



MICYRN Workshop

Ottawa, Ontario
October 13th, 2011

Research Ethics Harmonization

Introduction

This workshop was the second in a series, sponsored through CIHR Meeting Planning Dissemination grants, to bring together members from MICYRN-affiliated Research Ethics Boards with the objectives to:

1. Build trust through communication
2. Harmonize review
3. Improve quality of review

The collegial and strongly committed Working Group is comprised of members from self-standing pediatric REBs (Vancouver, CHEO, Sick Kids, Montreal Children's, Ste Justine, IWK); reps from regional and provincial REBs (Winnipeg, London, Alberta, Newfoundland); expert advisors in ethics, policy and law from the Center for Genomics and Policy (McGill University); and the Director, CIHR Ethics Office.

A first workshop held in February 2011 had led to strong interest in working together on consideration of different models for ethics review of multi-jurisdictional studies. Since that meeting, there had been work between individuals at Ste Justine (Montreal), Sick Kids (Toronto) and C&W (Vancouver) to determine the feasibility of inter-institutional reciprocity agreements. It became clear that existing provincial (Quebec) or institutional policies (UBC) would have to be changed in order for local boards to accept the review of another institution. Work then began towards development of a "central" or federated (= 'joint') national REB. It is being proposed that this be comprised of the Chairs and other members from the MICYRN-affiliated REBs, such that all necessary local jurisdictional issues could be brought to bear in a joint deliberation. The federated committee would not replace local REBs, but could save the need for repeat full board reviews if a site Chair had the authority to expedite applications they/their delegate had approved at the federated REB.

Presentation

Mr. Lee Black JD LLM presented on *The things we can't change: Variations in Privacy Legislation across Canada and how these affect Biobanks*. Highlights were presented from a report delivered to the Privacy Officer of Canada (August 1, 2011) from Mr. Black; Edward Dove, BCL/LLB; Denise Avard, PhD; and Bartha Maria Knoppers, PhD OC, Centre of Genomics and Policy, McGill University; and included:

1. Protection of health information is addressed differently in every jurisdiction across Canada, and the federal laws that could impact biobanks (the Privacy Act and PIPEDA) offer limited applicability.

2. Biobank practices are inconsistent (across and within each) when it comes to consent disclosures and the privacy and confidentiality for pediatric biobank participants
3. In the absence of specific legal (and ethical guidance), researchers and institutions will act on the limited guidance available, with disparate results.
4. Little information regarding the control and use of the biological material and information collected
5. Outside of laws determining competency for participation in research, various legislative responses to health information privacy do not reach the issue of parental versus child rights and interests

With the following recommendations for reform:

1. All jurisdictions should incorporate in relevant privacy legislation provisions for decision-making in pediatric research
2. Privacy legislation should be harmonized across Canada
3. Development of a well-defined conceptual framework across the general typology of biobanks
4. Genetic information and biological materials explicitly considered personal health information
5. Clear penalties and sanctioning and enforcement powers for privacy violations disclosing personal or health information
6. Development of more detailed professional Codes of Conduct that deal with specific pediatric biobank issues

Mock REB Review

A mock REB was formed to test the proposed 'federated' model. Ron Heslegrave, former chair of the Ontario Cancer REB (OCREB) agreed to act as Chair. A Common Application Form was developed by Dr. Junker, using web-accessible content from forms in place at the participating institutions. The Canadian Children's Cancer C17 Network completed applications for a Phase I and a Phase II clinical trial. Two chairs (4 in all) agreed to act as primary and secondary reviewer for each study. One study was rejected and the other was given provisional approval.

Conclusion

There was much discussion about how the federated REB would function, with concerns raised as to whether the deliberations of a federated REB could be accepted in provinces that have legislated provincial REBs (Quebec, Alberta, Newfoundland). There was great interest and willingness of participants to continue to meet. It was planned for a research associate at the MICYRN Ethics Core, the Centre of Genomics and Policy at McGill University, to undertake a review of this legislation.

Things We Can't Change: Variations of Privacy Legislation Across Canada



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The Context



2011

Privacy in Canadian Paediatric Biobanks: A Changing Landscape

*A Report Delivered to the
Office of the Privacy Commissioner of Canada*

Edward S. Dove, Lee Black, Denise Avaré & Bartha M. Knoppers
Centre of Genomics and Policy
REVISED August 1, 2011



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Karen McCloskey for The New York Times

CCP
CENTRE OF GENOMICS AND POLICY
OFFICE OF THE PRIVACY COMMISSIONER OF CANADA



What Are Our Current Challenges?



- Navigating the complex privacy landscape maze
- Applying privacy laws to paediatric biobanks
- Interpreting paediatric biobank policies and consent forms on privacy
- Working to develop improvements to paediatric biobank privacy protection



Balancing our aspirations for greater privacy protection with recognition of political and legal realities

Canadian Privacy Legislation



Canadian Privacy Legislation



- **Constitutional:**
 - Respect for privacy is a constitutional principle in Canada...but
 - ✦ no explicit right to privacy in the Constitution
 - ✦ The development of the concept and categories of privacy interests have been largely driven by *Canadian Charter of Rights and Freedoms* cases
 - Section 7 and Section 8
 - Québec's *Charter of Human Rights and Freedoms*
- **What about federal and provincial legislation?**

The Potholes of Privacy Protection



Coverage of Federal and Provincial Privacy Statutes in Canada

Jurisdiction	Right of Privacy	Statutory Tort	Protection of Personal Information – Public Sector	Protection of Personal Information – Private Sector	Protection of Personal Health Information
Canada	✓		✓	✓	
British Columbia		✓	✓	✓	✓
Alberta			✓	✓	✓
Saskatchewan		✓	✓		✓
Manitoba		✓	✓		✓
Ontario			✓		✓
Québec	✓	✓*	✓	✓	
Nova Scotia			✓		
New Brunswick			✓		✓
Prince Edward Island			✓		
Newfoundland and Labrador		✓	✓		✓
Yukon			✓		
Northwest Territories			✓		
Nunavut			✓		

*In Québec, art 5 of the *Québec Charter* and arts 35 and 1457 CCQ can probably be interpreted as equivalent to a statutory tort.

The Maze of Privacy Protection



Federal	<ul style="list-style-type: none"> • <i>Privacy Act</i> • <i>Personal Information Protection and Electronic Documents Act (PIPEDA)</i>
British Columbia	<ul style="list-style-type: none"> • <i>Personal Information Protection Act</i> • <i>Freedom of Information and Protection of Privacy Act</i> • <i>Privacy Act</i> • <i>E-Health (Personal Health Information Access and Protection Act of Privacy) Act</i>
Alberta	<ul style="list-style-type: none"> • <i>Personal Information Protection Act</i> • <i>Freedom of Information and Protection of Privacy Act</i> • <i>Health Information Act</i>
Saskatchewan	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i> • <i>The Health Information Protection Act</i> • <i>The Local Authority Freedom of Information and Protection of Privacy Act</i> • <i>The Privacy Act</i>
Manitoba	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i> • <i>The Personal Health Information Act</i> • <i>The Privacy Act</i>
Ontario	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i> • <i>Personal Health Information Protection Act, 2004</i> • <i>Municipal Freedom of Information and Protection of Privacy Act</i>
Québec	<ul style="list-style-type: none"> • <i>An Act respecting Access to documents held by public bodies and the protection of personal information</i> • <i>An Act respecting the protection of personal information in the private sector</i> • <i>Act respecting health services and social services</i> • <i>Civil Code of Québec</i> • <i>Charter of Human Rights and Freedoms</i>
New Brunswick	<ul style="list-style-type: none"> • <i>Right to Information and Protection of Privacy Act</i> • <i>Personal Health Information Privacy and Access Act</i>
Nova Scotia	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i> • <i>Municipal Government Act</i> • <i>Personal Information International Disclosure Protection Act</i>
Prince Edward Island	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i>
Newfoundland and Labrador	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i> • <i>Personal Health Information Act</i> • <i>Privacy Act</i>
Yukon	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i>
Northwest Territories	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i>
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How Does the Legislation Apply to Biobanks?



- Haphazardly!



- Paediatric biobanks are not necessarily inconsistent with the legislation, but
 - legislation does not contemplate the ever-evolving world of genomics and biobanking or the issues particular to paediatric biobanking.
- The lack of a rationalized and harmonized privacy framework could compromise the privacy of paediatric biobank participants.

Some Issues of Concern



- The legislation applies to public bodies, regional health authorities, universities, or other organizations...but not clear it covers a biobank
 - E.g. hybrid biobank structures, which often serve as resources for future, unspecified research, which may or may not be commercial in nature
 - “Personal information” → biological materials?
 - Lack of explicit parental consent requirements or guidance
 - (Parental) consent with collecting, using and disclosing personal info.
 - Protecting privacy in the context of secondary use
 - Access to biological samples and data by third parties
 - The lack of clear penalties and sanctioning and enforcement powers for privacy violations disclosing personal or health information

Exploring Three Major Policy Issues



- 1) Use and transfer of the child's data and samples**
- 2) Risks of unauthorized access by third parties**
- 3) Nature (i.e. characteristics and dimensions) of the shared relationship between the child, the parents and the researcher**

How do Paediatric Biobanks Address the Issues?



An analysis of Canadian and international paediatric biobanks:

1. Canadian Healthy Infant Longitudinal Development (CHILD) Study
2. Étude Découvrir, Développer, Devenir (Étude 3-D)
3. Finding of Rare Disease Genes in Canada (FORGE) Canada
4. National Children's Study (NCS)
5. Gopher Kids Study
6. Avon Longitudinal Study of Parents and Children (ALSPAC)
7. Copenhagen Studies on Asthma in Childhood (COPSAC)

Use and Transfer of the Child's Data and Samples



- Privacy legislation does not cover *transfer and use* of samples
- No explicit ability for participants to access biological materials
- Biobanks generally do not cover informational privacy risks in ICF (other than confidentiality provisions)

Risks of Unauthorized Access by Third Parties



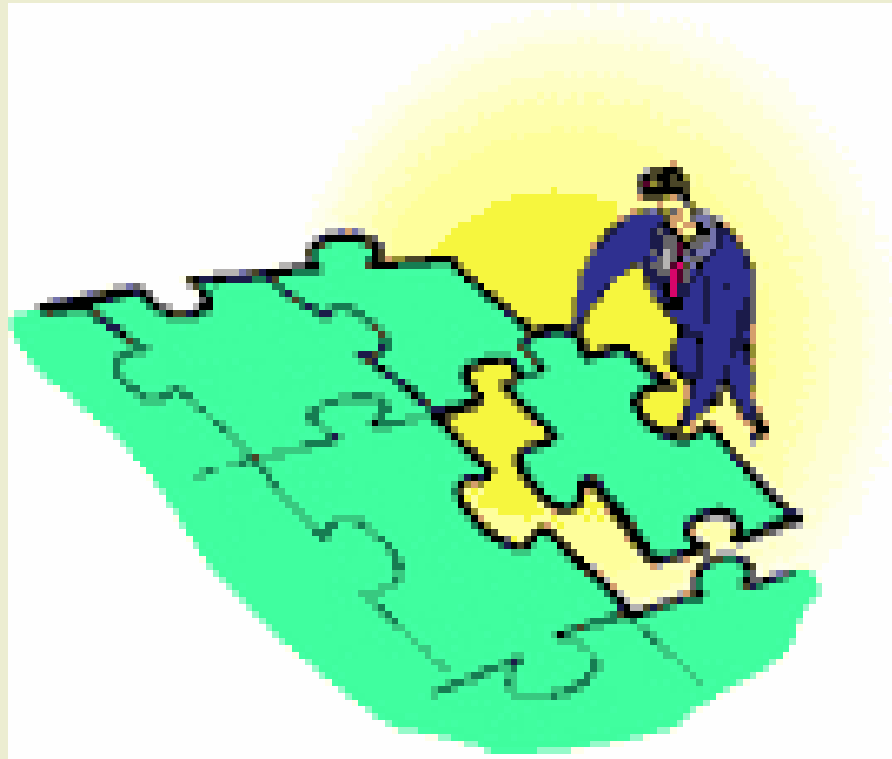
- **Increase in risk of unauthorized access?**
 - Long period of storage
 - Dissemination of data/samples
- **Steps by biobanks to protect:**
 - Coding
 - Secure storage
- **No legislation addresses parents' ability to disclose against child's wishes (or researcher's ability with parental consent)**
- **Legislation does not apply to biological material**
- **No specific penalties for disclosure**

Nature of the Tri-Partite Relationship



- **Involvement of parents in relationship between child and researcher**
 - Complicates child's privacy—not just them involved in discussion
- **Privacy legislation doesn't address concerns children may have about parental access to info**
- **Right to know info important to health?**
- **Maturing children, assent, consent, and withdrawal**

Putting it All Together: Some Conclusions



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- **Biobank practices are inconsistent (across and within each) when it comes to consent disclosures and the privacy and confidentiality for paediatric biobank participants**
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- **Little information regarding the control and use of the biological material and information collected**
- **Protection of health information is addressed differently in every jurisdiction across Canada, and the federal laws that could impact biobanks (the Privacy Act and PIPEDA) offer limited applicability**
- **Outside of laws determining competency for participation in research, various legislative responses to health information privacy do not reach the issue of parental versus child rights and interests**

Recommendations for Reform



- 1. All jurisdictions should incorporate in relevant privacy legislation provisions for decision-making in paediatric research**
- 2. Privacy legislation should be harmonized across Canada**
- 3. Development of a well-defined conceptual framework across the general typology of biobanks**
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Thank you!