between ethical principles. The conflicts that were resolved in policy consistently revealed a lexical ordering that placed the social consequentialist principle of research using personal health information at the top, the individual consequentialist principle of individual non-malfeasance next and the individual deontological principle of free and informed consent at the bottom.

The powers that REBs have under legislation to impose conditions on access to personal health information amount to a tool designed to achieve transparency, accountability and acceptability at a social level. The tool attempts to achieve a balance between the desire for privacy and the public interest in disclosure of information to researchers; it does so by imposing conditions for anonymizing identifiable information as much as possible so that any potential deleterious effect to any individual is minimized.

In summary the ethical principles that were identified in each data access policy can be connected back to the legal statutes governing the disclosure and use of personal health information. Those that wish to create organizations similar to the three studied in this thesis can look forward to a fairly consistent legislative regime in Canada on which to build policy. However none of the statutes of the various jurisdictions provide the ethical content for the policy. Rather it was in the creation of the data access policy of

each research organization (ICES, MCHP, PopDataBC) that the guiding ethical principles and their lexical ordering were fully realised.

5.3.2 Anonymization of Personal Health Information

All three organizations provided anonymized data to researchers as its default policy. PopDataBC however would on occasion provide identifiable data to researchers but this was very much the exception rather than the rule. The objective of anonymization was to respect the privacy of the subjects of personal health information. From an ethical perspective this practice was intended to avert harm to the individuals that were the subjects of the health information. This non-malfeasance falls into the individual consequentialist quadrant of the Veatch matrix.

Anonymization should be made clear when researchers make applications to the research ethics board (REB) for waiver of consent. The board considers potential harm to those whose personal health information is being used. If this information is anonymized at an early stage of disclosure, say before or shortly after transfer of health information to an organization that facilitates data access for researchers, REBs may consider the use of the health information to be of low enough risk to the individuals that a waiver of consent can be granted.

5.3.3 The transparency and accountability of data stewardship policy

In Section 4.2.3 it was observed that each of the three organizations used the same guideline from PIPEDA.[182] However of the three organizations PopDataBC made the most use of the *Model Code for the Protection of Personal Information* in publicly

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[182] *Personal Information Protection and Electronic Documents Act*.

articulating its policies on privacy protection and data access. Transparency on paper is an important step for any organization that wishes to follow the same path as these three organizations but in the Daniels A4R framework introduced in section 3.3.10 it is just one of the conditions, i.e. publicity.

PopDataBC and all responsible bodies once experienced a period where the relevance condition was satisfied. From 1996 to 2002 all data stewards used the same guideline to review data access requests. This guideline, known as the levels of ethical challenge, was congruent with the decision making process for each data steward because its primary responsibility and task was to ensure that the proposed research uses respected the privacy of the subjects of the health information.

The research ethics boards (REBs) had a role to play in the decision-making process that complemented that of the data stewards. Broadly speaking the REB oversight role was to review proposed research using PopDataBC data for its scientific and methodological soundness and to consider the potential harms to subjects of the health information as well as mitigation steps taken by the researchers to minimize harm. In short, research ethics boards reviewed proposed *uses* of PopDataBC data by researchers while the data stewards reviewed *disclosures* of PopDataBC data to researchers.

The enforceability condition of the Daniels A4R framework for the PopDataBC data access policy seemed to fall to the office of the information and privacy commissioner since it had the oversight authority for the legislation that governs the activities of PopDataBC, the data stewards, and the research ethics boards when personal health information is used in research. Informants indicated a close working relationship

existed between PopDataBC and the privacy commissioner to ensure that its activities conformed with the governing legislation.

Finally, the revisability condition of the A4R framework appeared to be satisfied in practice at PopDataBC. In section 4.4.7 a change in policy by one data steward was described that caused an adjustment in data access policy at PopDataBC. The adjustment for PopDataBC was to assist researchers in justifying requests for disclosure of data on the entire population. PopDataBC hoped that by pre-emptively responding to the data steward request for a justification it could reduce the approval time for the researcher.

5.4 Guiding advice to policy makers and research ethics boards

The options presented here are based upon the Canadian institutions and legislation that existed at the time of writing.

5.4.1 Anonymization of individual level health information

Personally identifiable information should be linkable but stripped of fields that would make the individual "readily ascertainable" before delivery to researchers.[183] This is a constraint that is called for by the individual consequentialist principle of non-malfeasance and would, for example, satisfy section 32(1) of the Alberta *Health Information Act* that states, "A custodian may disclose non-identifying information for any purpose."

5.4.2 Strict adherence to scope of review

Each oversight and review body should agree in writing amongst each other on the scope of review within its organization and make this agreement a public document –

[183] "readily ascertainable" is a term used in the definition sections of the *Health Information Act* section 1(1).

this is an A4R argument. From an Alberta perspective, as an example, the responsible bodies that participate in data access approval and their respective scope should be the following:

1. Office of the Information and Privacy Commissioner
2. The Research Ethics Boards named in the Alberta *Designation Regulation*
3. Custodians as defined in section 1(1)(f) of the Alberta *Health Information Act*
4. Data facilitation organization
5. Appeals board

5.4.3 Facilitation of data access as the only mandate

The organization that produces the data extracts for researchers should not have any other operational duty or purpose than to facilitate research. If the organization has duties besides its service role to researchers then delays in approval can occur that are external to the review process. Approval decisions would then be subject to reasons that are not relevant to facilitating research and therefore would be a violation of the relevance condition of A4R.

5.4.4 Enable scrutiny of approval process by researchers

This is an A4R requirement (appeals condition), but it is left to others to determine how this would be implemented. This thesis did not explore the appeals condition.

5.5 Study Limitations

5.5.1 English language material

The material covered in this thesis was limited by language to material available in English.

5.5.2 Literature Search and MeSH terms

The search terms "secondary use" and "data stewardship" were not among those in the Medical Subject Headings, or MeSH, catalogue. Therefore analogous terms were used as explained in section 2.1.3.

5.5.3 Time

For reasons of time constraint the researcher was unable to explore potential exemplars outside of Canada.

5.5.4 Access to Documents

The extent to which access to documents is a limitation is not possible to gauge. However it must be noted that the scope of material reviewed in this research was restricted to publicly accessible documents and those provided by the key informants.

5.5.5 Replicability

It was not possible to determine the extent to which results from Population Data BC would be transferrable or were indeed replicated in the other two organizations, namely MCHP or ICES.

5.6 Future research

5.6.1 Case study on Appeals Condition of A4R

The case study methodology was an effective way to track changes to data access policy over time and uncover the ethical dimensions of those changes. Subsequent studies on data access policy could include an extension of the case study to other Canadian organizations like MCHP or ICES. For example, the appeals condition of A4R was not explored in this thesis. A future case study on data access policy could focus specifically on appeals processes and the policy options that could be suggested.

5.6.2 Pilot study on Research Access to Personal Health Information

A more ambitious study to test the policy options suggested in this thesis could be built around a pilot project to facilitate research access to personal health information. Such a study would likely result from a provincial partnership between the information and privacy commissioner, one or more government ministries that hold personal health information and an academic institution that has inter-disciplinary faculty expertise in health informatics and public policy.

5.6.3 Public evaluation of ethics framework for policy analysis

The use of the Veatch matrix in combination with the Daniels and Sabin A4R conditions is a framework that could apply to other policy areas of health care. A workshop-style symposium could be crafted to present the ethics framework to policy makers, obtain feedback from participants and explore the viability of the framework as a policy tool. The proceedings of such a symposium would serve as a knowledge translation mechanism to policy makers.

5.6.4 Analysis of Requests for Data Access

This project would be a quantitative study of requests made by researchers for access to health information held by organizations that operate like ICES, MCHP and PopDataBC. The focus of such a study would be requests that are refused and the grounds for refusal. These kinds of requests could be analyzed using the ethics framework employed by this thesis to determine the consistency with which data access policy is applied.

5.6.5 A National Standard for Data Access

The legislative regime of each province and territory in Canada treats research access to personal health information similarly. Research access is regulated under the rubric of privacy in the respective acts of each province and territory. However any decision that permits data access within a province or territory does not have to be honoured by another province or territory. A future study could be performed to reconcile the differences in legislative regimes across Canada. The results of such a study could inform the recommendation of a national standard of access to personal health information for research purposes.

5.7 Dissemination of Results

5.7.1 Internal Education

It was discovered during the case study interviews that the participants' understanding of ethics was framed in terms of the work of research ethics boards and the concepts of research ethics found within the Tri-Council Policy Statement.[184] It is likely that this organization and others like it could benefit from a seminar that gives them the opportunity to reflect on their data access policy through the policy ethics framework of Veatch and Daniels that was used in this thesis.

5.7.2 Publication in health care policy journals

Certain sections of the thesis can be prepared for submission to health care policy journals. They include Section 2.3 (Canadian legislative frameworks), sections 3.3.8 to 3.3.10 (the policy ethics framework) and the case study methodology used to evaluate the development of data access policy.

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[184] Canadian Institutes of Health Research *et al*, *Tri-Council Policy Statement*.

5.7.3 Presentation at Academic Conferences

This thesis touches on topics that are germane to health services research, public policy ethics and more generally secondary use of personal health information. The author intends to make presentations at conferences where abstracts or posters based on this thesis are accepted.

5.7.4 Presentation to Case Study Participants

One of the commitments made by the author to the case study participants was to do a presentation of the study results with their team. This will be arranged when the thesis is ready for publication.

5.8 Concluding remarks and suggestions for policy guidance

5.8.1 National standards and repository

In light of the provincial nature of privacy legislation and the provincial power over matters of health in a province, it would be important to develop a national standard for interprovincial data transfer. Similarly it could be important to establish a mechanism for a national repository of personal health information, coupled perhaps with a repository for biosamples.

5.8.2 The ethics of seeking further contact with individuals following secondary analysis

Given current privacy provisions across Canada it is not normally appropriate for a researcher to try to re-identify the individuals whose personal health information was used through secondary access. However it can be very important for development and subsequent provision of appropriate health services to seek further clarifications at the individual level. It is therefore extremely important that there be oversight bodies fulfilling the role of research ethics boards to undertake review and provide guidance –

and where appropriate approval – that will determine when and how a researcher may seek further individual identifiable information.

Notwithstanding the importance of seeking information, under no circumstance should the researcher attempt to make direct contact given that the researcher is unknown to the individual. Such contact could erode trust and confidence in the public about the privacy of the information that they necessarily share with health professionals.

Recruitment of such individuals should occur and consent should be obtained only by a person or persons other than the researcher. Two suggestions would be 1) for a neutral agency – such as is in place with cancer registries – to be ascribed this function at the provincial and/or national level; and, 2) for a clinician with a direct health service relationship with the patient to provide that contact. The argument in favour of the former is that it is neutral across all types of research and with appropriate publicity conditions covering transparency and accountability could become a trusted public agency. An argument against it however is that it could become overly bureaucratic or inefficient if insensitive personnel occupy key positions of if otherwise well-functioning staff become too entrenched thereby making change difficult to introduce.

By contrast, looking at the clinician initiating contact, an argument in favour of this is that it is reasonable to suppose that there is a pre-existing good rapport between clinician and patient. However the very nature of that good rapport is the expertise and power differential which could make it difficult for a patient to understand what aspects are part of routine care as distinguished from those aspects to do with research follow-up.

Whichever route is chosen as the medium, it would be of the utmost importance that appropriate ethics education be in place as evidenced through certification under national standards.

5.8.3 People matter and political good will

As is apparent from section 5.8.2 it would be critical to ensure that all the key decision-makers and administrators can demonstrate a willingness to cooperate with each other, recognize the limits on their role capacity and do not engage in scope creep. The reason for this is that in a publicly accessible, publicly accountable and appropriately transparent process it is only by hiring and retaining competent and reflective managers and staff that the political will can be instantiated.[185]

[185] The astute reader will no doubt recognize this significance of virtue ethics and the role of the moral agent as described in 3.3.6.

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APPENDIX A: Key terms from the *Health Information Act*[186]

1(1) In this Act,

(c) "audit" means a financial, clinical or other formal or systematic examination or review of a program, activity or other matter under this Act;

(d) "collect" means to gather, acquire, receive or obtain health information;

(e) "Commissioner" means the Information and Privacy Commissioner appointed under Part 4 of the Freedom of Information and Protection of Privacy Act;

(f) "custodian" means

(i) the board of an approved hospital as defined in the Hospitals Act other than an approved hospital that is

(A) owned and operated by a regional health authority established under the Regional Health Authorities Act, or

(B) repealed 2008 cH-4.3 s18;

(ii) the operator of a nursing home as defined in the Nursing Homes Act other than a nursing home that is owned and operated by a regional health authority established under the Regional Health Authorities Act;

(ii.1) an ambulance operator as defined in the Emergency Health Services Act;

(iii) a provincial health board established pursuant to regulations made under section 17(1)(a) of the Regional Health Authorities Act;

(iv) a regional health authority established under the Regional Health Authorities Act;

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[186] *Health Information Act*, section 1(1).

(v) a community health council as defined in the Regional Health Authorities Act;

(vi) a subsidiary health corporation as defined in the Regional Health Authorities Act;

(vii) repealed 2008 cH-5.3 s18;

(viii) a board, council, committee, commission, panel or agency that is created by a custodian referred to in subclauses (i) to (vii), if all or a majority of its members are appointed by, or on behalf of, that custodian, but does not include a committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the Alberta Evidence Act;

(ix) a health services provider who is designated in the regulations as a custodian, or who is within a class of health services providers that is designated in the regulations for the purpose of this subclause;

(ix.1) the Health Quality Council of Alberta;

(x) a licensed pharmacy as defined in the Pharmacy and Drug Act;

(xi) repealed 2009 c25 s2;

(xii) the Department;

(xiii) the Minister;

(xiv) an individual or board, council, committee, commission, panel, agency, corporation or other entity designated in the regulations as a custodian,

but does not include

(xv) repealed 2008 cH-4.3 s18,

(xvi) a Community Board as that term is defined in the Persons with Developmental Disabilities Community Governance Act other than a Community Board that is designated in the regulations as a custodian;

(g) "data matching" means the creation of individually identifying health information by combining individually identifying or non-identifying health information or other information from 2 or more electronic databases, without the consent of the individuals who are the subjects of the information;

(k) "health information" means one or both of the following:

(i) diagnostic, treatment and care information;

(ii) registration information;

(k.1) "health information repository" means an agency, corporation or other entity designated by the Minister to act as a health information repository in accordance with Part 6.1;

(m) "health service" means a service that is provided to an individual for any of the following purposes:

(i) protecting, promoting or maintaining physical and mental health;

(ii) preventing illness;

(iii) diagnosing and treating illness;

(iv) rehabilitation;

(v) caring for the health needs of the ill, disabled, injured or dying,

but does not include a service excluded by the regulations;

(n) "health services provider" means an individual who provides health services;

(p) "individually identifying", when used to describe health information, means that the identity of the individual who is the subject of the information can be readily ascertained from the information;

(q) "Minister" means the Minister determined under section 16 of the Government Organization Act as the Minister responsible for this Act;

(r) "non-identifying", when used to describe health information, means that the identity of the individual who is the subject of the information cannot be readily ascertained from the information;

(s) "personal health number" means the number assigned to an individual by the Department to uniquely identify the individual;

(t) "record" means a record of health information in any form and includes notes, images, audiovisual recordings, x-rays, books, documents, maps, drawings, photographs, letters, vouchers and papers and any other information that is written, photographed, recorded or stored in any manner, but does not include software or any mechanism that produces records;

(u) "registration information" means information relating to an individual that falls within the following general categories and is more specifically described in the regulations:

(i) demographic information, including the individual's personal health number;

(ii) location information;

(iii) telecommunications information;

(iv) residency information;

(v) health service eligibility information;

(vi) billing information,

but does not include information that is not written, photographed, recorded or stored in some manner in a record;

(v) "research" means academic, applied or scientific research that necessitates the use of individually identifying health information;

(v.1) "research ethics board" means a body designated by the regulations as a research ethics board;

(w) "use" means to apply health information for a purpose and includes reproducing the information, but does not include disclosing the information.

APPENDIX B: List of MeSH Search Terms

collection*
community-based participatory research
comparative effectiveness research
computeri*
confidential*
confidentiality
data
data collection
database*
dissemination
electronic
electronic health records
ethics
ethics, institutional
ethics, medical
ethics, research
health
health care reform
health care surveys
health policy
health services needs and demand
health services research
human experimentation
information
information dissemination
information storage
internet
jurispruden*
jurisprudence
link*
making
medical
medical record linkage
medical records
medical records systems, computerized
needs assessment
organizational case studies
patient
patient rights
personnel*
polic*
policy
policymaker*

recor*
record
research
research personnel
research subjects
researcher*
retriev*
retrieval
right*
steward*
storage
subjects

APPENDIX C: Excerpts from the Canadian Charter of Rights and Freedoms[187]

Section 1, Rights and Freedoms in Canada: The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Section 2, Fundamental Freedoms: Everyone has the following fundamental freedoms:

(a) freedom of conscience and religion;

(b) freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication;

(c) freedom of peaceful assembly; and

(d) freedom of association.

Section 7, Life, Liberty, and Security of the Person: Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

Section 8, Security from unreasonable search or seizure: Everyone has the right to be secure against unreasonable search or seizure.

Section 12, Treatment or Punishment: Everyone has the right not to be subjected to any cruel and unusual treatment or punishment.

Section 15, Equality before and under law and equal protection and benefit of law:

(1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular,

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[187] *The Constitution Act, 1982*, Schedule B to the Canada Act 1982 (UK), 1982, c 11.

without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

(2) Subsection (1) does not preclude any law, program or activity that has as its object the amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

Section 25, Aboriginal rights and freedoms not affected by Charter: The guarantee in this Charter of certain rights and freedoms shall not be construed so as to abrogate or derogate from any aboriginal, treaty or other rights or freedoms that pertain to the aboriginal peoples of Canada including

(a) any rights or freedoms that have been recognized by the Royal Proclamation of October 7, 1763; and

(b) any rights or freedoms that now exist by way of land claims agreements or may be so acquired.

Section 36 (1), Commitment to promote equal opportunities:

(1) Without altering the legislative authority of Parliament or of the provincial legislatures, or the rights of any of them with respect to the exercise of their legislative authority, Parliament and the legislatures, together with the government of Canada and the provincial governments, are committed to

(a) promoting equal opportunities for the well-being of Canadians;

(b) furthering economic development to reduce disparity in opportunities; and

(c) providing essential public services of reasonable quality to all Canadians.

APPENDIX D: Interview Script and Questions

Introduction

My name is Allen Dong and I am a graduate student at the University of Calgary in the Department of Community Health Sciences. Thank you for agreeing to participate in this project which is entitled "Data Stewardship in Electronic Medical Records and the Policy Challenges for Researchers: A Canadian Perspective". I hope you are still comfortable with being interviewed by me. In this phase of the project I am doing a series of interviews with key informants at Population Data BC. I have invited you to participate in this project as a key informant because of your knowledge of the policy and procedures in considering data access requests from researchers. The project I am doing is considered research and falls under the jurisdiction of the research ethics board at the University of Calgary. Before we proceed would you be willing to sign this informed consent document for my records? It is intended to give you information about this research, what you are being asked to do, and where your participation fits within the research project. Please read through it and feel free to ask questions.

[TURN ON RECORDER]

1. Let's talk about data access requests from researchers.	"Policy in Practice"
a) Have you handled a routine data access request within the last month? [If no, proceed to question 2]	
b) What was the process for considering the most recent request where a final decision had been reached?	
c) Under what conditions was the request made?	
d) Did this request require escalation to a "higher authority" or committee?	

e) Do you know whether this request resulted in a change in policy? [If no, skip to question k)]	
f) Were ethical considerations brought into the discussion of this request? [If no, skip to question h)]	
g) If yes, what were those considerations?	
h) How will the policy change affect the decision process for data access requests?	
i) Would you say that for this data access request the application of the policy change would result in a different outcome than the application of the previous policy?	
j) [Skip to question 2]	
k) How was the data release policy reflected in the final decision?	
l) How do you become aware of changes to data release policy?	
2. I am going to be moving on to another set of questions. Before I do, is there anything more you would like to add? Let's talk about the most difficult or most memorable case.	"The difficult or memorable case"
a) What is the most difficult/memorable data access request you recall where a final decision was reached?	
b) As best as you can recall, what was the process for considering this request?	
c) Under what conditions was the request made?	
d) Did this request require escalation to a "higher authority" or committee?	
e) Do you know whether this request resulted in a change in policy? [If no, skip to question k)]	
f) Were ethical considerations brought into the discussion of this request? [If no, skip to question h)]	
g) If yes, what were those considerations?	
h) How will the policy change affect the decision process for data access requests?	

i) Would you say that for this data access request the application of the policy change would result in a different outcome than the application of the previous policy?	
j) [Skip to question 3]	
k) How was the data release policy reflected in the final decision?	
3. I am going to be moving on to another set of questions. Before I do, is there anything more you would like to add? Let's talk about a decision or event that resulted a major change in data access policy	"The transformative case or event"
a) Can you recall key requests or types of requests or an event that led to a change in data access policy? Examples of events could be repeat requests of the same type, a technology change, a legislative change, or a regulatory change. [If no skip to question 4]	
b) Please describe this event.	
c) Please tell me how this event affected decision-making processes for data access requests.	
d) When deliberating over the changes to policy did ethical considerations come into the discussions? [If no skip to question 4]	
e) If yes, what were those considerations?	
4. I am going to be moving on to another set of questions. Before I do, is there anything more you would like to add? Finally, let's talk about health care policy ethics.	
a) Have you received training in healthcare policy ethics? If yes,	
b) Please describe this training.	Examples: TCPS training, Canadian Bioethics Society, PHEN, CIHR training
c) Is this training a mandatory requirement for the work that you do?	
d) Are there any refresher requirements?	

e) Do you find this training to be helpful in your job?	

These are all of the questions I wanted to ask. Thank you so much for your participation.

Are you comfortable with my calling you if I have any questions about our interview?

Would you like me to send you a summary of my results?

[If time permits] At this time I would like to invite you to ask any questions or add any comments.

[If time does NOT permit]. Here is my contact information. If you have any questions or would like to make more comments about the topics covered in the interview then I invite you to get in touch with me.

[TURN OFF RECORDER]