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Privacy in Canadian Paediatric Biobanks: A Changing Landscape

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

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List of Abbreviations

ALSPAC:	Avon Longitudinal Study of Parents and Children (UK)
BPHR:	<i>Best Practices for Health Research Involving Children and Adolescents</i> (Canada)
CIHR:	Canadian Institutes of Health Research
CHEO:	Children's Hospital of Eastern Ontario
CHILD:	Canadian Health Infant Longitudinal Development Study
COPSAC:	Copenhagen Studies on Asthma in Childhood (Denmark)
CPGDS:	Canadian Pediatric Genetic Disorders Sequencing Consortium
DTA:	Data Transfer Agreement
FORGE:	Finding of Rare Disease Genes in Canada
FRSQ:	Fonds de la recherche en santé du Québec
GINA:	<i>Genetic Information Nondiscrimination Act</i> (USA)
IRNPQEO:	Integrated Research Network in Perinatology of Québec and Eastern Ontario
MTA:	Material Transfer Agreement
NCS:	National Children's Study (USA)
NIH:	National Institutes of Health (USA)
OECD HBGRD Guidelines:	Organisation for Economic Co-operation and Development <i>Guidelines for Human Biobanks and Genetic Research Databases</i>
OPC:	Office of the Privacy Commissioner of Canada
OPHIPA:	<i>Personal Health Information Protection Act, 2004</i> (Ontario)
OTB:	Ontario Tumour Bank
PIPEDA:	<i>Personal Information Protection and Electronic Documents Act</i> (Canada)
REB:	Research Ethics Board
TCPS:	<i>Tri-Council Policy Statement</i> (Canada)
UNESCO:	United Nations Educational, Scientific and Cultural Organization

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Executive Summary

Privacy is notoriously nebulous. Yet, many believe that privacy has clear, key contours that address distinct concerns. This Report aims to systemically analyze privacy contours in the specific context of those paediatric biobanks created and used for research purposes, which serve to acquire scientific and medical knowledge for the benefit of children's (and society's) health and development. This Report also intends to demonstrate that protecting personal information privacy in the context of paediatric biobanks is an exigent endeavour compounded by constitutional parameters, fractured societal discourse and complex, mismatching and incomplete legislation and guidance.

Paediatric biobanks are rapidly evolving in terms of governance structures, participant population size, typology, geographic distribution and field(s) of study. Ensuring that personal information is sufficiently protected by way of legislation is challenged by such burgeoning, evolving expansion and rapid advances in technology. One particular field of evolution is that of genetics and genomics; much discussion in the Report will focus on this since many paediatric biobanks store and use genetic data and samples.

Despite these various challenges and exigencies, it remains the goal of the Report to illuminate the main privacy issues and offer a rich discussion on the ethical and legal interplay of paediatric privacy protection in this changing landscape.

The Report examines privacy and confidentiality of paediatric biobanks from three different perspectives: the operation of current Canadian and International paediatric biobanks, Canadian privacy legislation and its applicability to paediatric biobanks, and ethical norms. Note that the discussion in this Report excludes tissue legislation in Canada. Part I of this Report will

discuss the methodology and rationale for our exploration of seven biobanks, various national and international ethical norms, and Canadian privacy legislation. Part II will discuss the biobank framework, inside and outside Canada. In particular, it will explain the general structure of biobanks and the various typologies, as well as the context of the specific biobanks that we have analyzed and our reasons for choosing them. Part III will explore the legislative privacy framework in Canada and focus on its applicability to biobanks. Part IV will consider in depth three particular policy issues framing the current privacy landscape in paediatric biobanks: 1) the use and transfer of the child's data and samples, 2) the risks of unauthorized access by third parties, and 3) the nature (i.e. characteristics and dimensions) of the shared relationship between the child, the parents and the researcher. Within each issue will be an inter-woven examination of the ethical, legal and biobank practice dimensions that affect the processes and outcomes of paediatric biobanking and privacy protection.

This Report demonstrates that legislation, ethical norms and biobank practices are inconsistent when it comes to the privacy and confidentiality of paediatric biobank participants. Legislation cannot solve all of the potential risks to children, as is noted in the Report recommendations. However, this Report shows that researchers and institutions that establish biobanks will, in the absence of specific legal and ethical guidance, act on the limited guidance available, with disparate results.

This Report's recommendations are that the OPC should consider the following:

1. All jurisdictions should incorporate in relevant privacy legislation (e.g. health information privacy statutes if applicable, otherwise private/public sector privacy statutes) proportionality-based provisions for decision-making in paediatric research, such as the determination of competency and assent, consistent with current law and the *Tri-Council Policy Statement*.

2. Privacy legislation must be *reactive* but also *prospective*.
3. Privacy legislation should be harmonized across Canada.
4. Privacy legislation should allow federal and provincial privacy commissioners to play an integral part in the regulatory framework for biobanks created for research. Privacy commissioners should incorporate in their regulatory scrutiny a bottom-up approach through ongoing dialogue with REBs and the broader biobanking community.
5. The OPC should work with the broader biobanking community on developing a well-defined conceptual framework across the general typology of biobanks.
6. The OPC should work to foster greater public education and awareness of biobanks and privacy issues.
7. The OPC should specify in privacy legislation that genetic information and biological materials are considered personal health data.
8. The OPC should provide clear penalties and sanctioning and enforcement powers for privacy violations disclosing personal or health information.
9. The OPC should prepare a web-based, open access federally-administered database of all Canadian biobanks.
10. The OPC should push for the development of more detailed professional Codes of Conduct that deal with specific paediatric biobank issues.

Introduction

Privacy is notoriously nebulous. It has been described as a “chameleon-like word”,¹ “protean”,² a “haystack in a hurricane”,³ and a “broad and somewhat evanescent concept.”⁴ Yet within this theoretical fog, many believe that privacy has clear, key contours that address distinct concerns. For example, one legal scholar calls privacy a “state of affairs” which contains an informational and spatial component.⁵ Another scholar defines privacy as “a set of protections from a plurality of problems that all resemble each other, yet not in the same way”.⁶ Four privacy dimensions have been identified: (1) informational privacy concerns about access to personal information; (2) physical privacy concerns about access to persons and personal spaces; (3) decisional privacy concerns about governmental and other third-party interference with personal choices; and (4) proprietary privacy concerns about the appropriation and ownership of interests in human personality.⁷ Our Report aims to penetrate the conceptual haze and systemically analyze all of these privacy contours in the specific context of paediatric biobanks created and used for research purposes, serving to acquire scientific and medical knowledge for the benefit of children’s (and society’s) health and development.⁸

However, our Report also intends to demonstrate that protecting personal information privacy in the context of paediatric biobanks is an exigent endeavour compounded by constitutional parameters, fractured societal discourse and complex, mismatching and incomplete legislation and guidance. There are several possible explanations for this. For example, there are certain constitutional constraints in Canada that complicate the ability to enact legislative rules on paediatric biobanking. Specifically, civil rights and health are provincial matters.⁹ While Canada’s National DNA Bank is federally regulated because criminal law is constitutionally a federal matter,¹⁰ paediatric biobanks largely revolve around (provincial) health matters, even if

they are national in scope. The recent Supreme Court reference decision on the *Assisted Human Reproduction Act*¹¹ demonstrates that attempts by the federal government to address concerns that are health legislation in pith and substance could well be ruled unconstitutional. Thus, the development of pan-Canadian paediatric biobank privacy legislation would face an uphill battle. Consequently, reliance by stakeholders on soft law ethical norms and guidelines, professional codes of conduct, and provincial health and privacy laws will likely continue.

Another explanation is that views on biobanking that place less weight on a self-determination privacy frame (i.e. autonomy, respect for persons, and deontology) and more on a “benign stewardship”¹² frame (i.e. data protection safeguards, public good, consequentialism, and beneficence) may emphasize the need for protocols to safeguard information *in general*, rather than the need for children to have more rights regarding the control over their personal information and samples. Moreover, differing views as to the proper balance between privacy and the sharing of data and samples make the formulation of a broadly accepted biobank governance structure a challenging undertaking.

Finally, paediatric biobanks are rapidly evolving in terms of governance structures, participant population size, typology, geographic distribution and field(s) of study. Ensuring that personal information is sufficiently protected by way of legislation is challenged by such burgeoning, evolving expansion and rapid advances in technology. One particular field of evolution is that of genetics and genomics; some discussion in our Report will focus on this since many paediatric biobanks store and use genetic data and samples.

Despite these various challenges and exigencies, it remains the goal of our Report to illuminate the main privacy issues and offer a rich discussion on the ethical and legal interplay of paediatric privacy protection in this changing landscape.

Part I of this Report will discuss the methodology and rationale for our exploration of seven biobanks, various national and international ethical norms, and Canadian privacy legislation. Part II will discuss the biobank framework, inside and outside Canada. In particular, it will explain the general structure of biobanks and the various typologies, as well as the context of the specific biobanks that we have analyzed and our reasons for choosing them. Part III will explore the legislative privacy framework in Canada and focus on its applicability to biobanks. Part IV will consider in depth three particular policy issues framing the current privacy landscape in paediatric biobanks: 1) the use and transfer of the child's data and samples, 2) the risks of unauthorized access by third parties, and 3) the nature (i.e. characteristics and dimensions) of the shared relationship between the child, the parents and the researcher. Within each issue will be an inter-woven examination of the ethical, legal and biobank practice dimensions that affect the processes and outcomes of paediatric biobanking and privacy protection. Finally, this Report will conclude with recommendations to confront the possible gaps and shortcomings in the current Canadian privacy framework.

A key objective is to assess whether the findings from the paediatric biobank case studies echo the guidance contained in national and international ethical norms (though certain gaps are noted); whether there are privacy legislation limits to the effectiveness and regulatory oversight needed to adequately protect children's privacy in paediatric biobanks; and how to foster public trust in future paediatric research using biobanks.

1. Methodology and Rationale

Our Report explores the privacy landscape in paediatric biobanks by focusing on three dimensions: legal, ethical and biobank policy. For each dimension, we used a common template which extracted the following information on eight topics, where applicable, deemed relevant to privacy and confidentiality:

- assent or consent of the child;
- potential risks/benefits;
- return of individual results to the parents and/or child (including incidental findings);
- length of storage of data and samples;
- access by child and/or parents to data and samples;
- transfer of data and samples/secondary use;
- right of withdrawal; and
- handling of privacy and confidentiality/protection against unauthorized access by third parties.

In line with our definition of paediatric biobank (see Subsection 2.2), for this Report we identified biobanks constructed for research purposes. To capture the diversity of paediatric biobanks in Canada and internationally, we developed a purposive sampling frame that included, among other characteristics, biobanks from various countries (Canada, United States, England, Denmark) and venues (e.g. hospital, academic or research institution, governmental institution), and which differed by length of biological sample and data collection timeline (e.g. pregnancy, birth until two years, age 1 until 11, or indefinite), type (population-based and disease-based),

and nature (comprises mother and child or family “trio” with father included). Table 2 summarizes the diversity of characteristics.

The sample consists of seven publicly funded biobanks: 1) CHILD (Canada); 2) Étude 3-D (Canada); 3) FORGE Canada (Canada); 4) National Children’s Study (NCS) (United States); 5) Gopher Kids Study (United States); 6) ALSPAC (United Kingdom); and 7) COPSAC (Denmark). Most information was obtained from one or more sources: 1) policies listed on each biobank’s or regulator’s (e.g. data protection authority) website; 2) consent forms; and 3) personal correspondence with the biobank researchers, ethicists and administrators.

This Report also examines ethical norms from Canadian and international sources in Part IV. Although Canada is a signatory to many of the international documents cited, reference to documents from other countries or organizations that are not controlling in Canada, such as the *OECD Guidelines for Human Biobanks and Genetic Research Databases* (hereinafter HBGRD Guidelines), is done for the sake of comprehensiveness and to demonstrate trends in ethical guidance. Ethical norms were identified using the HumGen database, a repository of Canadian, national and international ethics and genetic policy documents,¹³ and internet searches on international medical and research organization websites. Those norms most relevant to privacy and confidentiality in biobank research were retained. Appendix 1 contains summaries of relevant provisions from Canadian and international ethics policy documents.

Finally, this Report examines Canadian federal, provincial and territorial privacy legislation. This legislation was located through searches on Westlaw, LexisNexis and provincial and federal websites. We also used *A Compendium of Canadian Legislation Respecting the Protection of Personal Information in Health Research*,¹⁴ developed by the Canadian Institutes of Health Research (CIHR) and last updated in 2005, as a base-point reference.

2. The Biobank Framework

2.1. Exploring the Biobank Typology

As illustrated by Table 1 below, there is an open-end typology in the rich tapestry of biobanks.¹⁵ For example, biobanks can differ on population types (e.g. patients or unaffected individuals, specific or general community), the nature and size of the biological samples included (e.g. blood, tissue, urine), the data included (e.g. genetic, health, genealogical, lifestyle), the context of collection (e.g. clinical, research), the form of storage and handling, the level of data security (coded, anonymized, anonymous), the underlying scientific purpose (e.g. association studies, genetic epidemiology, pharmacogenomics), the primary financial support (public, private or public-private), and the source of the biobank (e.g. hospital, government, industry). Biobanks can also be created *de novo* or by converting pre-existing collections of biological samples and associated data into a biobank.¹⁶

Table 1: General Typology of Biobanks

Classification	Characteristics (open-ended)
Nature of Biobank	<ul style="list-style-type: none"> • De novo (prospective) • Retrospective collection of biological samples and associated data
Type of Biobank	<ul style="list-style-type: none"> • Population-based • Disease-based
Size and Scope	<ul style="list-style-type: none"> • Small-scale/Large-scale • Specific community/communities • Regional • National • International
Nature of Biological Samples	<ul style="list-style-type: none"> • Blood • DNA • Tissues • Urine • Saliva
Type of Data	<ul style="list-style-type: none"> • Genetic • Phenotypic • Health-related • Genealogical • Lifestyle
Purpose of Collection	<ul style="list-style-type: none"> • Clinical/Pathological • Research • Public Health • Forensic*
Period of Storage	<ul style="list-style-type: none"> • Fixed • Indefinite
Level of Data Security	<ul style="list-style-type: none"> • Coded • Anonymized • Anonymous
Funding	<ul style="list-style-type: none"> • Public • Private • Public-private
Venue of Biobank	<ul style="list-style-type: none"> • Hospital • Academic or research institution • Governmental institution • Industry • Foundation

* Forensic biobanks will not be specifically discussed as part of this Report.

2.2. Defining “Paediatric Biobank”

The term “paediatric biobank” must be defined in order to determine the applicable scope of privacy laws, ethics guidelines, and the extent of our discussion in this Report. A definition has legal consequences for the stakeholders involved.¹⁷ Finding a common and broadly applicable definition has proven difficult given the diversity of biobanks, as described above. Yet, failing to define the subject matter will change the outcome of this Report. For example, Canada’s forensic National DNA Bank is governed by explicit biobank legislation¹⁸ and includes oversight bodies and a variety of safeguards.¹⁹ As will be discussed below, such is not the case for research biobanks. In addition, the terms “child” or “minor”, which can be used as synonyms for “paediatric”, must be explicated. In Canada, a minor is a person who is not an adult, non-emancipated, and is under the age of majority (18 or 19 years of age is considered the legal age of majority, depending on the jurisdiction).²⁰ Where addressed, the age for consent to medical care or to research varies across Canada,²¹ and can include the “mature minor” doctrine which focuses more on the capabilities of the minor to understand rather than a presumed age of consent to medical care or research. It is also important to note that biobanks, paediatric or otherwise, are often administered and funded by public bodies, including universities, hospitals, and government departments and agencies.

For this Report, a paediatric biobank is *a systematically organized and searchable collection of data and material used for one or more research purposes. Data and material therein comprises stored human biological material and associated information on persons who have either (a) not yet reached the age of legal majority or otherwise acquired the ability to consent at the time of the donation of such information or materials, or (b) not yet reached the age of majority to consent in accordance with the law respecting consent to medical treatment or research at the time of the donation of such information or materials.*

Before discussing the legislative dimensions of privacy in paediatric biobanks, we note at the outset that **ethical norms govern paediatric research and biobanks**. For instance, the three Canadian paediatric biobanks (Table 2) should be in conformity with the 2010 edition of the *Tri-Council Policy Statement* (TCPS) guidelines governing research involving human subjects²² and therefore certain policies or principles not directly addressed in the consent forms may nonetheless be covered by the TCPS. Similarly, while certain issues are not addressed in the ALSPAC consent forms or policies, the biobank may still adhere to University of Bristol, United Kingdom (Medical Research Council, Nuffield Council on Bioethics and the Wellcome Trust) and European norms (e.g. the Council of Europe's 1997 *Convention on Human Rights and Biomedicine*).

2.3. An Overview of the Biobanks

The following presents a brief overview of the biobanks (Table 2).

Canadian Healthy Infant Longitudinal Development Study (CHILD)

The Canadian Healthy Infant Longitudinal Development (CHILD) Study is a national, longitudinal, population-based birth-cohort study of 5,000 children enrolled “pre-birth” and followed for five years. Publicly funded by the federal government in 2008 via CIHR and AllerGen NCE Inc., the purpose of the study is to determine the roles of a range of environmental factors and their interactions with genetic and host factors (e.g. psychosocial and immunological) in the development of children’s health. The primary goal is to study the development of allergy and asthma in children, but CHILD will also investigate the development of other health outcomes (e.g. preschool wheeze, eczema, food allergy, immunologic outcomes). The consent forms vary depending on the location of the recruitment hospital (Vancouver, Edmonton, Winnipeg and Toronto).

Étude 3-D/Integrated Research Network in Perinatology of Quebec and Eastern Ontario

Approximately 5,000 families are being recruited across Québec and Eastern Ontario (May 2010-May 2012) to participate in a CIHR-funded study (Étude 3-D - Découvrir, Développer, Devenir) aimed at understanding the effects of perinatal events (lifestyle, heredity, nutrition, employment, familial status, etc.) on child development. The participation of the mother, father and future child starts from the onset of pregnancy and finishes when the child is two years old.

Finding of Rare Disease Genes in Canada (FORGE Canada)

In February 2011, the Government of Canada announced a new funding initiative to identify the genes that cause the most challenging types of cancer and rare diseases in children, and to find new treatments.²³ The federal government is investing \$4.5 million for two projects, one based at the Children's Hospital of Eastern Ontario (CHEO) and the other at the University of British Columbia (UBC). The CHEO project will study more than seventy childhood genetic disorders and aim to discover disease-causing genes, while the UBC project will examine the genomes of up to six of the most challenging childhood cancers and sequence participating patient samples using exome or whole-genome re-sequencing. Enrolment of patients will run from June 2011 to November 2012.

National Children's Study (NCS), USA

The National Children's Study (NCS) will examine the effects of the environment and genetics on the growth, development and health of children across the United States, following them from before birth until age 21 years. With an enrolment goal of at least 100,000 families, it is the largest long-term study of environmental and genetic influences on children's health ever conducted in the United States. The study is led by the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health (NIH), in

collaboration with a consortium of federal government partners. While preliminary enrolment began in 2009, NCS's Main Study is targeted for April 2012 commencement.

Gopher Kids Study, USA

The University of Minnesota is conducting a study of healthy children between the ages of 1 and 11 in order to understand how genes contribute to children's normal health and development. The study enrolled 841 children from 534 families through an exhibit at the 2010 Minnesota State Fair. It asked them to return for measurement and sample collection at the 2011 and 2012 State Fairs.²⁴

Avon Longitudinal Study of Parents and Children (ALSPAC), UK

The Avon Longitudinal Study of Parents and Children (ALSPAC), also known as Children of the '90s, is a long-term prospective health research project that has been studying over 14,000 mothers enrolled during pregnancy between April 1991 and December 1992 around the Bristol and Bath, England area. More than 22,000 individuals (mothers, fathers, children and the children's offspring) are now involved in the study. Unlike many other paediatric biobanks, ALSPAC has never imposed a cut-off point for data collection (though it plans to stop when children reach the age of 70).²⁵ As evidenced by a new data collection plan for 2011-2013, the study, along with collaborative researchers, intends to continue collecting biological samples and data indefinitely, creating a long-term family research tree.²⁶ ALSPAC receives core funding from the Wellcome Trust and the United Kingdom's Medical Research Council.

Copenhagen Studies on Asthma in Childhood (COPSAC), Denmark

The Copenhagen Studies on Asthma in Childhood (COPSAC) is a clinical research unit for paediatric asthma research (birth through adolescence) that aims to develop evidence-based prevention strategies. There were two prospective cohort studies, beginning in 2000 and 2010. The COPSAC₂₀₀₀ cohort and COPSAC₂₀₁₀ cohort policies and guidelines analysis is limited as the

consent forms are not available on the study website and several attempts to reach the research unit were unsuccessful.²⁷

The foregoing summaries demonstrate that the paediatric biobank landscape is not uniform. There is a range of characteristics, which as will be discussed below, reflecting varying privacy legislation coverage, ethical norms, and biobank consent forms and policies.

Table 2: Characteristics of the Selected Biobanks

Biobank & Year in Which Study Commenced	Country	Nature of Biobank	Type of Biobank	Requirements for Participation	Participants for Data/Biological Sample Collection	Size	Biological Samples	Data	Period of Storage	Venue of Biobank
Canadian Healthy Infant Longitudinal Development (CHILD) Study 2008 –	Canada (B.C., Alta., Man., Ont., Qc.)	Prospective (includes mother, and father, if possible)	Population-based (<30 weeks into pregnancy)	<ul style="list-style-type: none"> Pregnant women over the age of 18 (19 in Vancouver) who are less than 30 weeks into pregnancy and planning to deliver at one of the participating hospitals 	Pregnancy - 5 years	5000 families (15,000 participants)	<ul style="list-style-type: none"> Blood Urine Faeces 	<ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 	Indefinite (see Table 5 for more info)	Hospitals and Academic Institutions (coordinating centre at McMaster U.)
Étude Découvrir, Développer, Devenir (Étude 3-D) 2010 –	Canada (Ont. and Qc.)	Prospective (includes mother, and father, if possible)	Population-based (≥14 weeks into pregnancy)	<ul style="list-style-type: none"> Pregnant women who are at least 14 weeks into pregnancy and plan to deliver in one of the participating hospitals 	Pregnancy - 2 years (possibly beyond, if funding permits)	5700 participants	<ul style="list-style-type: none"> Cord blood Placenta Meconium Blood Urine Tissues (hair) 	<ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 	Indefinite	Hospitals and Academic Institutions (centred at CHU Sainte-Justine)
Finding of Rare Disease Genes in Canada (FORGE) Canada 2011 –	Canada (all provinces and territories)	Prospective	Disease-based (identifying genes in rare paediatric diseases)	<ul style="list-style-type: none"> Canadian patients with a disorder that is congenital or develops in childhood/adolescence Disorder is monogenic and gene is unknown If condition is etiologically heterogeneous, known genetic causes have been excluded 	Birth – adulthood (all ages)	500 patients	<ul style="list-style-type: none"> Blood Saliva 	<ul style="list-style-type: none"> Genetic Phenotypic 	Indefinite (see Table 5 for more info)	Hospital (CHEO)
National Children's Study (NCS) 2009 –	United States (43 states presently)	Prospective (includes mother or women anticipating pregnancy, and father, if possible)	Population-based	<ul style="list-style-type: none"> Women (age 18-49) who live within pre-selected study location areas Pregnant or may become pregnant during the recruitment period 	Pregnancy – 21 years	100,000 families	<ul style="list-style-type: none"> Cord blood Umbilical cord samples Blood Urine Saliva 	<ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 	Indefinite	Government (NIH and Federal Consortium)
Gopher Kids Study 2010 –	United States (Minnesota and Wisconsin)	Prospective (includes mother, and father, if possible)	Population-based (role of genes in child's growth, health, and development)	<ul style="list-style-type: none"> Children between age 1-11 at 2010 Minnesota State Fair Residents of Minnesota or two metro-area counties of Wisconsin (Pierce and St. Croix) Had at least one biological parent available to donate DNA 	1-11 years	534 families (831 children)	<ul style="list-style-type: none"> Saliva Blood (optional) Nail clippings (optional) 	<ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 	Indefinite	Academic Institution (University of Minnesota)
Avon Longitudinal Study of Parents and Children (ALSPAC) 1991 –	United Kingdom (Avon)	Prospective (includes mother, and father, if possible)	Population-based (≥18 weeks into pregnancy)	<ul style="list-style-type: none"> Mothers had to be resident in Avon while pregnant. Date of delivery had to lie between 1st April 1991 and 31st December 1992 inclusive. 	Pregnancy – 70 years	14,000 mothers (>22,000 total participants as of 2011, including 10,000 children)	<ul style="list-style-type: none"> Placenta formalin Blood Tissues (e.g. hair, nails) Urine Saliva 	<ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 	Indefinite	Academic Institution (University of Bristol)
Copenhagen Studies on Asthma in Childhood (COPSAC) 2000 – and 2010 –	Denmark (greater Copenhagen for COPSAC ₂₀₀₀ Cohort; eastern Denmark for COPSAC ₂₀₁₀ Cohort)	Prospective (includes mother)	COPSAC ₂₀₀₀ Cohort: Disease-based	<ul style="list-style-type: none"> COPSAC₂₀₀₀ Cohort: <ul style="list-style-type: none"> Pregnant women Physician's diagnosis of asthma and need for daily treatment of asthma after age of 7 years 	COPSAC ₂₀₀₀ Cohort: Pregnancy – 13 years	COPSAC ₂₀₀₀ Cohort: 411 participants	<ul style="list-style-type: none"> COPSAC₂₀₀₀ Cohort: <ul style="list-style-type: none"> Blood Urine Tissues Faeces 	<ul style="list-style-type: none"> COPSAC₂₀₀₀ Cohort: <ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 	Indefinite	Hospital (Copenhagen University Hospital)
			COPSAC ₂₀₁₀ Cohort: Population-based	<ul style="list-style-type: none"> COPSAC₂₀₁₀ Cohort: <ul style="list-style-type: none"> Pregnant women in second trimester, planning to deliver at collaborating sites 	COPSAC ₂₀₁₀ Cohort: Pregnancy - 3	COPSAC ₂₀₁₀ Cohort: 800 participants	<ul style="list-style-type: none"> COPSAC₂₀₁₀ Cohort: <ul style="list-style-type: none"> Blood Urine Tissues Faeces 	<ul style="list-style-type: none"> COPSAC₂₀₁₀ Cohort: <ul style="list-style-type: none"> Genetic Phenotypic Health-related Lifestyle 		

3. The Legislative Privacy Framework

We will see that in addition to ethical norms which govern the privacy dimensions of paediatric research and biobanks, various international legal instruments to which Canada is a signatory acknowledge an individual's right to privacy and confidentiality.²⁸ In Canada, privacy legislation comprises various federal, provincial, and territorial statutes and regulations, professional codes of conduct, guidelines, standards, the common law, and constitutional law. The subsections below briefly discuss the constituent parts of the legislative privacy framework and the applicability of this framework to paediatric biobanks.

3.1. Constitutional Protections

Respect for privacy is a constitutional principle in Canada, but there is 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*²⁹ (*Canadian Charter*) cases. The generally accepted categories include personal, territorial and informational privacy.³⁰ Two provisions in the *Canadian Charter* have been interpreted as protecting a person's privacy. Section 7, which guarantees everyone "the right to life, liberty and security of the person", has been interpreted to include the right to be free of the psychological stress resulting from unauthorized disclosure of one's personal health information.³¹ Section 8, which grants the "right to be secure against unreasonable search or seizure", includes the protection of an individual's informational privacy. The Supreme Court of Canada has stated that "...what is protected by s. 8 is people, not places or things. The principal right protected by s. 8 is individual privacy, and the provision must be purposively applied to that end."³²

Section 52(1) of the *Canadian Constitution Act, 1982* provides that the Constitution of Canada is the supreme law of Canada and that "any law that is inconsistent with the provisions of

the Constitution is, to the extent of the inconsistency, of no force or effect.”³³ However, there are at least three limitations to the privacy protections it provides. First, the *Canadian Charter* only applies to the Parliament and government of Canada and the legislature and government of each province and territory.³⁴ Second, with regard to rights protected under sections 7 through 14 of the Charter, section 7 states that “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*” (emphasis added). Thus, a law could be found to be constitutional even if it deprives a person of life, liberty, or security of the person, if it conforms to the principles of fundamental justice. Third, section 1 of the *Canadian Charter* provides a limitations clause which allows the government to legally limit an individual's Charter rights.

Québec's *Charter of Human Rights and Freedoms*³⁵ (*Québec Charter*), which applies equally to the provincial government and private parties (although the *Canadian Charter* and the *Canadian Human Rights Act*³⁶ are still applicable in Québec), also guarantees every person the right to “respect for his private life” (Article 5) and “non-disclosure of confidential information” (Article 9).

3.2. Coverage of Privacy Legislation

Table 3 presents an overview of the coverage of federal and provincial privacy legislation (e.g. PIPEDA), as well as the *Canadian Charter*, *Québec Charter*, and *Civil Code of Québec*.

Table 3: 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	✓	✓ ³⁷	✓	✓	
Nova Scotia			✓		
New Brunswick			✓		✓
Prince Edward Island			✓		
Newfoundland and Labrador		✓	✓		✓
Yukon			✓		
Northwest Territories			✓		
Nunavut			✓		

3.3. Federal, Provincial and Territorial Privacy Legislation

It is beyond the scope of our Report to intricately analyze the contours of each privacy statute in the provinces and territories, but Table 4 below lists and briefly explains the relevant privacy-related statutes currently in force in each jurisdiction.

Table 4: Privacy Legislation in Canadian Provinces and Territories

Federal	<ul style="list-style-type: none"> • <i>Privacy Act</i>³⁸ <ul style="list-style-type: none"> ◦ Applies to more than 250 federal government departments and agencies, governing the collection, use, and disclosure of personal information ◦ A government department or agency must ensure that it has the legal authority to collect, use or disclose personal information • <i>Personal Information Protection and Electronic Documents Act (PIPEDA)</i>³⁹ <ul style="list-style-type: none"> ◦ Establishes rules for the management of personal information by organizations that collect, use and disclose personal information in the course of a commercial activity which takes place within a province, unless the province has enacted legislation deemed by the Governor in Council to be “substantially similar” to the Act.
British Columbia	<ul style="list-style-type: none"> • <i>Personal Information Protection Act</i>⁴⁰ <ul style="list-style-type: none"> ◦ Applies to the private sector ◦ Deemed “substantially similar” to PIPEDA • <i>Freedom of Information and Protection of Privacy Act</i>⁴¹ <ul style="list-style-type: none"> ◦ Applies to public bodies (e.g. governmental bodies, hospitals, universities) • <i>Privacy Act</i>⁴² <ul style="list-style-type: none"> ◦ Statute makes it a civil wrong for a person, wilfully and without a claim of right, to violate the privacy of another person without justification • <i>E-Health (Personal Health Information Access and Protection Act of Privacy) Act</i>⁴³ <ul style="list-style-type: none"> ◦ Facilitates the creation of consolidated databases of electronic personal health information (health information banks) ◦ Allows individuals to exercise control over disclosure of their personal health information, through the

	<p>issuance of "disclosure directives" by which the individual may request that access to his or her personal health information be blocked</p> <ul style="list-style-type: none"> o Researchers may request access to information contained in a health information bank from a data stewardship committee, which may impose additional security and confidentiality requirements on disclosure o For health-related research, the requests are approved on the condition that the information cannot be used for contacting an individual to participate in health research. If a researcher wishes to directly contact the individual whose information has been disclosed, the researcher must receive approval from the Information and Privacy Commissioner for B.C.
Alberta	<ul style="list-style-type: none"> • <i>Personal Information Protection Act</i>⁴⁴ <ul style="list-style-type: none"> o Applies to all private sector organizations, including non-profits and professional regulatory associations o Deemed "substantially similar" to PIPEDA o Does not apply to health information • <i>Freedom of Information and Protection of Privacy Act</i>⁴⁵ <ul style="list-style-type: none"> o Applies to public bodies (e.g. educational bodies, health care bodies, government departments) • <i>Health Information Act</i>⁴⁶ <ul style="list-style-type: none"> o Applies to custodians with respect to health information (e.g. health care facilities, regional health authorities) o Provides rules for REBs and researchers and private individuals or companies who receive personal health information from a trustee
Saskatchewan	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i>⁴⁷ <ul style="list-style-type: none"> o Applies to institutions (e.g. government departments, health professionals, health care organizations) o Does not apply to health information • <i>The Health Information Protection Act</i>⁴⁸ <ul style="list-style-type: none"> o Applies to trustees with respect to personal health information (e.g. health care facilities, universities, government departments) o Provides rules for research ethics boards and researchers and private individuals or companies who receive personal health information from a trustee • <i>The Local Authority Freedom of Information and Protection of Privacy Act</i>⁴⁹ <ul style="list-style-type: none"> o Applies to local authorities (e.g. universities, regional health authorities, special care homes) • <i>The Privacy Act</i>⁵⁰ <ul style="list-style-type: none"> o Statute makes it a civil wrong for a person, wilfully and without a claim of right, to violate the privacy of another person without justification
Manitoba	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i>⁵¹ <ul style="list-style-type: none"> o Applies to public bodies (e.g. universities, certain hospitals, government departments) o Does not apply to personal health information • <i>The Personal Health Information Act</i>⁵² <ul style="list-style-type: none"> o Applies to trustees with respect to personal health information (e.g. health care facilities, universities, government departments) o Provides rules for research ethics boards and researchers and private individuals or companies who receive personal health information from a trustee • <i>The Privacy Act</i>⁵³ <ul style="list-style-type: none"> o Statute makes it a civil wrong for a person to substantially, unreasonably, and without claim of right, to violate the privacy of another person
Ontario	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i>⁵⁴ <ul style="list-style-type: none"> o Applies to institutions (e.g. ministries, agencies, community colleges) • <i>Personal Health Information Protection Act, 2004</i>⁵⁵ <ul style="list-style-type: none"> o Applies to health information custodians and their agents, with respect to personal health information (e.g. hospitals, health care practitioners who provide healthcare, pharmacies, medical laboratories) o Provides rules for research ethics boards and researchers and private individuals or companies who receive personal health information from a health information custodian o Deemed "substantially similar" to PIPEDA • <i>Municipal Freedom of Information and Protection of Privacy Act</i>⁵⁶ <ul style="list-style-type: none"> o Applies to institutions (e.g. municipalities, boards of health, designated agencies)
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>⁵⁷ <ul style="list-style-type: none"> o Applies to public bodies (e.g. universities, CEGEPs, health care facilities) • <i>An Act respecting the protection of personal information in the private sector</i>⁵⁸ <ul style="list-style-type: none"> o Applies to persons carrying on an enterprise (e.g. health care providers in private practice, private research companies) o Deemed "substantially similar" to PIPEDA • <i>Act respecting health services and social services</i>⁵⁹ <ul style="list-style-type: none"> o Allows the director of professional services of an institution or, if there is no such director, the executive director, to authorize a professional to examine the record of a research participant for research purposes. However, the authorization must be granted for a limited period and with conditions, and is contingent on the director ascertaining that the criteria determined under section 125 of the <i>Act respecting Access to documents held by public bodies and the Protection of personal information</i> are satisfied • <i>Civil Code of Québec</i>⁶⁰ <ul style="list-style-type: none"> o Applies to all sectors and persons o Offers right to protection of privacy (Arts. 35, 37) • <i>Charter of Human Rights and Freedoms</i>⁶¹ <ul style="list-style-type: none"> o Applies to provincial government and private parties (other than federally regulated activities) o Guarantees every person the right to "respect for his private life" (Art. 5) and "non-disclosure of confidential information" (Art. 9)
New Brunswick	<ul style="list-style-type: none"> • <i>Right to Information and Protection of Privacy Act</i>⁶² <ul style="list-style-type: none"> o Applies to public bodies (e.g. government departments, school boards, regional health authorities) • <i>Personal Health Information Privacy and Access Act</i>⁶³ <ul style="list-style-type: none"> o Applies to and governs personal health information that is collected, used or disclosed by a custodian (e.g. public bodies, health care providers, researchers conducting a research project approved in accordance with the Act), or that is in the custody or control of a custodian o Provides rules for research ethics boards and researchers and private individuals or companies who receive personal health information from a custodian
Nova Scotia	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i>⁶⁴ <ul style="list-style-type: none"> o Applies to public bodies (e.g. universities, hospitals, government departments and agencies) • <i>Municipal Government Act</i>⁶⁵ <ul style="list-style-type: none"> o Applies to municipalities • <i>Personal Information International Disclosure Protection Act</i>⁶⁶ <ul style="list-style-type: none"> o Applies to municipalities and public bodies and employees, officers and directors of public bodies o Makes it illegal for public bodies and municipalities to disclose information outside of Canada, or store personal information at (or allow it to be accessed from), locations outside Canada, unless certain circumstances exist (e.g. research purposes and only after satisfaction of certain criteria)

Prince Edward Island	<ul style="list-style-type: none"> • <i>Freedom of Information and Protection of Privacy Act</i>⁶⁷ <ul style="list-style-type: none"> ◦ Applies to public bodies (e.g. government departments, agencies, designated education and health bodies)
Newfoundland and Labrador	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i>⁶⁸ <ul style="list-style-type: none"> ◦ Applies to all records in the custody of or under control of a public body (e.g. universities, health boards, municipalities, government departments) • <i>Personal Health Information Act</i>⁶⁹ <ul style="list-style-type: none"> ◦ Applies to custodians of personal health information (e.g. health care professionals, provincial health departments, the Public Health Laboratory) ◦ Provides rules for research ethics boards and researchers and private individuals or companies who receive personal health information from a health information custodian • <i>Privacy Act</i>⁷⁰ <ul style="list-style-type: none"> ◦ Statute makes it a civil wrong for a person to substantially, unreasonably, and without claim of right, to violate the privacy of another person
Yukon	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i>⁷¹ <ul style="list-style-type: none"> ◦ Applies to public bodies (e.g. government departments, agencies, boards)
Northwest Territories	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i>⁷² <ul style="list-style-type: none"> ◦ Applies to public bodies (e.g. government departments, agencies, boards)
Nunavut	<ul style="list-style-type: none"> • <i>Access to Information and Protection of Privacy Act</i>⁷³ <ul style="list-style-type: none"> ◦ Applies to public bodies (e.g. government departments, agencies, boards)

3.4. Privacy Legislation and Paediatric Biobank Applicability

The most pressing matter at the intersection of children and biobanks is the existence of structures (legal, ethical or otherwise) that ensure the protection of privacy. As the HBGRD Guidelines make clear, particular care in this area is essential: “The operators of the HBGRD should give careful consideration to any special issues related to the participation of vulnerable populations or groups, and their involvement should be subject to protective conditions in accordance with applicable law and ethical principles.”⁷⁴

Our analysis of this privacy framework indicates **a lack of rationalized and harmonized privacy coverage, which could compromise the privacy of paediatric biobank participants. Indeed, Canadian privacy legislation reveals that its applicability to paediatric biobanks is tenuous.** Paediatric biobanks are not necessarily inconsistent with the legislation, but much of the legislation does not contemplate the ever-evolving world of genomics and biobanking, much less the issues particular to paediatric biobanking. As one commentator notes, “there is no coherent legal framework to appropriately address the health-related privacy issues that are relevant in the context of biobanking”.⁷⁵ Because these laws were likely drafted without paediatric biobanks in mind, their utility is incomplete for addressing substantive issues regarding personal information protection and biobank governance.

While most legislation applies to public bodies, regional health authorities, universities, or other organizations, it may not cover a biobank. Much of the complexity rests in the composition and governance of a biobank: they are structured *resources* often built around the *collaboration* of distinct funders, donors, custodians and researchers (and potentially, one day, genomics or pharmaceutical companies and their customers). Indeed, some biobanks are public-private partnerships, such as the now-completed, open source, International HapMap Project (<http://hapmap.ncbi.nlm.nih.gov/>). Further, **large-scale paediatric biobanks do not so much resemble discrete research projects as they do infrastructures**, given their budget size, management structure, and administrative support (e.g. the National Children’s Study in the United States). It may be that “research biobanks” are in fact complementary scientific infrastructures to traditional discovery science.⁷⁶

There is no legislative or jurisprudential guidance on what determines whether a biobank is a “person”, “public body”, “organization”, “institution”, or similar designation. Indeed, because a biobank has been defined by the OECD as a “structured resource”⁷⁷ — a term unfamiliar to Canadian privacy legislation — its very composition is uncertain, especially when analyzing the geographic coverage and control of the biobank. **Consequently, the frequent, watertight dichotomy between public sector *or* private sector privacy legislation fails to recognize current hybrid biobank structures, which often serve as resources for future, unspecified research which may or may not include commercial support or use. Constitutional divisions between trade and commerce (federal jurisdiction) and healthcare and civil rights (provincial jurisdiction) also complicate the modern, mixed picture.** Though the *Personal Information Protection and Electronic Documents Act* (PIPEDA) does apply to “personal health information” that crosses interprovincial borders,⁷⁸ it does not specifically address one of the main issues posed in our

Report, *viz.* the applicability of the statute itself (or any statute) to the *structure* (i.e. biobank) of that information-holding entity, rather than only to some of its contents (i.e. data and samples).⁷⁹

Unless the governance model clearly divides roles and responsibilities and creates an unambiguous management structure, and a well-documented funding apparatus, determining whether a paediatric biobank falls under public sector or private sector privacy legislation will prove challenging. This challenge has not gone unnoticed by CIHR, which has remarked:

...the activities of health researchers themselves will be difficult to categorize as either commercial or non-commercial in nature. Increasingly, academia, private sector, voluntary charitable organizations and government are joining forces to engage in innovative research partnerships and to transform this new knowledge into forms which are beneficial to the population. In an era where such partnerships are actively encouraged, a whole spectrum of public-private arrangements have begun to emerge.⁸⁰

This limitation is demonstrated in many statutes that apply only to “commercial activity”, “federal government institutions” or “the legislature and government of each province”. For example, it is unclear whether PIPEDA, a commercial activity statute, applies to a paediatric biobank stored in a hospital or university since the paramount purpose is research-related and is not commercial in character. Yet, the requirement by many federal funding agencies (e.g. Genome Canada⁸¹) to have matching funds from the private sector (or non-government organizations or provincial governments) could involve PIPEDA. Researchers who request biological samples as part of a commercially-funded study may in fact be participating in a commercial activity. Thus, it remains unresolved whether researchers seeking neither profit nor commercial exploit still face PIPEDA scrutiny.

On the other hand, health information privacy legislation at times seems applicable. For example, it is voluntary for biobanks to register as “prescribed persons” under Ontario’s *Personal*

Health Information Protection Act, 2004 (OPHIPA) in order to receive personal health information from health information custodians. The Ontario Institute for Cancer Research's Ontario Tumour Bank (OTB) is a "prescribed person" under paragraph 39(1)(c) of OPHIPA.⁸² As a result, the OTB is entitled to collect, use, and disclose personal health information without consent strictly "for the purposes of facilitating or improving the provision of health care, or that relates to the storage or donation of body parts or bodily substances".⁸³ The "prescribed person" status makes it easier for the OTB to enrich its database with valuable follow-up information such as patient treatment and vital statistics by linking in to other data holdings, such as those held at Cancer Care Ontario.⁸⁴ To maintain the "prescribed person" status, the OTB is required to have policies that describe how it collects, retains, and protects personal health information and anonymized data, as well as circumstances under which personal health information and anonymized data may be disclosed and to whom. Participants in the OTB fully consent to the provision of samples and are informed of their status within OPHIPA and the intended use of the data.

Nonetheless, the legal landscape is not uniform across Canada and applicability remains uncertain. Given the uncertainty and variant coverage, public bodies have called on legislatures to amend current laws or create new ones that specifically address biobanks. For example, the Fonds de la Recherche en Santé du Québec⁸⁵ (FRSQ) (since July 2011, officially the Fonds de recherche du Québec – Santé) has recommended that "laws making provision for personal information protection be adapted to the emerging trends in health research so that such laws recognize the legal validity of data banks and biobanks and of research exploring themes rather than specific hypotheses".⁸⁶

4. Exploring the Privacy Landscape in Paediatric Biobanks

Paediatric biobanks must navigate the rapids of socio-ethical, professional and legal norms while simultaneously advancing knowledge in biomedical research. While some of these norms transcend national boundaries, such as the requirement to obtain voluntary and informed consent, others are specific and contextual, dependent on research ethics board (REB) oversight, legislative decree, or biobank governance infrastructure. A grand challenge in the navigation of this turbulent domain is properly addressing privacy issues that impact not only biobanks in general, but paediatric biobanks specifically. This Report explores the privacy landscape in paediatric biobanks by focusing on the three issues that particularly highlight the tension between the scientific promises of research and the ethical and legal obligations to respect privacy and confidentiality of the child's information: 1) the use and transfer of the child's data and samples; 2) the risks of unauthorized access by third parties; and 3) the nature of the shared relationship between the child, the parents and the researcher.

4.1. Use and Transfer of the Child's Data and Samples

Many concerns related to use and transfer of the child's data and samples exist, even when such use and transfer is authorized. Although the risk of misuse by authorized individuals and institutions is not the same as those by unauthorized individuals, as discussed in Subsection 4.2 below, the act of transferring data and samples outside of the original repository *ipso facto* increases risks, and raises questions of what the child or parents consented to and what effect additional access can have on the child's privacy and confidentiality.

4.1.1. The Ethical Dimensions

Researchers around the world rely on access to data contained in biobanks for multitudinous research purposes, including secondary use of the samples and data. Ethical norms and guidelines recognize the importance of collaboration between researchers to advance the goals of research and avoid duplication.⁸⁷ However, to protect research participants, access to data is often restricted in some manner, such as the requirement to obtain the informed consent of the research subject, collaborate with the researchers linked to the underlying research project, obtain REB approval, obtain steering or executive committee approval, and obtain data access committee approval upon the submission of a data transfer agreement (DTA) or material transfer agreement (MTA).⁸⁸

In Canada, the TCPS permits access to biobank data and samples by authorized third parties, such as researchers or other institutions. In general, participants — or, in the case of paediatric research, the participant's parents⁸⁹ — must consent to such access or certain conditions must be met.⁹⁰ Specific consent for each instance of access is not necessarily required; the use of broad consent decreases the impact that such a requirement might have. Indeed, in Québec, the FRSQ has advocated for change in provincial law to specifically permit a general consent in order to harmonize with ethical standards and further participants' autonomy.⁹¹

The TCPS also briefly addresses mechanisms by which researchers and institutions can access data and samples contained within biobanks: "...researchers may be required to apply to the organization for permission to access biological samples, and they may be required to enter into an agreement with the organization that sets out conditions for research access and use of materials in the biobank."⁹² However, the TCPS does not specifically address material and data transfer agreements, which are commonly used by biobanks.

The *Best Practices for Health Research Involving Children and Adolescents* (BPHR) provides similar details for access to paediatric data and samples. Data-sharing agreements should be used and access “should be limited to the information needed to conduct the proposed research efficiently.”⁹³ The BPHR also places responsibility for those accessing the biobank squarely on the shoulders of the researchers or institutions responsible for the biobank.⁹⁴

Internationally, the OECD HBGRD Guidelines are perhaps the most detailed on the issue of access to biobanks for research purposes. Article 7 addresses access issues, such as requirements for projects wishing to access the data or materials (including privacy and confidentiality protections), limiting access to coded or anonymized data or samples, and the use of access and confidentiality agreements.⁹⁵ Essentially, the biobank must have in place numerous protection mechanisms and ensure that those wishing to access the biobank have similar mechanisms.

Although allowing access for research purposes is generally accepted in ethical guidance, commentators do not always agree with the extent of such activities in the paediatric context.⁹⁶ Recent debate has centred on the time at which it is ethically permissible to disseminate samples and data to researchers (through properly approved mechanisms). Some commentators have distinguished between disease-based and population-based biobanks in this regard.⁹⁷ Although disease-based biobanks should function as they currently do, i.e. permitting researchers to access data and samples even before the child attains decision-making capacity, population-based biobanks should not send samples outside of the jurisdiction until the child can consent and does so.⁹⁸ However, critics of this proposition point out that policies should focus on limiting the data shared and improving protections, rather than an outright prohibition.⁹⁹ The commentators have countered that privacy policies of the past are no longer sufficient in the face of technological advances that no longer guarantee anonymity.¹⁰⁰

This debate demonstrates that there are genuine, potential risks to privacy that accompany access to data and samples — especially in the absence of legislative protection, strong security measures, and a sound biobank governance infrastructure. Ethical norms generally support access by third-party researchers with certain safeguards, and although the BPHR supports access even in the paediatric context, the continuing debate over how data and samples can remain private in a world of advancing technologies illustrates the ethical uncertainties that remain.¹⁰¹

4.1.2. The Legislative Dimensions

While informed consent is recognized as an obligation of primary importance to protect privacy (and respect the person), its effect is detrimentally impacted by legislative gaps in protecting access, use and transfer of data and samples. A core obligation under privacy legislation, such as PIPEDA, is that organizations can disclose personal information only for purposes that a reasonable person would consider appropriate in the circumstances,¹⁰² or, as in the case of the federal *Privacy Act*, for the primary purpose for which it was collected or for directly related secondary purposes.¹⁰³ There is currently no similar obligation applicable to the disclosure or transfer of biological materials. This means that while privacy statutes prohibit organizations (possibly including biobanks) from disclosing information *derived* from a biological sample without the individual's consent (subject to limited exceptions), there is no explicit prohibition under the *Act* to the disclosure or transfer of the biological sample itself. This has a profound impact on informed consent. A biobank may face regulatory, contractual, or other consequences for disclosing or transferring the samples without proper consent, but **under privacy legislation the transfer and use of samples is not covered** (although tissue-related legislation can require consent for the *taking* of tissue). A paediatric biobank's very purpose is to manage and distribute data and samples. Maintaining this purpose under the backdrop of

legislative clarity and oversight is possible. Currently, however, little privacy protection for non-consented sample transfer is afforded through legally enforceable mechanisms.

Similarly, privacy legislation generally allows an individual (participant) to access their information. But **the legislation does not explicitly permit participants to access their biological materials**. It may be argued that individuals need not have such access because they can provide another sample. However, the amount of biological materials stored is limited and the tissue may be rare (e.g. tumours). Cell lines can be made, but this is expensive. This is also problematic in a paediatric context since a child may wish to have access to their donated samples as they reach maturity for purposes of medical testing, diagnosis, or treatment.

Many Canadian privacy statutes, such as the federal *Privacy Act*, PIPEDA, and OPHIPA combine “fair information practices”¹⁰⁴ or “principles” (i.e. internationally accepted principles regarding the collection, use and disclosure of personal information) with research ethics norms to govern the access to personal health information for research purposes. Depending on the source, these accepted principles may not include an independent consent principle, which is why some statutes (e.g. the federal *Privacy Act*) generally allow the collection of personal information without consent, whereas others (e.g. PIPEDA) mandate consent (unless there is an explicit exception).¹⁰⁵ Those statutes which do not operate on this combined fair information practices/research ethics model nonetheless contain exceptions to consent for research purposes. Those provinces which have personal health information protection legislation also have particular rules governing disclosure of personal health information without the individual’s consent.¹⁰⁶

4.1.3. Biobank Practice Dimensions

Regarding the Canadian paediatric biobanks (CHILD, FORGE, and Étude 3-D), the CHILD consent forms provide no information about secondary use by other (i.e. external) researchers. The forms only state that, “Researchers involved in the study might be interested in follow-up after the five year time period, and participants may be asked in the future about their interest in participating in further studies.”¹⁰⁷ The FORGE consent forms state that all data and samples will be shared with Canadian investigators who are members of the Canadian Pediatric Genetic Disorders Sequencing Consortium (CPGDS).¹⁰⁸ Before such sharing, however, the data and samples will be coded. Researchers outside of Canada may access the coded data (in a controlled access database) and samples following the approval of the CPGDS scientific committee and relevant REBs.¹⁰⁹ General research results and anonymized data (i.e. that cannot be linked back to the patient or the patient’s child) will be available to researchers in an open access database.¹¹⁰

Researchers who wish to obtain access to data or biological materials from the Étude 3-D study must obtain REB and Board of Principal Investigators authorizations. Even if such authorizations are given, further conditions may be imposed, including an obligation to obtain specific consent for a project (from an adult for him- or herself or in a child’s stead) or the assent of a child, and anonymization of the data or biological material before they are sent to an investigator (rather than sending them encoded).¹¹¹ A Data/Biomaterial Transfer Agreement is also required, which requires the researchers to, *inter alia*, not transmit data or biological material to unauthorized recipients, respect the participants’ confidentiality and not attempt to reidentify participants, and destroy all the data obtained at the end of the research and destroy or return to the biobank any biological material that remains unused.¹¹²

The NCS in the United States requires that researchers wanting to use the information (1) get certified by the National Children’s Study and the federal government; (2) receive permission from a group of doctors, scientists, and community members (the iSMOC); (3) sign an affidavit of nondisclosure; and (4) only disclose group results of research rather than individual results to each participant.¹¹³ The NCS says it will track researchers to make sure they are keeping participants’ information safe and will regularly review ways to keep information and samples secure.¹¹⁴ The NCS data collection, processing, and access policies aim to conform to federal regulations and guidelines regarding data confidentiality and disclosure limitation, and to the commitment to confidentiality espoused in the informed consent form.¹¹⁵ Indeed, it should be noted that the NCS must conform to Part 46 of the U.S. Code of Federal Regulations (Protection of Human Subjects) (the Common Rule),¹¹⁶ which applies to all federally funded research involving human subjects. The Gopher Kids Study consent form states that the child will be contacted “when he or she turns 18 to see if we can continue storing his or her samples”. As for secondary use of the DNA, it only states that “research that uses you and your child’s DNA might be done a long time after they’re collected”.¹¹⁷

Researchers wishing to work with ALSPAC data in the UK must submit an ALSPAC Research Proposal Form, which includes a section setting out the rules for access and use of ALSPAC data. The ALSPAC study team is prohibited from linking potentially identifying data collected to the published data resource. Instead, a two-stage process is required whereby the potentially identifying data are sent as a separate file with an identifier, but unmatched to any other data. Researchers must then derive new variables that are less specific and could not be used to identify an individual and return these to the study team so that they can be added to the rest of the researchers’ data request. If the data request is novel, the study team must ask the ALSPAC Ethics and Law Committee to review and approve the proposal. If the proposal requires

detailed potentially identifying data, the researchers may be required to complete a DTA.¹¹⁸ Similarly, research using genotype data requires a DTA between the University of Bristol and the researchers' host institution. Biological samples, including DNA, are provided under the terms of a MTA. Both the DTA and MTA impose several privacy requirements on researchers.¹¹⁹

Danish biobanks, such as COPSAC, must register with the Danish Data Protection Agency, in accordance with the rules on notification and authorization in chapters 12 and 13 of the *Act on Processing of Personal Data*.¹²⁰ With respect to “research biobanks” (as defined in the Act), when the research project is completed (or material is no longer to be used for scientific purposes), the biobank’s material must be destroyed or anonymized (i.e. irreversibly delinked).¹²¹ “Anonymous” biological material, on the other hand, may continue to be stored and used without further authorization from the Danish Data Protection Agency.¹²² The disclosure of biological material for use in other scientific projects may only be carried out with special authorization from the Danish Data Protection Agency.¹²³ This also applies if the entire biobank is to be transferred to another researcher or is to be used for another scientific purpose.¹²⁴

Finally, we note that the biobank consent forms, in their discussion of potential risks, focus primarily on physical and emotional risks to participants. An important set of risks not commonly noted in these consent forms — related to the use of and access (both authorized and unauthorized) to information — are privacy risks. While the consent forms do discuss the confidentiality and security protections, they barely mention the risks of potential use or misuse of information, if at all. This may be due to the fact that the very purpose of many biobanks is to allow the dissemination of data and biological samples to researchers and institutions.

Table 5 illustrates the biobank practice dimensions relating to access, use and transfer.

Table 5: Biobank Practices Relating to Access, Use and Transfer of the Child's Data and Samples

Biobank	Access or use by child and/or parents to data and samples	Transfer of data and samples/secondary use	Length of storage of data and samples
Canadian Healthy Infant Longitudinal Development (CHILD) Study	<ul style="list-style-type: none"> No discussion of possibility to access or use data and samples by either parent or child, but if parent decides to withdraw from study, parent will not be included in follow-up data collections and study will only use data parent/child provided during study participation 	<ul style="list-style-type: none"> Consent form mentions that researchers involved in study may be interested in longer term follow-up after the five-year time period, and parent may be asked about interest in participating in additional studies in the future Data or sample-requesting individual or group of investigators must submit a letter of request to the Director at the National Coordinating Centre, stating: 1) purpose of the request; 2) data which are requested as precisely as possible; 3) population for whom data are requested; 4) use which will be made of the data including statistical approach to analysis where appropriate; 4) how the data should be best formatted; and 5) when the data are required 	<ul style="list-style-type: none"> Samples will usually be processed in a local laboratory for long-term storage in a centralized liquid nitrogen facility, pending determination of best methods and facilities for analysis, and acquiring necessary funding Process is overseen by a Biological Samples Committee Data will be used for study only and will be kept as long as required, then destroyed as required by local study centre policies
Étude Découvrir, Développer, Devenir (Étude 3-D)	<ul style="list-style-type: none"> No discussion of possibility to access or use data and samples by either parent or child, but parent may request that all data and samples provided be destroyed 	<ul style="list-style-type: none"> Biobank will be resource for various researchers conducting research on the course of pregnancy and the impacts of mother's and father's health on the child's health and development Authorization required Possibility of obligation of seeking child's assent Data or biological material sent to researchers are identified with a code Data/Biomaterial Transfer Agreement also required 	<ul style="list-style-type: none"> Indefinite, unless parent requests destruction
Finding of Rare Disease Genes in Canada (FORGE) Canada	<ul style="list-style-type: none"> No discussion of possibility to access or use data and samples by either parent or child, but if there is withdrawal from the study completely, samples and data will be destroyed where possible (already published data and already used samples cannot be destroyed) 	<ul style="list-style-type: none"> All coded data and samples are shared with Canadian investigators who are members of the Canadian Pediatric Genetic Disorders Sequencing Consortium Coded data and samples will be shared externally for research related to the study of rare genetic disorders, following approval from the Consortium scientific committee and the relevant REB 	<ul style="list-style-type: none"> Indefinite (data) DNA samples and any cell lines will be kept until the gene for the rare genetic disease in patient's family has been identified and the mechanisms leading to the health issues related to the disorder are understood
National Children's Study (NCS)	<ul style="list-style-type: none"> No discussion of possibility to access or use data and samples by either parent or child, but parent may decline to provide genetic samples, answer questions, provide data, etc. in the study. The parent may also request that all unused samples provided be destroyed (but data already provided will continue to be used) 	<ul style="list-style-type: none"> Information from biological samples may be shared directly with researchers or through a secure national research database. The goals of these future studies will be similar to the goals of the NCS Consent form requires agreement to allow possible use of participant's information and samples for future studies on child and maternal health and disease Independent Safety Monitoring and Oversight Committee (ISMOC) to oversee information and samples will only be used to meet the goals of the NCS 	<ul style="list-style-type: none"> Indefinite, unless parent (or child, after given opportunity to consent) requests destruction
Gopher Kids Study	<ul style="list-style-type: none"> No discussion of possibility to access or use data and samples by either parent or child Parent can request destruction of parent's or child's samples at any time 	<ul style="list-style-type: none"> No discussion (only mentions that samples will be used for research by the head investigator and his associates, though research "might be done a long time after they are collected") 	<ul style="list-style-type: none"> Indefinite, unless parent requests destruction Study will contact child when he or she turns 18 to see if possible to continue storing samples
Avon Longitudinal Study of Parents and Children (ALSPAC)	<ul style="list-style-type: none"> No discussion of possibility to access or use data and samples by either parent or child, but at this point in the study, both parent or child can withdraw (children given this right starting at age 16) 	<ul style="list-style-type: none"> According to original consent form, pregnant mother's biological materials may be used "for research purposes" Transfer of data and samples to external researchers is governed by a Collaboration Policy, which requires a Research Proposal Form and may require a Data Transfer Agreement and/or Material Transfer Agreement 	<ul style="list-style-type: none"> Indefinite
Copenhagen Studies on Asthma in Childhood (COPSAC)	<ul style="list-style-type: none"> According to Danish Data Protection Agency, participants in a research project do not have a right to access data about themselves (or others) that is included in the project. Though participants always have a right to withdraw from the project, they do not have the right to demand that their data be handed over or deleted, unless this is agreed upon in advance with the researcher 	<ul style="list-style-type: none"> According to Danish Data Protection Agency, the transfer of data or samples for use in other scientific projects may only be carried out with special authorization from the Danish Data Protection Agency. This also applies if the entire biobank is to be transferred to another researcher or is to be used for another scientific purpose 	<ul style="list-style-type: none"> According to Danish Data Protection Agency, when the research project is completed (or samples are no longer to be used for scientific purposes), samples must be destroyed or anonymized. "Anonymously" biological samples may continue to be stored and used without further authorization

4.2. Risks of Unauthorized Access by Third Parties

Risk of unauthorized access to identifiable, sensitive medical information (including genetic information) is a traditional concern of research. Biobanks collect a substantial amount of information on children which might be stored and used for prolonged periods — or indefinitely. Access to data and samples by third parties (e.g. the government, employers, insurers, educational institutions) raises particular privacy concerns since the information can be used by them to discriminate against a child in (future) employment, insurance coverage, and education.

The increasing use of banked tissue samples and data has certainly augmented the prospect of a breach of privacy, simply because the information, now often stored in electronic form, is much more widely available and distributed than it once was. This holds true for both paediatric and adult participants in biobank-based research. However, the special circumstance of children — generally non-consenting participants in research — requires additional consideration. What guidance do researchers have from ethical norms to protect the information from access? How do governments across Canada limit access to sensitive health and genetic information, and what are the consequences for a breach? How do established paediatric biobanks seek to prevent unauthorized access?

4.2.1. The Ethical Dimensions

A consensus exists among international and national norms that personal information should not be disclosed to third parties unless the parents have consented to such disclosure.¹²⁵ The goal of the available ethical guidance is to encourage researchers and research entities to address these concerns pre-emptively. To that end, over time, ethical guidance has become more nuanced with regard to the protection of personal, identifiable information against unauthorized access by third parties.

International and national guidelines address the protection of participants' personal information collected for health research. Internationally, protection of information against unauthorized access is a common theme found in ethical guidance. For example, the United Nations Educational, Scientific and Cultural Organization (UNESCO) recognizes that

Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights.¹²⁶

In addition, the OECD HBGRD Guidelines state that "...the operators and users of the HBGRD should ... secure the protection of participants' privacy and the confidentiality of data and information".¹²⁷ The Guidelines also provide a detailed discussion of ways in which to ensure confidentiality and privacy of data and samples.¹²⁸ Similarly, according to the National Health and Medical Research Council in Australia, "[t]he biobank custodian [e.g. a researcher or institution] should ensure a robust infrastructure is in place, consisting of both hardware and software components, so as to prevent unauthorised access to databases".¹²⁹

Nationally, the 2005 *CIHR Best Practices for Protecting Privacy in Health Research*¹³⁰ suggests three categories of measures to be adopted by researchers: 1) organizational safeguards (e.g. data sharing agreements and limited access); 2) technological measures (e.g. data coding, password protection); and 3) physical security (e.g. secured storage facilities and surveillance).¹³¹ This categorization is mirrored in the second draft of the BPHR, which provides detailed discussion of specific steps to protect paediatric privacy.¹³²

The TCPS provides guidance on privacy and confidentiality (chapter 5) as well as biobank-specific guidance (chapters 12 and 13). It defines privacy as "an individual's right to be

free from intrusion or interference by others”¹³³ and confidentiality as “the obligation of an individual or organization to safeguard entrusted information”.¹³⁴ Together, these two definitions mean that researchers must protect entrusted information against access by unauthorized third parties.¹³⁵ In addition, researchers must fully disclose to REBs proposed means to protect the information, including security measures,¹³⁶ and institutions where data (and, presumably, biological samples) are held are also responsible for establishing safeguards.¹³⁷

Finally, the TCPS contains biobank-specific provisions, requiring those who maintain biobanks to “establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorized handling”.¹³⁸ These provisions signify the seriousness with which the TCPS takes the potential for unauthorized access to personal information. However, as a broadly applicable guidance document, the TCPS does not explicate the types of security measures to be taken under each category or how to address unauthorized access to the information contained within a biobank.

The BPHR provides more detailed information on privacy practices and risks specifically for paediatric research. It states strongly that “researchers and members of the research team should never disclose personal information...to a third party unless the competent child or the incompetent child’s parents consented to such disclosure...”.¹³⁹ In addition, it provides examples and in-depth discussion of organizational safeguards and physical and technological measures that should be implemented to safely protect personal information.¹⁴⁰

Although these provisions, with the exception of the BPHR, do not apply specifically to paediatric research, their message is universal: the privacy and confidentiality of biobank participants must be protected against unauthorized access. The lack of detail regarding specific methods to protect privacy is more an indication of the limitations of ethical guidance than a failure to recognize the importance of privacy.

4.2.2. The Legislative Dimensions

Canada's privacy statutes generally prohibit access to personal (and possibly genetic) information by third parties unless the person concerned consents to such access. Also, those who are governed by these access/non-disclosure requirements are "custodians", "public bodies" or similar entities. New Brunswick's *Personal Health Information Privacy and Access Act*, for instance, defines "personal health information" as including "the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any body part or bodily substance".¹⁴¹ The Act states that custodians are prohibited from disclosing personal health information without consent, except under specified circumstances (e.g. by law, health related purposes, health care programs, health and safety, proceedings, enforcement purposes, research purposes, etc.). Yet, custodians "may disclose personal health information that has been de-identified [all identifying information has been removed] for any purpose".¹⁴² Thus, if a child's data or samples have been anonymized, a custodian may disclose the samples or associated information to third parties.

However, it is unclear what happens in the context of paediatric biobanks where the consent is provided by the parents and the child might oppose the disclosure of any personal information. Given the uncertainty regarding privacy legislation to biobanks, their applicability to biobank policies regarding third party access is also unclear, especially in light of consent and the opinions of the parents and child. Indeed, most large-scale paediatric biobanks rely on private ordering (via access/transfer agreements) to determine the scope of third party access and sanctions for violations. However, it is uncertain whether this operates under the backdrop of privacy legislation - wherein consent of the parent or child is required to permit disclosure - or in spite of it, following rules developed through ethical norms.

Applicability to biobanks aside, **none of the statutes address scenarios that arise in a paediatric context, where both parents and researchers may have a greater access to genetic information and may disclose it to third parties**, such as the child's doctor, teacher or coach, precisely because the parent exercises consent as a proxy for the child. Nevertheless, it should be remembered that, internationally and nationally, ethics norms and professional codes prohibit genetic testing in children and minors for adult onset diseases, so the risk of privacy harms is minimized in this specific context.¹⁴³

In addition, protection against unauthorized third party access to biobanks should also be coupled with meaningful penalties for privacy violations. Some foreign jurisdictions contain specific penalties for genetic privacy violations.¹⁴⁴ While the absence of such legislation in Canada is not problematic in and of itself, the absence of meaningful, enforceable penalties for privacy violations may be. This is not to say that genotypic and phenotypic data or material contained in biobanks are exceptional, but concerns associated with them are often amplified in comparison to other health information. For example, obtaining genetic material without properly informed consent violates basic human dignity and autonomy and also breaches a person's privacy. Non-consensual disclosure of information related to the material can affect a plethora of areas, including the child's (future) health, kinship, parentage, relationships and employment.

Currently, privacy legislation provides only limited protection against the non-consensual collection, retention, or disclosure of health data or biological material. Several examples illustrate this point. First, the legislation does not apply specifically to biological material and the complete applicability to "genetic information" is unclear, although one legal opinion states that biological material is indeed considered "personal information" under the *Privacy Act*.¹⁴⁵ Second, an organization is exempt from PIPEDA if it does not collect, use or disclose personal information

in the course of *commercial activities*, and it is not axiomatic that a biobank engages in commercial activity.

Health information legislation contains penalty provisions, but they are narrowly drafted. OPHIPA, for instance, requires that an individual seeking damages prove “actual harm” for a breach of privacy, but only after the information and privacy commissioner has made an order, or a person has been convicted of an offence under the legislation that has become final as the result of there being no further right of appeal.¹⁴⁶ Further, damages for mental anguish are capped at \$10,000 and applicable only if the violation was wilful or reckless.¹⁴⁷ A person may be fined for collecting, using or disclosing personal health information in contravention of the statute or its regulations, but only if it is “wilful”,¹⁴⁸ imposing a higher evidentiary burden.

By contrast, under the *Genetic Information Nondiscrimination Act*¹⁴⁹ (GINA) in the United States, the federal Department of Labor may sue to enforce GINA, and penalties up to \$100 per day may be imposed on health insurers, with a minimum penalty of \$2,500 for de minimis, uncorrected violations and \$15,000 for significant violations. There is no cap on the penalty amount for violations resulting from wilful neglect or intentional misconduct. Additionally, an aggrieved person may seek compensatory damages as well as punitive damages against an employer if he or she demonstrates that the employer acted maliciously or with reckless indifference to the individual’s rights.¹⁵⁰ However, this “genetic” legislation should be viewed in the American context, where there is no universal health care and the law addresses primarily health insurance and employment discrimination.

In sum, **the lack of specific penalties for privacy violations concerning health data and biological materials in the context of biobanks fails to address the potentially unique harms that**

arise from non-consensual third party collection, use, and disclosure of such information or material.

4.2.3. Biobank Practice Dimensions

As discussed in Subsection 4.1.3. above, paediatric biobank policies and consent forms generally disclose the measures taken to safely store and secure participants' data. Some provide further measures or obligations that the biobank will undertake. The FORGE Canada consent forms state that "Information will not be disclosed to insurance companies or employers"¹⁵¹ and that "no information that discloses your/your child's identity will be shared or published without your specific consent to the disclosure".¹⁵² The U.S. Department of Health and Human Services gave the NCS a Certificate of Confidentiality, which means the study cannot be forced by a court order or subpoena to disclose information that might identify participants.¹⁵³ However, there is variability in protection. For example, the Gopher Kids Study consent form notes only the "small risk" that personal information could accidentally be released to someone other than study staff,¹⁵⁴ and that "confidentiality is not absolute".¹⁵⁵ No other information about third party access risks is discussed.

Table 6 illustrates the biobank practice dimensions relating to unauthorized third party access.

Table 6: Biobank Practices Relating to Unauthorized Third Party Access

Biobank	Handling of privacy and confidentiality/protection against unauthorized access by third parties	Potential risks (regarding unauthorized third party access)	Assent or consent of the child (regarding access by third parties to data/samples)
Canadian Healthy Infant Longitudinal Development (CHILD) Study	<ul style="list-style-type: none"> Personal data, including name of each participant, is available only to the respective local study centre coordinators and co-PI at each site, for purposes of contacting families, and ensuring appropriate follow-up. All other access to individual data is based on ID numbers and not names Multiple levels of access to CHILD data (from full access by e.g. Data Manager to extremely limited by access by e.g. data entry personnel) Copies of all data sets are held at secure sites by CHILD, with backup at alternate secure sites Research records and medical records may be inspected in the presence of the investigator or his/her delegate by representatives of Health Canada and the hospital's REB for auditing purposes 	<ul style="list-style-type: none"> Consent form mentions that in rare instances it will not be possible to ensure confidentiality because of mandatory reporting laws 	<ul style="list-style-type: none"> No discussion of possibility for child's assent
Étude Découvrir, Développer, Devenir (Étude 3-D)	<ul style="list-style-type: none"> Name of participants are coded; linking key is placed under the responsibility of the project's principal researchers Research records and medical records may be inspected in the presence of the investigator or his/her delegate by representatives of CIHR and the hospital's REB for auditing purposes 	<ul style="list-style-type: none"> Consent form mentions that there is a risk of disclosure of results to third parties, which may compromise or decrease the parent, child or family's chance of insurability (life, health, invalidity, etc.) 	<ul style="list-style-type: none"> IRNPOEO Databank and Bank of Biological Material Management Policy addresses possibility of obtaining assent of children "when they are old enough to understand" and consent when they become adults Policy states that need for assent is based on maturity and intelligence of the child
Finding of Rare Disease Genes in Canada (FORGE) Canada	<ul style="list-style-type: none"> All data and samples will be kept securely at the research facility Any record that identifies patient by name or initials not allowed to leave investigator's offices Data and samples that will be shared with other researchers will first be coded (coded data will also be stored in a controlled access database) Research records and medical records may be inspected in the presence of the investigator or his/her delegate by representatives of Health Canada and the hospital's REB for auditing purposes 	<ul style="list-style-type: none"> No risk regarding unauthorized third party access discussed 	<ul style="list-style-type: none"> Children age 14-18 specifically asked to provide assent (or consent when foreseen under legislation) to participate Children under age 14 must have study explained to them at a level that is appropriate and they must provide assent to participate
National Children's Study (NCS)	<ul style="list-style-type: none"> Code to label samples and other information Number code kept separate from name, address, and other personal information. Information will be analyzed using number code Test results and other information kept in a secure computer database Samples and other information kept in secure place Regular safety review on ways to keep information and samples secure and private Certificate of Confidentiality to prevent court order or subpoena to disclose information that might identify participant in any court Requirement to disclose personal information to police/social services agency if study learns participant or someone else is harming parent, child, or others around them 	<ul style="list-style-type: none"> Consent form mentions that there is a chance that personal information or identity could be disclosed, and that there is always some chance that technology could be developed that would make it possible to identify participants of their family members 	<ul style="list-style-type: none"> Assent will be sought when child is considered to be able to understand the study procedures When the child reaches the legal age of majority in the area in which they live, the child as a study participant will have the opportunity to consent
Gopher Kids Study	<ul style="list-style-type: none"> Records of study will be kept private All personal information kept in locked file cabinets or in password-protected computer databases, with only staff having access Record is subject to review by departments at the University of Minnesota with appropriate regulatory oversight 	<ul style="list-style-type: none"> Possibility that parent or child's personal information could accidentally be released to someone other than study staff 	<ul style="list-style-type: none"> No assent or consent of the child (only when child turns 18 will study contact him or her directly for consent to continue storing data/samples)
Avon Longitudinal Study of Parents and Children (ALSPAC)	<ul style="list-style-type: none"> Code to label samples and other information Identifying data sent to external researchers as separate file with an identifier, but unmatched to any other data; researchers must derive new variables that are less specific and could not be used to identify an individual and return these new variables to the study team so that these new variables can be added to the rest of researcher data request Data/Material Transfer Agreement requirements: (a) data stored in secure location on premises and no unauthorized access; (b) no third party data transfers; (c) data must be used only to carry out the research described in DTA, only for research that has appropriate ethical approval, and not for any commercial purposes; (d) return or destruction of data upon, inter alia, withdrawal of consent of the relevant study participant; and (e) no attempt to identify study participants Genome-wide data to be analyzed only in Bristol, England 	<ul style="list-style-type: none"> Study investigators or staff will disclose personal information if required to by statute (e.g. criminal law) or public interest (e.g. if someone's life is endangered) Possibility that samples will be required to be released pursuant to statutory obligations (e.g. court order requiring evidence) 	<ul style="list-style-type: none"> By age 16, parental consent was no longer required, allowing the child to authorize access or use of data and samples by third parties
Copenhagen Studies on Asthma in Childhood (COPSAK)	<ul style="list-style-type: none"> Confidentiality of participants protected in accordance with Guidelines, EU Clinical Trials Directive (2001/20/EC) According to Danish Data Protection Agency, samples must be stored in a technically defensible manner that ensures the material is not accidentally or illegally destroyed, lost or damaged. It is also necessary to ensure that samples do not become known to unauthorized third parties, nor otherwise abused or used in violation of the legislation. Researcher is therefore required to produce special guidelines for the storage and use of the project's samples 	<ul style="list-style-type: none"> N/A (unable to access consent form and relevant policies) 	<ul style="list-style-type: none"> N/A (unable to access consent form and relevant policies)

4.3. The Nature of the Shared Relationship between the Child, the Parents, and the Researcher

The inclusion of children in research is accepted both in Canada and internationally.¹⁵⁶ However, due to the limited maturity and comprehension of all but older minors, children do not have the capacity to consent to their own participation.¹⁵⁷ Consequently, permission or consent for children's participation in research must come from another source: generally parents, but also other legal guardians. For the purpose of our Report, we will refer to this additional party as the parents, while recognizing that there are other legal relationships that grant decision-making authority over children.

Such an arrangement complicates the privacy of children, as they are then not the only person aside from the researcher involved in decision-making and with access to information derived from research. The inclusion of parents in the process generally gives them access to sensitive information concerning their child, which is a loss of privacy not common in research involving adults. Relevant issues include information that may be disclosed only to the parents, information that may be disclosed only to the child when he or she is mature, and the possibility that a child can request some information to remain private.¹⁵⁸

Indeed, the balancing of the confidentiality and privacy rights of the child and the authority legally and ethically granted to parents creates additional risks for the child. In fact, an argument can be made that the need for privacy increases as the child matures, and a child's perspective on what is private may vary considerably from an adult's perspective.¹⁵⁹ It is for these reasons that this tri-partite relationship — between the child, researcher and parents — must be scrutinized from an ethical, legal and biobank practice dimension.

4.3.1. The Ethical Dimensions

The relationship between the child, parents and researcher creates ethical tensions, especially with regard to carrying out research and the information discovered through research. When providing information about the child, such as results or incidental findings, to whom should the researcher communicate? How are particularly sensitive matters that might impact the parent-child relationship handled?

The 1989 *Convention on the Rights of the Child* sets forth a general right of the child “...to seek, receive and impart information and ideas of all kinds...”.¹⁶⁰ In addition, children have rights to the enjoyment of the highest attainable standard of health,¹⁶¹ the expression of their own views,¹⁶² and the ability to have their interests override those of their parents.¹⁶³ *Prima facie*, these rights are in opposition to guidance that at the very least tempers them with the age and maturity of the child. However, as the *Convention* is a broad document covering many aspects of a child’s life, it is difficult to stretch these general statements to the particularities of biomedical research.

International ethical norms more directly relevant to biomedical research affirm that research participants are entitled to know any of their personal information collected in the course of research.¹⁶⁴ As decision-makers for children, parents typically are granted a right to access this information. Ethical guidance is generally limited to recognizing the parents’ right to their child’s information and whether to disclose it to their child:

Parents have the right to know about the state of a child’s health, whether the illness be curable or not....It is their duty, if necessary in agreement with genetic counsellors and pediatricians, to decide to what extent, when and in what form the child be informed about his/her genetic data.¹⁶⁵

The right of *children* to be informed is not otherwise addressed. The guidelines that examine the right of participants to be informed generally focus on adult participants,¹⁶⁶ with only the

European Commission specifying that children have a right of access to their health information, but this is in the limited context of clinical trials.¹⁶⁷

In contrast, the Canadian BPHR raises the issue of access to information from the paediatric perspective. Although endorsing the general proposition that parents of an incompetent child receive the information, it calls for researchers to disclose directly to competent children and, “[i]f feasible, the incompetent child should be informed.”¹⁶⁸ Furthermore, although the wishes of the parents should be respected, if the health of the child is at risk, the information should be disclosed regardless of the parents’ desire not to know.¹⁶⁹ In this regard, the privacy of the parents as decision-makers will not trump the rights and health of the child.

Although ethical norms provide little guidance on this issue, commentators have had occasion to address the question of sharing information between the researcher, child and parents. Although parents are still commonly viewed as the party to whom information should be given, certain information necessitates limited disclosure.¹⁷⁰ For example, discoveries about late-onset disorders or information derived from whole-genome sequencing should not be provided to parents out of respect for the child’s autonomy, although they would be ordinarily provided to a competent adult.¹⁷¹ Conversely, parents do not have a right to *not* receive information about severe and treatable early onset diseases.¹⁷²

Particularly sensitive information, such as pregnancy status, drug use, sexual history or potential abuse can create conflicts between the parent and child different from disease and genetic information. If a biobank includes questionnaire data, researchers might be asked by parents about their child’s responses. In these instances, researchers should be clear and upfront with parents about information that will and will not be disclosed to them.¹⁷³ If a child is

found to be pregnant, ethical guidance likewise indicates that her parents not be informed without the minor's consent.¹⁷⁴

Guidance determining when parents and child participants should and should not be informed of information gathered for or resulting from research is based primarily on the best interest of the child. Although parents are generally considered the arbiters of "best interests",¹⁷⁵ the above discussion demonstrates that there are occasions when the parents' interest and that of their child do not coincide. Therefore, ethical guidance supports the privacy and autonomy of the child by limiting parental access to information when such access could be against the best interest of the child, and by permitting the child access to information when they are able to understand it.

4.3.2. The Legislative Dimensions

As noted previously, in all jurisdictions, the individual providing the consent to the collection, use and disclosure of personal information must have the legal capacity to consent. Because children do not have the legal capacity to consent, several statutes recognize that in certain circumstances information can be collected, used, or disclosed without the knowledge and consent of the child.¹⁷⁶ However, **Canadian privacy legislation does not address concerns about sensitive information that children may not want their parents to know, were they to have the capacity to consent. Nor does it clearly mandate the right of children to know information that may be necessary to protect or promote their health.**

Several statutes stipulate who may give substituted consent on behalf of minors, including incorporating, by reference, surrogate decision-makers appointed for related purposes under other statutes.¹⁷⁷ OPHIPA details capacity issues related to consent and stipulates certain factors that the substitute decision-maker must take into consideration before providing or refusing consent, withdrawing consent, or providing an express instruction.¹⁷⁸

Québec distinguishes the age of consent for research by minors from that of consent for required treatment/clinical care. Québec does not employ the doctrine of the “mature minor”¹⁷⁹; the age of consent to research is 18¹⁸⁰ unless the minor is fully emancipated, while the age of consent to required medical care is 14.¹⁸¹ Ontario, on the other hand, carves out from OPHIPA consent by minors under age 16 to the collection, use or disclosure of information relating to treatment within the meaning of the *Health Care Consent Act, 1996* (wherein the age of consent to medical care is 16).¹⁸² According to OPHIPA, a minor who is at least age 16 can consent to the collection, use or disclosure by a health information custodian of personal health information (including for research purposes), provided he or she is capable of consenting.¹⁸³ Minors under age 16 must have a surrogate decision-maker irrespective of actual maturity.¹⁸⁴

While specifying an age avoids arbitrary medical decisions concerning capacity and creates certainty, the attribution of different statuses to minors and adults in privacy legislation, as happens in healthcare and consent legislation, is controversial because it assumes differences in kind between the two groups, rather than differences in degree, including the level of maturity of members of each age-based group.¹⁸⁵ Indeed, neuroscience and psychological research suggests that it is unwise to generalize about the development of decision-making maturity.¹⁸⁶

Furthermore, **privacy legislation does not adequately address the various and ethically difficult issues surrounding maturing children and the varying nature of the information to be collected and its possible disclosure.** This may in fact be a consequence of the paediatric context. Western, liberal society emphasizes the individual as the locus of privacy protection. Might privacy have a different meaning when the individual is not accorded full legal rights because of age or competency?¹⁸⁷ Two key questions emerge from this theoretical perspective: 1) do children have the same privacy “rights” as adults; and 2) if not, what are the limitations on those rights? We generally acknowledge that as between parent and child, the child cannot

expect privacy centred on self-determination or security to the same extent as an adult. This is expected (or accepted) because society expects parents to protect their children. Conversely, a complete abrogation of privacy by the parents would sacrifice the child's flourishing and autonomy and destroy the trust relationship. As a society, we want children to develop their personhood, self-reliance, and creativity.¹⁸⁸

Yet, from the perspective of this tri-partite relationship, can we say that a researcher also has a trump card over the child's privacy? Can we say that children, viewed less as autonomous decision-makers and more as individuals connected to and dependent on others,¹⁸⁹ must yield their privacy to society or their extended family? Even if we acknowledge that a child's limited autonomy necessitates a diminished role for controlling information, does it follow that others, including researchers, have a greater role to play in administering that control? Does it, or should it, depend on whether the parents consent? How should researchers and parents address the fact that children are also members of society with important population and/or public health concerns that may have bearings on autonomy and privacy?

In sum, there is little consensus about the privacy dynamic between parents and children, and even less between children, researchers and others. Neither privacy legislation nor policy guidelines on research address the position that the harm of infringing upon the child's privacy, from both self-determination and security perspectives, should be taken into account. Consequently, both the abstract, theoretical issues of a child's autonomy and self-determination, and the practical issues of information control, return of results, and consent/assent are left unanswered.

A related problem, stemming from both ethical and legal standards, is the **inconsistent level or lack of privacy expertise, training, and oversight of REB members**. As certain

commentators have noted, REBs are accustomed to reviewing consent in the context of traditional medical research.¹⁹⁰ Biobanks involve specialized areas of knowledge, such as the nature of population and longitudinal studies and the security of information over time. Health information privacy legislation requires parties who collect, use or disclose health information to maintain adequate security to prevent unauthorized disclosure. While statutes require REBs to consider whether adequate safeguards are in place to protect the privacy and confidentiality of the health information in question, “to do so requires specialized knowledge regarding information systems and anonymisation protocols that is unclear REB members possess”.¹⁹¹ Indeed, “[t]he problem is not so much that they do not know what research will be undertaken, but that they cannot be sure that the risk of privacy violation is adequately, or consistently, dealt with.”¹⁹²

Nor can it be said that REBs have consistent levels of experience with respect to vulnerable populations, such as children, and the ensuing ethical and legal implications of ensuring researchers have proper plans to secure the privacy of their research subjects: “Ethics review is hardly an appropriately democratic and accountable locus of responsibility and authority for resolving the significant privacy issues posed by biobanking, nor for ensuring that our privacy rights and interests are adequately represented and weighed.”¹⁹³

Consequently, it may be inappropriate for privacy legislation to assume and trust that REBs have the capacity and competency to handle the privacy-related issues affecting paediatric biobanks.

4.3.3. Biobank Practice Dimensions

In line with international and national biobanking policies, the paediatric biobanks analyzed require the permission of parents prior to collecting, storing and using the biological material and data of their child. However, there is variation in the level of disclosure regarding potential risks, the scope of the right to withdraw, potential re-contact, and types of material or data to be collected. Indeed, there is even variation within jurisdictions (e.g. Canada) and biobanks themselves (e.g. CHILD Study), suggesting that providing guidance to REBs is as important as regulating biobanks.

The Gopher Kids Study consent form, for example, does not discuss potential secondary use of the data and mentions that a possible risk is an accidental release of personal information, but does not provide any further details on how this is possible and what the ramifications or remedies would be. On the other hand, the CHILD Study Toronto consent form is 22 single-spaced pages and provides what may be considered a deluge of information that could overwhelm parents and cloud important information on privacy matters.

Additionally, only the Gopher Kids Study explicitly states that children will be contacted at a later point to ask for their consent to continue storing the data/samples. A similar policy can be inferred from the NCS materials, but the lack of a clear statement on the consent form does not lend to any conclusion. While on the surface an appealing idea, this re-contact may be both impractical, costly, and create additional privacy concerns in non-longitudinal paediatric studies.

Further, even though many international policies and norms on research involving human subjects emphasize the need to obtain the assent of the child before the research commences,¹⁹⁴ and several studies conclude that 7-13 years of age is an appropriate age at which to first seek the child's assent,¹⁹⁵ only the FORGE Canada, Étude 3-D and ALSPAC policies or consent forms explicitly consider a child's input before age 16. For children under 14 years of age in the

FORGE Canada study, the consent form includes a section that states that the study has been explained to the child at a level that is appropriate and they have assented to participate.¹⁹⁶ For children between 14-18 years of age (“minors” in the consent form), the consent form includes a section specifically for their assent to participate in the study. In provinces with a legal age for consent to participation in research (i.e. Ontario and Québec), the legal age would prevail. ALSPAC provided consent forms to children at age 13 and 15; they began getting both parents and children to sign the consent for various tests and studies from age 12.¹⁹⁷ Although the child’s signature was not considered legally valid, the ALSPAC ethics committee thought it would provide children a formal time and opportunity to ask questions. By age 16, parental consent was not needed.¹⁹⁸

According to its policies, the NCS will seek a child’s assent when he or she is considered to be able to understand the study procedures.¹⁹⁹ When the child reaches the legal age of majority in the area in which they live, the child will have the opportunity to consent. The NCS consent form only states that parents “who have any other questions about ...your child’s rights as a Study participant, now or in the future ...can contact the people listed on the page that we will ask you to sign.”²⁰⁰

This biobank policy variation demonstrates that the “soft law” nature of international and national norms and guidelines does not sufficiently compel paediatric biobanks to explicitly address these privacy and autonomy issues for children or parents in the consent forms.

There are similar normative guidelines that encourage biobanks to respect a child’s decision to withdraw from research if the child has the capacity to make an independent choice.²⁰¹ Withdrawing from the research study raises privacy and security questions about the use, disposal or modification of data and samples already collected. With the exception of

FORGE Canada and Étude 3-D, none of the paediatric biobanks surveyed explicitly and unequivocally address the child's decision to withdraw. ALSPAC prohibits minors under age 16 from withdrawing.²⁰² This policy appears to reflect the idea that because participants under age 16 cannot consent in their own right, they also cannot withdraw, though it is unclear how this policy corresponds to ethics guidelines which state that an individual's refusal to participate must always be respected.²⁰³ The NCS's policy appears to allow withdrawal if the child is between the ages of 14-18 years, but it is unclear whether the child may withdraw when under the age of 14 (although parents can withdraw at any time).²⁰⁴ The other biobanks do not address withdrawal or dissent. Although overarching ethical norms of the jurisdiction (e.g. TCPS) could require researchers to respect the dissent of a child or permit continued participation in the face of dissent in limited circumstances,²⁰⁵ the consent forms should more clearly state to the parents (and the assent form to the child) that the child is free to withdraw, and the circumstances when withdrawal of the child and/or his or her data or samples is not possible.

Table 7 illustrates the biobank practice dimensions relating to the nature of the shared relationship between the child, the parents, and the researcher.

Table 7: Biobank Practices Relating to the Nature of the Shared Relationship of the Child, Parents, and Researcher

Biobank	Assent or consent of the child	Return of individual results (and incidental findings) to the parents and/or child	Potential risks/benefits	Withdrawal
Canadian Healthy Infant Longitudinal (CHIL) Development Study	<ul style="list-style-type: none"> No discussion of assent or consent of the child 	<ul style="list-style-type: none"> No return of individual study research results to parent or child, but if required by parent, health test results may be disclosed (e.g. parent may request that skin test results or lung function test results be sent to family physician or paediatrician) No discussion of handling of incidental findings, but consent form states that "If new information arises that may affect your willingness to remain in this study, you will be advised of this information promptly". 	<ul style="list-style-type: none"> Benefits <ul style="list-style-type: none"> Participation may help future children born in Canada avoid allergy and asthma, or other conditions related to environmental exposures Risks <ul style="list-style-type: none"> Unease with some questions in questionnaire Light headedness or coughing from breathing tests Children may get wheezy during methacholine test Bleeding, light headedness, bruising and/or infection from blood samples Children may experience stress during blood test Allergic reaction and itchiness from allergy tests 	<ul style="list-style-type: none"> Parent may withdraw at any time If parent decides to withdraw from study, parent will not be included in follow-up data collections and study will only use data parent/child provided during study participation Unclear whether child has right of withdrawal
Étude Découvrir, Développer, Devenir (Étude 3-D)	<ul style="list-style-type: none"> IRNPQEO Databank and Bank of Biological Material Management Policy addresses possibility of obtaining assent of children "when they are old enough to understand" and consent when they become adults Policy states that need for assent is based on maturity and intelligence of the child 	<ul style="list-style-type: none"> Parent will not receive individual results If results reveal a significant health or developmental problem that parent's doctor should be aware of in order to follow up the pregnancy, the mother, the father or the child appropriately, the parent's doctor will be informed in order to take charge of the follow-up. These results could be added to the medical files 	<ul style="list-style-type: none"> Benefits <ul style="list-style-type: none"> Contribution to the advancement of knowledge on pregnancy, health and development of the child Discoveries in the project may contribute to the development of commercial products Risks <ul style="list-style-type: none"> Blood collection may cause pain, slight bleeding, bruising, dizziness or infection (rarely) The child (at age 2 years) must have fasted for a period of 8 hours prior to collection Fatigue and slight discomfort may occur when removing the self-adhesive electrodes in heart rate variability test Developmental test may reveal a significant problem in child's development or health Certain questions in questionnaires may make parent uncomfortable or cause stress Unauthorized disclosure of results Results could reveal non-paternity (information will not be disclosed to participant) 	<ul style="list-style-type: none"> Parent may withdraw at any time, as may child whose maturity allows him/her to understand the implications of withdrawing
Finding of Rare Disease Genes in Canada (FORGE) Canada	<ul style="list-style-type: none"> Children aged 14-18 specifically asked to provide assent to participate Children under age 14 must have study explained to them at a level that is appropriate and they must provide assent to participate 	<ul style="list-style-type: none"> Not all information regarding patient's sequenced entire genome will be reviewed in detail Children/Minors consent form: <ul style="list-style-type: none"> Patient will be informed of the results of the study of the rare disease in family by patient's doctor who is part of the study. Patient will be informed of the identification of other disease-causing mutations that could alter the management of patient's health during childhood by patient's doctor who is part of the study Information relating to non-paternity or adult onset disorders may be discovered but will not be disclosed in the context of the study Affected/Unaffected/Incompetent Adults consent form: <ul style="list-style-type: none"> Patient will be informed of the results of the study of the rare disease in family by patient's/ward's doctor who is part of the study. Patient has the option to be 	<ul style="list-style-type: none"> Benefits <ul style="list-style-type: none"> Possible that study will identify genetic cause of the genetic condition in family Possible future test or treatment for genetic condition Risks <ul style="list-style-type: none"> Drawing blood may cause dizziness and discomfort and small chance of infection 	<ul style="list-style-type: none"> Parent may withdraw at any time Children aged 14-18 years may withdraw at any time Unclear whether child under 14 years of age has right of withdrawal

Biobank	Assent or consent of the child	Return of individual results (and incidental findings) to the parents and/or child	Potential risks/benefits	Withdrawal
		informed by personal physician about the identification of additional disease-causing mutations that have clinical significance, and where prevention and treatment are available		
National Children's Study (NCS)	<ul style="list-style-type: none"> Assent will be sought when child is considered to be able to understand the study procedures When the child reaches the legal age of majority in the area in which they live, the child as a study participant will have the opportunity to consent 	<ul style="list-style-type: none"> Will not disclose any information about parentage Study will share "some" individual information it learns about parent and child when it is available. No mention if child has right to results If study knows the results from tests conducted during a visit (e.g. weight, blood pressure), they will share them with parents 	<ul style="list-style-type: none"> Benefits <ul style="list-style-type: none"> Study may help researchers better understand health factors that could benefit future generations Risks <ul style="list-style-type: none"> Some of the questions asked and some of the methods of sample extraction may be uncomfortable Giving a blood sample may cause a small amount of pain Home visits may interrupt daily routine Possibility of identifying biological parents or adoption Chance that personal information or identity could be disclosed Possibility that specific study findings will be associated with particular racial and ethnic groups 	<ul style="list-style-type: none"> Parent may withdraw at any time, and may leave and return If participant leaves, study will not ask for any new information, but will keep using the information and samples already provided If participant requests the destruction or return of any unused samples, study will comply "Young children and adolescents" may also withdraw (age not specified)
Gopher Kids Study	<ul style="list-style-type: none"> No discussion of assent/consent of the child (aged 1-11 in study) Child will be contacted when age 18 years to request consent to continue storing samples 	<ul style="list-style-type: none"> Will not disclose results related to paternity or adoption 	<ul style="list-style-type: none"> Benefits <ul style="list-style-type: none"> Study may benefit society by discovering genes related to normal growth and development Risks <ul style="list-style-type: none"> Parent's or child's personal information could accidentally be released by someone other than study staff Possibility of identifying paternity or adoption 	<ul style="list-style-type: none"> Parent may withdraw at any time No mention if child has right of dissent/withdrawal
Avon Longitudinal Study of Parents and Children (ALSPAC)	<ul style="list-style-type: none"> Children aged 12 and above were given the ability to "consent", though their signature was not considered legally valid (it was seen as giving them a formal time and opportunity to ask questions) By age 16, parental consent was no longer required 	<ul style="list-style-type: none"> Certain information/measurements obtained from tests in the presence of the participants (e.g. blood tests which reveal if child has low haemoglobin) can be disclosed According to Policy on Disclosure of Biomedical Information to Participants, the general rule is that information should not be disclosed to participants. This general policy is set aside when it is reasonably certain that the benefits of disclosure clearly outweigh any possible risks to the participants or their families. This in turn will arise when three conditions are met: <ol style="list-style-type: none"> That an item of data gives clear, unequivocal information of an existing or future health problem That the health problem identified is amenable to treatment of proven benefit That the participant has indicated beforehand that they wish to be informed if such a problem is identified Decision whether to inform individuals is taken by the Ethics & Law Committee, drawing on advice from clinical experts. This would keep such decisions independent of the researchers and would be consistent with the Committee's role of protecting the interests of participants 	<ul style="list-style-type: none"> Original consent form provided to pregnant women in 1991 did not address benefits/risks Multiple consent forms provided to mothers, fathers, and children discuss risks specific to the nature of the test or study (e.g. blood sample, DXA scan, questionnaire, etc.) 	<ul style="list-style-type: none"> Parent may withdraw at any time No right of withdrawal for children under age 16
Copenhagen Studies on Asthma in Childhood (COPSAC)	<ul style="list-style-type: none"> N/A (unable to access consent form and relevant policies) 	<ul style="list-style-type: none"> N/A (unable to access consent form and relevant policies) Novel findings are communicated through publications and lectures 	<ul style="list-style-type: none"> N/A (unable to access consent form and relevant policies) 	<ul style="list-style-type: none"> Parent may withdraw at any time (according to Danish Data Protection Agency rules) N/A to determine whether child has right to dissent or withdraw

4.4. Summary

It is clear from the analysis of the above three issues (the use and transfer of the child's data and samples; the risks of unauthorized access by third parties; and the nature of the shared relationship of the child, parents and researcher) that ethical norms, legislative standards, and biobank practice are inconsistent (across and within each) when it comes to the privacy and confidentiality of paediatric biobank participants. Legislation cannot solve all of the potential risks to children, as will be discussed below in the Recommendations. However, biobank practice demonstrates that, in the absence of specific legal and ethical guidance, researchers and institutions will act on the limited guidance available, with disparate results.

The analysis of paediatric biobank practices reveals that all address, albeit in varying degrees, the privacy and informed consent *of the parents*. Largely absent from the policies and consent forms is information regarding the control and use of the biological material and information collected. Further, as noted above in Subsection 4.1.3., it is troubling that the “potential risks” sections focus exclusively on the *clinical risks*, i.e. reactions to blood tests or heart rate variability tests, rather than the *ethical risks*, namely, autonomy and privacy concerns (though it is noted that the NCS consent forms address privacy risks), or what has been called concerns about “physical privacy”, amongst others.²⁰⁶

The ethical literature identifies three types of risks associated with the use of biological samples for paediatric research and pertinent to this Report: 1) risks of physical and emotional burden; 2) informational (privacy) risks; and 3) risks of breaching the values of the child.²⁰⁷ Generally, consent forms focus much attention only on the first type of risk, *viz.* emotional and physical burdens. The latter types are rarely mentioned in the biobank policies analyzed in this Report, and have just as much, if not more, potential to arise as a result of the research. Should it not be disclosed as a potential risk to the mother that her child may desire the results of a

genetic test before he or she is the age of majority? Should it not be disclosed that despite the parents' informed consent, their child's wishes should be considered, and in fact, outweigh the parents if the (non-infant) child is of sufficient age and/or intelligence and emotional maturity? This lack of encompassing potential risk disclosure and variability of privacy discussion might be a reflection of legislative gaps and differences in knowledge, training and expertise among REBs and REB members.

Finally, current legislation is nominally applicable to biobanks in general, but contain even less guidance for paediatric biobanks. 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. Furthermore, outside of laws determining competency for participation in research, these various legislative responses to health information privacy do not reach the issue of parental versus child rights and interests.

The current focus by paediatric biobanks on individual rights and autonomy — of the parents — risks entrenching the parent-as-decision-maker as the benchmark in most or all ethical considerations. Although parents have traditionally been provided wide latitude in issues pertaining to their children, current ethical trends indicate that it is the autonomy and rights of the child, not solely the parents, which are truly at stake. Legislative responses and biobank policies should reflect this in order to best protect children's privacy and autonomy when participating in biobanks.

Yet, it bears discussing recent efforts to mould other, new ethical principles such as reciprocity, mutuality, citizenry, universality and solidarity as possible strategies, which would likely do much to not only acknowledge the role of the child in the research process, but also to protect his or her privacy.²⁰⁸ Indeed, the principle of solidarity corresponds well in the paediatric

biobank context, where the purpose is to serve as a resource for future unspecified research. Envisioning solidarity as a willingness to share *and* protect information for the benefit of others (e.g. parents sharing research results or other disclosed information with the child, researchers taking into account the child's views regarding the research, etc.), rather than as an autonomy-based argument for a right to know results in order to promote one's own (i.e. parents') interests, grounds moral responsibility and respect for privacy as a human *bond* between researcher, parent, and child. In a system of solidarity, therefore, it could be argued that the parents' "right not to know" should not be respected where the discovered findings are analytically valid, clinically useful and actionable (i.e. treatment or prevention is possible) during childhood. However, it will be important to provide appropriate educational resources to both parents and children if a principle of solidarity is to become the basis for paediatric participation in biobank-based research. In order to truly participate, all parties involved must understand what they are participating in.

5. Conclusion and Recommendations

Achieving an appropriate balance between privacy protection of children (and those who give consent on behalf of children) and the rapid dissemination of new scientific knowledge from biobanks to promote the health of children is a difficult, but not impossible, task. Unfortunately, Canadian privacy laws have not adequately addressed this issue. While forensic biobanks created to collect DNA from criminals, such as Canada's National DNA Data Bank, are afforded explicit biobank legislation, oversight bodies, and a variety of safeguards, **research and clinical biobanks suffer from a patchwork of under-inclusive regulatory provisions. Indeed, our analysis has shown that there is a lack of regulation for many aspects of research biobanks. Accountability and transparency could diminish in the face of such regulatory discrepancy.**

International comparative analysis reveals that some countries adopt specific biobank governance legislation to address the issues identified above, yet they too may remain inadequate in addressing the needs of particular research groups, such as minors. That privacy protections available to Canadians vary from one province or territory to another, and from one sector (public) to another (private or hybrid), adds a further cumbersome, outdated, and inadequate structural dimension to paediatric biobanks. While acknowledging and respecting constitutional parameters, **the federal government — and the Office of the Privacy Commissioner of Canada (OPC) — may be best placed to facilitate the development of a rationalized and harmonized approach to resolve these pressing privacy issues that will enable all Canadians, of all ages, to benefit equally from new advances in scientific research in this changing landscape.**

Many of the gaps in legislative protection are remedied in the ethical norms of the TCPS, but this guidance suffers from flaws of its own. Unfortunately, the TCPS is applicable only to research funded by the agencies that authored the document or certain health and social service

institutions in provinces which have policies endorsing it (e.g. Québec). Furthermore, penalties for violation of TCPS provisions are limited to the ineligibility to receive or suspension of agency funding, unless the breach constitutes a criminal act.²⁰⁹ Reliance on ethical requirements alone, therefore, does not ensure the protection of children, especially as the TCPS is specific neither to children nor biobank research.

We conclude with recommendations in order to offer possible avenues to bridge the gap between norms, laws and practice. This guidance is intended to assist agencies, legislators, researchers, and REBs when developing and interpreting laws and regulations pertaining to paediatric biobanks.

5.1. A Broad Appeal

This Report illustrates the incomplete applicability of current privacy legislation to paediatric biobanks and the related aspects of privacy. Various models for reform are possible, including a national law, policy or guideline for biobanks and privacy protection. However, we recognize legislative and policymaking constraints in short-term reform, including the difficulty of obtaining the necessary political capital to effect broad changes such as the adoption of a *de novo* law. Short of this long-term challenge, **we recommend the Office of the Privacy Commissioner of Canada urge the incorporation into current privacy statutes of the paediatric biobank privacy issues raised in this Report.**

We do not recommend the approach taken in the United States, which has been the adoption of a federal law prohibiting genetic discrimination, due in part to the absence of universal health care in that country.²¹⁰ Genetic privacy issues generally mimic informational privacy issues, such as consent and the privacy of medical records and other health information. We acknowledge, though, that genetic privacy issues may “amplify” privacy concerns because of its characteristics. These characteristics do not make genes “exceptional”, but they do perhaps

make them “sensitive”. This is why the European Commission considers genetic information as “sensitive data”, with clear, specified conditions for collection, use and disclosure.²¹¹

Rather than ignore the tension that exists between individuals and society, researchers and participants, and children and parents, legislation should embrace it by acknowledging in current privacy statutes the contextual situations that exist in paediatric biobanking.

5.2. General Recommendations

1. **All jurisdictions should incorporate in relevant privacy legislation (e.g. health information privacy statutes if applicable, otherwise private/public sector privacy statutes) proportionality-based provisions for decision-making in paediatric research, such as the determination of competency and assent, consistent with current law and the *Tri-Council Policy Statement*.**

As our Report notes, most privacy legislation does not address criteria for determining the competency of minors. The majority of medical consent statutes are not readily applicable to paediatric biobanks since they relate to clinical or therapeutic contexts, not research contexts. Moreover, these contexts vastly differ with respect to issues such as benefits, risks, proportionality, and intervention. Since age of competency for participation in human subjects research often differs from competency to consent to clinical care, provisions in privacy legislation for decision-making in paediatric research should not track health care consent legislation. Instead, decision-making competency criteria should reflect the modern research environment and its plethora of possibilities (e.g. disease-specific, longitudinal, epidemiological, gene-gene interaction, gene-environment interaction, etc.). Thus, the appropriate age of competency or assent for one project may not be appropriate for another. Proportional decision-making criteria that aligns competency with the degree of risk/harm of the research would recognize that, like children, not all paediatric research is alike.

Further, methods for assessing the competency of minors need not rely on age stratification, though we recognize this is often a preferable option for policymakers and legislators due to its apparent objectivity, efficiency and predictability. Determining competency can also rely on the true capabilities of the individual minor to understand his or her participation (i.e. the mature minor doctrine), and such a method is used in various provinces as well as in the United States. Ever since the famous Gillick case in England,²¹² norms, literature, and legislation have acknowledged that age is an arbitrary marker that should be replaced by a test of maturity of the child. Such a test would determine whether the child can understand the nature of a health decision to be made and the consequences likely to follow from the selection of the available options.²¹³

For those minors deemed immature and therefore incapable of providing consent, we recommend that amendments to privacy legislation should be enacted that ensure children can provide assent, when capable, in the decision-making process. Canada must meet its obligations under the *Convention on the Rights of the Child* (particularly, article 12). Furthermore, “soft law” guidelines and norms²¹⁴ do not carry sufficient force to pledge faith to these obligations. Giving children a voice in the process will improve the bi-directional informational flow between participant and researcher and in so doing, likely afford a greater degree of trust in those promising to keep medical information wholly or partly secret and build awareness about the research in which the child is participating.

2. Privacy Legislation Must be *Reactive* but also *Prospective*.

The goal of legislation should be to not only regulate, enforce, and protect certain activities so as to prevent certain wrongs from occurring, but also to prospectively build the tools of the future based on the practical experiences of those directly and indirectly affected by the legislation. Our review of ethical policies, legislation, and selected biobank-based studies evidences the practical difficulties of defining “genetic information”, “risk”, “biobanks” and other related terms. This is understandable, given that with biobank research, especially when based in genetics, no one knows the full nature, extent or ramifications of privacy and confidentiality. Hence, privacy legislation that addresses biobanks and paediatric issues should not be narrowly drafted; rather, it must be explicit and contoured enough to inject certainty but appropriate adaptability to the expanding field of personal health data.

3. Privacy Legislation Should Be Harmonized Across Canada.

The lack of harmonization is a recurring problem for biobank stakeholders, as it is an additional cost and administrative burden. Legal dissimilarity creates the risk of distorting the equivalent level of protection that the privacy laws are supposed to achieve and ensure. Australia, which also has various levels of privacy laws (federal, state, and territorial), has advocated harmonization of its privacy legislation. In 2002, the Office of the Privacy Commission of New South Wales noted that:

A uniform approach to genetic information privacy is essential to ensure that all persons have equal protection regardless of where they live and who handles their genetic information. Widely differing standards of protection not only undermine human rights, they also undermine public confidence in the way that institutions handle their personal information, especially in an increasingly networked information environment. Lack of uniformity can also add to confusion

for those responsible for handling personal information, as well as obstruct cross-border flows of information.²¹⁵

We do not advocate a particular avenue to achieve harmonized privacy legislation. Various models can be envisioned, such as new, uniform federal and provincial privacy or biobank legislation, or a regulatory framework specifically for biobanks that applies to all sectors. However, we note two qualifications. First, as discussed above, there are roadblocks to achieving sweeping reform in the way of legislation and we recognize that in the short-term, legislative amendments are more likely than legislative constructions. Second, much success is already being achieved and can be envisioned in health information protection legislation, such as OPHIPA. Amending that statute to better incorporate specific biobank-related issues and encouraging the remaining provinces and territories that have yet to enact health information protection legislation to do so, on a harmonized plane, may be suitable paths to protect privacy in paediatric biobanks. Regardless, what we do advocate is a recalibration of current legislation so that it adequately and harmoniously addresses paediatric biobanks and related privacy concerns.

- 4. Privacy legislation should allow federal and provincial privacy commissioners to play an integral part in the regulatory framework for biobanks created for research. Privacy commissioners should incorporate in their regulatory scrutiny a bottom-up approach through ongoing dialogue with REBs and the broader biobanking community.**

REBs cannot and should not be expected to perform and address the kind of privacy-related review and oversight that is needed for research biobanks. Such reliance will overburden already-taxed REBs (as was found in two 1999 U.S. Government Accountability Office reports on privacy oversight on research and medical records²¹⁶). Further, as this Report has discussed, short of a complete overhaul of the REB system in Canada, it is dangerous to assume that REBs have the competency to engage in the level of privacy oversight needed. Canada's National DNA

Bank is governed by explicit biobank legislation and includes oversight bodies and a variety of safeguards. In particular, it is overseen by the National DNA Data Bank Advisory Committee, on which a representative of the Office of the Privacy Commissioner sits to ensure that the Data Bank has access to expert advice in the field of individual privacy. The DNA Data Bank is also subject to auditing by the Office of the Privacy Commissioner at any time. We think that paediatric biobanks, having similar privacy concerns, should be subject to greater regulatory scrutiny and oversight by privacy commissioners.

This policy recommendation should not be constrained by constitutional parameters *per se* (i.e. the provincial domain of health and civil rights), as we do not advocate the creation of a federal biobanking law. Provincial privacy commissions and the Office of the Privacy Commissioner can collaboratively work with provincial (and federal) policymakers and REBs to develop a dialogue to improve competency in privacy oversight. This recommendation, therefore, is bidirectional: privacy commissions should inject more regulatory scrutiny into the REB process (a top-down approach), while REBs – and other stakeholders, such as researchers and the general public – should provide privacy commissions with critiques and recommendations regarding privacy and biobanking issues (a bottom-up approach). This is not to diminish or eliminate the role of REBs. Rather, it is to better protect the privacy interests of children by including in the review and oversight by REBs competent and experienced experts, who themselves have been informed by a broad community of various biobanking stakeholders.

5. The OPC should work with the broader biobanking community on developing a well-defined conceptual framework across the general typology of biobanks.

In Table 1 of our Report, we presented an open-end typology of biobanks, which demonstrates their rich tapestry. To our knowledge, there has not yet been a nationally or internationally coordinated attempt to implement a universal system for biobank typology with

standardized classifications and definitions. This is problematic. There is a range of ways in which to conceptualize biobanks, and the various characteristics comprising a biobank carry vastly different meanings (e.g. the meaning of “retrospective” versus “prospective”), ethical issues (e.g. tissue such as tumour cells collected from clinical care), and governing laws (e.g. Canada’s federal *DNA Identification Act*²¹⁷ for the forensic National DNA Data Bank). Our quasi-Cartesian layout in Table 1 (i.e. research biobank versus forensic biobank; population-based biobank versus disease-based biobank) is somewhat simplistic since many biobanks are in fact composed of interchangeable characteristics. For example, a “disease-based” biobank may be retrospective but also prospective and include both healthy volunteers and sick patients.

Commentators in the past have called for an understandable and common nomenclature for biological sample identifiability, namely, “coded” and “anonymized”.²¹⁸ Among the many reasons for this, commentators note that the proliferation of terminology to describe the identifiability of data renders it difficult to share and use samples between jurisdictions, as REBs and researchers have no means of ensuring equivalency between the labels of identifiability.²¹⁹

Moving this recommendation upstream from clarification of sample identifiability terminology to biobank typology, we advocate the development of a harmonized, agreed-upon typology of biobanks. It is important that the OPC work with the broader biobanking community, ideally on an international level, to achieve clarity about what is meant by, for example, a “research” biobank, and how they are constructed. This would assist REBs and researchers in working with universally equivalent concepts (terminology, characteristics, definitions, etc.), which in turn would aid in ethics approval (and oversight) of biobanking matters, including the protection of privacy. Indeed, achieving better privacy protection for children in paediatric biobanks will only be aided by the development of an understandable and common typology and nomenclature.

6. The OPC should work to foster greater public education and awareness of biobanks and privacy issues.

The OPC has a role to play in explaining the purpose of biobanks and the uses and potential misuses (even if miniscule) of personal information to the Canadian public. First, an understanding — prior to enrolling a child — of what a biobank entails and the role of the child in decision-making will provide an opportunity for increased parental comprehension of what will happen to their child. Providing this information well before a parent is faced with a decision to have their child participate could limit false assumptions about biobank-based research.

Second, given that we recommend the encompassing of genetic information and material into the definition of personal or health information, this public education and awareness should include a discussion of genetic privacy. Parents must understand the implications for their child, adolescents, and other family members, of genetic information — as well as the limitations on information dissemination intended to protect the child's privacy.

We believe that people often fear what they do not know, and an informed public is a less fearful public. Websites, workshops, reports and media dissemination will go a long way to assuaging the public about privacy concerns associated with paediatric biobanks. This is not to downplay the privacy threat, as it is real, but educating the public will diminish the difference between irrational fear and rational concern.

5.3. Specific Recommendations

1. **The OPC should specify in privacy legislation that genetic information and biological materials are considered personal health data.**

We think that legislation should specify that personal or health information includes genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or a genetic relative, and whether or not the information is collected in relation to the health of, or the provision of a health service to, the individual or a biological relative.²²⁰ Making explicit that genetic information and material is covered by privacy legislation would go far to protect the privacy interests of all individuals, including children, though we note the particular issues that can arise in this context, such as conflicts between a parent and a child in accessing genetic information.

Genetic material should also be included in the definition of biological material and of personal information or health information, as the two often go hand-in-hand. Noting the particular paediatric context, the legislation should provide legally enforceable privacy standards for the collection, storage, use and transfer of genetic material.

As a corollary, privacy legislation should grant a mature individual conditional access to his or her own biological material and information. Because of logistical and scientific constraints, we recommend that such access should be made only for the purpose of medical testing, diagnosis or treatment. Further, the right to access can be refused where (a) it is not physically possible to provide part of the material; (b) providing part of the material means that the remaining portion is insufficient for the purposes of the biobank retaining it; or (c) releasing the material to an individual raises public health concerns.²²¹ We wish to emphasize that we distinguish access from withdrawal from research, which should continue to follow norms and

guidelines concerning the de-identification of samples and/or their destruction or removal from further research, as per the wishes of the research participant.

2. The OPC should provide clear penalties and sanctioning and enforcement powers for violations disclosing personal or health information.

We agree with recent public statements by the Privacy Commissioner of Canada that PIPEDA (and other privacy statutes) should be amended to allow for greater sanctions against those who violate privacy.²²² In particular, we think that the Privacy Commissioner should have the power to impose more meaningful, significant, attention-getting fines on individuals and entities (including biobanks) that breach privacy. In addition, the Privacy Commissioner should have order-making powers and the ability to compel entities to report privacy breaches to the office. Our Report discusses the sensitive nature of genetic information. Given the recent public backlash against the well-publicized privacy breach involving tens of millions of a company's online customers, including some in Canada, we think a similar backlash and resultant diminishment in trust would result from privacy breaches in paediatric biobanks. More meaningful penalties, combined with sanctioning and enforcement powers, would encourage biobanks to take a proactive and preventative approach to protecting privacy.

5.4. Possible Long-Term Recommendations and Avenues for Future Research

The following recommendations are considered long-term measures that can improve the protection of privacy in paediatric biobanks. We consider these long-term because each should involve prior comprehensive research, cost-benefit analysis, and discussions with various stakeholders. As well, their creation and implementation should be carefully planned. Their enactment and enforcement will likely take years of dedicated political and regulatory will. Nevertheless, we consider these recommendations crucial for building a better privacy foundation for biobanks and biobank participants.

1. **The OPC should prepare a web-based, open access federally-administered database of all Canadian paediatric biobanks.**

Internationally (at the World Health Organization²²³ and in the United States²²⁴), open access databases now exist for clinical trials. These databases offer up-to-date information for locating both publicly and privately supported clinical trials for a variety of diseases and conditions. Given the success of these databases and the exponential growth of biobanks, we recommend that the Office of the Privacy Commissioner, in collaboration with Health Canada, explore the possibility of preparing a federally-administered, web-based open access database of all Canadian paediatric biobanks including clinical and research databases. Each record in the database could include information on the following (similar to ClinicalTrials.gov): 1) underlying scientific purposes/intended use; 2) title, description and design of the study (if clinical or research-based); 3) requirements for participation (if clinical or research-based); 4) location(s) of the biobank; and 5) contact information.

Such a database would allow regulators and the public to have a better Canadian biobank map, thereby improving knowledge about the scope and content of Canadian paediatric biobanking. It would also allow potential future biobank participants and their parents to inform themselves about the nature of biobanks and perhaps guide them in deciding whether to participate in a particular research or clinical biobank. Furthermore, a database would improve transparency and public engagement, and allow regulators and policymakers to keep track of biobanks' adherence to external and internal policies (legislative or otherwise) that impact privacy, among other matters. In turn, this would strengthen the value and validity of paediatric biobank research and clinical outcomes.

2. The OPC should push for the development of more detailed professional Codes of Conduct that deal with specific paediatric biobank issues.

While revisions to current professional codes of conduct must ultimately come from the professional bodies that regulate their members, the OPC should consider the possibility of pushing for changes that adequately address vulnerable populations and the particular privacy issues surrounding paediatric biobanks. Since paediatric biobanks affect a variety of communities, it is important that a vast array of professional bodies harness the political and social will, supplemented with an OPC-led commitment, to revise their codes. These professional bodies should include not only paediatricians, clinicians, researchers, geneticists and genetic counsellors, but also professionals from other fields and contexts (e.g. lawyers, access and privacy administrators, mental health professionals, and social workers and family therapists). Privacy protection for children involved in paediatric biobanks will be enhanced if multiple professional orders and institutions are grounded in well drafted deontological codes, statutes, rules, and guidance that specifically address this evolving but ever-important area.

Appendix 1: Privacy and Confidentiality in Canadian and International Ethical Norms

Instrument	Relevant Provision(s)
<p>Canadian Institutes of Health Research</p> <p><i>CIHR Best Practices for Protecting Privacy in Health Research</i></p>	<p>Element #2: Limiting the collection of personal data Researchers should plan to collect personal data only as necessary for the research. The amount of personal information collected and the level of identifiability and sensitivity of this information should be restricted to what is necessary to achieve the research objectives. Consider first whether individually identifiable data are needed, or whether non-identifiable data or aggregate data would serve the research objectives (e.g. data on individuals grouped by age or some other meaningful variable).</p> <p>Element #7: Safeguarding personal data Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards. Data security safeguards should include organizational, technological and physical measures. Researchers should take a risk assessment and management approach to protecting research data from loss, corruption, theft or unauthorized disclosure, as appropriate for the sensitivity and identifiability of the data. REBs should review and approve researchers' proposed measures for safeguarding any personal data to be collected.</p> <p>Element #8: Controlling access and disclosure of personal data Data sharing for research purposes— whether of linked or unlinked data sets— is an important way of enabling socially valuable research. It avoids unnecessary duplication of data collection, which reduces the burden on research participants and permits researchers to use limited or scarce resources more productively. However, once approved by an REB, there should be strict limits on access to data and secure procedures for data linkage, subject to data-sharing agreements. When personal data are essential to research objectives and questions, researchers need a plan for making public the results of research in ways that do not permit tracing back to individuals if they do not wish their identities to be known. [...]Data-sharing agreements bind data providers and researchers to their respective responsibilities and obligations for protecting personal data. Data-sharing agreements should set out the terms and conditions under which data providers will allow researchers to access personal data for research purposes.</p> <p>Element #10: Ensuring accountability and transparency in the management of personal data Individuals and organizations engaged in health research involving personal data are accountable for the proper conduct of such research in accordance with applicable funding policies, privacy principles and/or legislation. Processes and practices must be clearly established and implemented in order to give meaningful effect to these policies, principles or laws. Proper accountability and transparency practices require adequate resources for things as communication, education and training relating to privacy. Roles and responsibilities of all those involved in the conduct and evaluation of research should be clearly defined and understood, including those of researchers, their employing institutions, REBs, any data stewardship committees, Privacy Commissioners and other legally-designated privacy oversight agencies. Their concerted efforts should aim to provide a coherent governance structure for effective and efficient data stewardship.</p>
<p>Fonds de la Recherche en Santé du Québec</p> <p><i>Governance Framework for Data Banks and Biobanks Used for Health Research</i></p>	<p>Recommendation 6 That laws making provision for personal information protection be adapted to the emerging trends in health research so that such laws recognize the legal validity of data banks and biobanks and of research exploring themes rather than specific hypotheses.</p>
<p>Fonds de la Recherche en Santé du Québec</p> <p><i>FRSQ Standards on Human Health Research Ethics and Scientific Integrity</i></p>	<p>20. LES PARTICULARITÉS DE L'EXPÉRIMENTATION SUR LE MINEUR ET LE MAJEUR INAPTE L'article 21, al. 2 du <i>Code civil du Québec</i> énonce que l'expérimentation ayant pour sujet un mineur ou un majeur inapte doit laisser espérer:</p> <ul style="list-style-type: none"> • si elle ne vise que ce sujet, un bienfait pour sa santé; • si elle vise un groupe de personnes, « des résultats qui seraient bénéfiques aux personnes possédant les mêmes caractéristiques d'âge, de maladie ou de handicap que les membres du groupe. » <p>De plus, cette expérimentation doit être mise en oeuvre dans le cadre d'un projet de recherche approuvé et suivi par un CER que le ministre de la Santé et des Services sociaux a reconnu ou institué.</p> <p>21. L'OPPOSITION DU MINEUR OU DU MAJEUR INAPTE Le refus de participer à un projet de recherche exprimé par un sujet pressenti qui est légalement inapte prévaut sur le consentement provenant de son représentant légalement autorisé. Cette norme, qui protège l'inviolabilité personnelle, est exprimée dans la Règle 2.7 de l'<i>Énoncé de politique</i>: <i>« Lorsque le consentement libre et éclairé a été donné par un tiers autorisé et que le sujet légalement inapte comprend la nature et les conséquences de la recherche à laquelle on lui demande de participer, les chercheurs s'efforceront de comprendre les souhaits du sujet à cet effet. Le dissentiment du sujet pressenti suffit pour le tenir à l'écart du projet 19. »</i></p> <p>L'article 21, al. 1 du <i>Code civil du Québec</i> adopte un dispositif similaire en déclarant qu'un mineur ou un majeur inapte ne peut être soumis à une expérimentation « à laquelle il s'oppose alors qu'il en comprend la nature et les conséquences ». Le Code civil attribue donc au mineur et au majeur inapte un droit de refus quant à l'expérimentation dont il comprend la nature et les conséquences.</p>

<p>Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada</p> <p><i>TCPS 2: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</i></p>	<p>Article 5.3 Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal. [...] Factors relevant to the REB's assessment of the adequacy of the researchers' proposed measures for safeguarding information include: (a) the type of information to be collected; (b) the purpose for which the information will be used, and the purpose of any secondary use of identifiable information; (c) limits on the use, disclosure and retention of the information; (d) risks to participants should the security of the data be breached, including risks of re-identification of individuals; (e) appropriate security safeguards for the full life cycle of information; (f) any recording of observations (e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants; (g) any anticipated uses of personal information from the research; and (h) any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records</p> <p>Article 5.5 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 (f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.</p> <p>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.</p> <p>Article 12.2 To seek consent for use of human biological materials in research, researchers shall provide to prospective participants or authorized third parties, applicable information as set out in Article 3.2 as well as the following details: (a) the type and amount of biological materials to be taken; (b) the manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition; (c) the intended uses of the biological materials, including any commercial use; (d) the measures employed to protect the privacy of and minimize risks to participants; (e) the length of time the biological materials will be kept, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal, if applicable; (f) any anticipated linkage of biological materials with information about the participant; and (g) the researchers' plan for handling results and findings, including clinically relevant information and incidental findings.</p> <p>Article 12.5 Institutions and researchers that maintain biobanks: (a) shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards; and (b) shall establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorized handling.</p> <p>Article 13.7 (a) Researchers who propose research involving the collection and banking of genetic material shall indicate in their research proposal, and in the information they provide to prospective participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups. (b) Researchers who propose research involving the secondary use of previously collected and banked genetic material shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.</p>
<p>Canadian Institutes of Health Research, National Council on Ethics in Human Research, Maternal, Infant, Child and Youth Research Network, Centre of Genomics and Policy</p> <p><i>Best Practices for Health Research Involving Children and Adolescents: Genetic, Pharmaceutical, Longitudinal Studies and Palliative Care Research (Second Draft)</i></p>	<p>Section 2.2 Consent Form – Essential Elements to Include:</p> <ul style="list-style-type: none"> • potential risks and benefits (both immediate and long-term); • right to withdraw from the research at any time, without the child suffering any harm, as well as the situations where withdrawal is impossible (e.g. anonymized data and samples); • mechanisms for protection of and limitations to privacy and confidentiality;

- access to the information collected by the participant and third parties;
- access to the findings and/or results of the research (general or individual research results);
- plan for handling incidental findings;
- disclosure of findings with a potential of leading to interventions;
- reasons to terminate the participation;

Additional elements that should be included, if applicable:

- possibility of future uses (secondary uses) of data or samples collected;
- storage and destruction of data and samples collected;
- disclosure of new information that may affect the willingness of the participant to participate in the research;....

Secondary Use of Personal Information and Tissues:

- when using identifiable information or tissue: REB approval is required;
- REBs may require the consent of the participant or parents;
- if the tissue is anonymized or anonymous and there are no potential harms for the participant, consent is not needed.

Section 3.2

To the extent possible, researchers should obtain the assent of the child according to his/her level of development and capacities. When the child develops the legal capacity to provide a fully informed consent or attains the legal age of majority, researchers should obtain an informed consent.

Section 4.2

The dissent of the child, who is capable of understanding, must be respected.

Dissent may be verbal or behavioural (e.g. body movements) and may be expressed at any time during the research. It must be respected even if the parents consented to their child's participation in the research project.

Section 6.2

Consideration of Potential Harms:

- consideration of potential harms must include harms that are physical, psychological, social or financial; and harms that may affect individuals or communities
- cumulative harms should be considered in assessing the individual harms that occur from research participation.
- potential harms should be evaluated from a child's perspective.

Section 7.2

In order to ensure that privacy and confidentiality are maintained, researchers should adopt appropriate safeguards, subject to applicable law.

Access to the Information Collected:

- subject to applicable law, access to the information collected in research is dependent on the consent of the competent child or, if incompetent, the parents. If feasible, the assent of the incompetent child should be obtained;
- the principal researcher is responsible for controlling access to the information collected;
- control of this access is similar to the control exercised over delegated medical acts;
- those authorized to access such information are under the supervision of the principal researcher;
- participants should have access to their information, if feasible (e.g. data is not anonymized);
- access may be allowed for monitoring, auditing, review or regulatory inspections.

Limits to Confidentiality:

The duty of confidentiality is not absolute. Personal information may be disclosed without the consent of the participant or parents in some exceptional circumstances, such as child abuse or neglect or communicable and sexually transmitted disease (when notification is required by law).

Moreover, absolute confidentiality may be difficult to ensure in some very special circumstances (e.g. children suffering from a very rare condition or disease). In this case, even if researchers comply with all the safeguard measures, the disclosure of confidential information of the child may still occur, and the child may be identifiable just by virtue of the rarity of the condition. Therefore, researchers should inform the participant and/or parents about this possibility during the informed consent process.

Disclosure to Third Parties:

- researchers and members of the research team should never disclose personal information about a participant to a third party unless the competent child or the incompetent child's parents consented to such disclosure in writing. If feasible, the assent of the incompetent child should be obtained;
- in exceptional circumstances, and subject to the applicable law, researchers may have an obligation to disclose genetic information to the child's family, despite opposition of the incompetent child or the refusal of the competent child or, if incompetent, of the parents. Three conditions should be met before considering the possibility of disclosure in such circumstances:
 - 1) non-disclosure could lead to serious and foreseeable harm for members of the biological family;
 - 2) members of the biological family are identifiable; and
 - 3) the risk of harm could be avoided by prevention or treatment. In this evaluation, the risk of harm resulting from disclosure should not be greater than the risk of harm to family members from non-disclosure;
- where there is no legal obligation to disclose, the decision to disclose or not is one of professional ethical judgment;
- the competent child or, if incompetent, the parents should be informed of the consequences that could result from the disclosure of genetic information. The incompetent child should also be informed, if feasible.
- if non-consensual disclosure is necessary, collaboration with the treating physician is recommended to encourage discussion with the child and parents about the family follow-up and the consequences of refusing to communicate the information in question;
- other than in the exceptions foreseen by law, no genetic information can be transmitted to insurers, employers, educational institutions, or other public institutions, without the consent of the competent child or, if incompetent, the parents. If feasible, the assent of the incompetent child should be obtained;
- in cases where non-paternity is discovered during research, unless it can be shown to be in the immediate and best interest of the health of the child, it should not be disclosed;
- unless participants consent to the publication of identifiable data and there is a reason to do so, researchers should only publish non-identifying and/or aggregated data.

Organizational Safeguards:

- There should be ongoing commitment to privacy and continued emphasis of its importance by all involved in the research and the institution/organizational management.
- All involved in the research project should be subject to a pledge of confidentiality.
- Access to personal information should be strictly limited in terms of numbers of persons, for legitimate purposes, and strictly on a realistic need-to-know basis.
- Data-sharing agreements between the researcher/institution and all involved should be signed prior to providing any access to data.
- Consequences for breach of confidentiality, including dismissal and/or loss of institutional privileges, should be clearly stipulated.
- Institutions and organizations housing research projects and archived data should, with ongoing commitment of adequate resources:
 - develop, monitor and enforce privacy and security policies and procedures;
 - appoint privacy officers and create data stewardship committees as needed; and
 - implement internal and external privacy reviews and audits.
- Access to the information should be limited to authorized researchers and to those responsible for the operation and maintenance of the information;
- Access should be limited to the information needed to conduct the proposed research efficiently.

Technological Measures:

- Encryption, scrambling of data and other methods of reducing the identifiability of data should be used to eliminate unique profiles of potentially identifying information.
- Direct identifiers should be removed or destroyed at the earliest possible opportunity.
- If direct identifiers must be retained, they should be isolated on a separate dedicated server/network without external access.
- Camouflage sampling [...] or other techniques should be used, when appropriate, to prevent researchers from viewing health-related information of eligible individuals prior to gaining their consent.
- Authentication measures (such as computer password protection, unique log-on identification, etc.) should be implemented to ensure only authorized personnel can access data.
- Special protection for remote electronic access to data should be installed.
- Virus-checking programs and disaster recovery safeguards such as regular back-ups should be implemented.
- Where possible, a detailed audit trail monitoring system should be instituted to document the person, time, and nature of data access, with flags for aberrant use and "abort" algorithms to end questionable or inappropriate access.
- Unique identifiers should be assigned to each participant (e.g. coded);
- The principal researcher should be the person in charge of maintaining the link between the code and the information collected;
- Standard Operating Procedures (SOPs) should be implemented.

Physical Measures:

- Computers and files that hold personal information should be housed in secure settings in rooms protected by such methods as combination lock doors or smart card door entry, with paper files stored in locked storage cabinets.
- The number of locations in which personal information is stored should be minimized.
- Architectural space should be designed to preclude public access to areas where sensitive data are held.
- Routine surveillance should be conducted.
- Physical security measures should be in place to protect data from hazards such as floods or fire.

<p>United Nations <i>Convention on the Rights of the Child</i></p>	<p>Article 12: 1. States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child. ...</p> <p>Article 13: 1. The child shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of the child's choice. 2. The exercise of this right may be subject to certain restrictions, but these shall only be such as are provided by law and are necessary: (a) For respect of the rights or reputations of others; or (b) For the protection of national security or of public order (ordre public), or of public health or morals.</p> <p>Article 16: 1. No child shall be subjected to arbitrary or unlawful interference with his or her privacy, family, or correspondence, nor to unlawful attacks on his or her honour and reputation. 2. The child has the right to the protection of the law against such interference or attacks.</p>
<p>United Nations Educational, Scientific and Cultural Organization <i>Universal Declaration on the Human Genome and Human Rights</i></p>	<p>Article 5 (a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law. (b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest. (c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected. (d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines. (e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.</p> <p>Article 7 Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.</p> <p>Article 9 In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.</p>
<p>United Nations Educational, Scientific and Cultural Organization <i>International Declaration on Human Genetic Data</i></p>	<p>Article 6 – Procedures (a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints. (b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects. (c) When the collection, processing, use and storage of human genetic data, human proteomic data or biological samples are carried out in two or more States, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.</p>

	<p>(d) It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a penalty for the person concerned.</p> <p>Article 9 – Withdrawal of consent</p> <p>(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.</p> <p>(b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.</p> <p>(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.</p> <p>Article 14 – Privacy and confidentiality</p> <p>(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, family or, where appropriate, group, in accordance with domestic law consistent with the international law of human rights.</p> <p>(b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.</p> <p>(c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.</p> <p>(d) Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law.</p> <p>(e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.</p>
<p>United Nations Educational, Scientific and Cultural Organization</p> <p><i>Universal Declaration on Bioethics and Human Rights</i></p>	<p>Article 5 – Autonomy and individual responsibility</p> <p>The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.</p> <p>Article 7 – Persons without the capacity to consent</p> <p>In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:</p> <p>(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;</p> <p>(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.</p> <p>Article 9 – Privacy and confidentiality</p> <p>The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.</p>

<p>Council for International Organizations of Medical Sciences</p> <p><i>International Ethical Guidelines for Biomedical Research Involving Human Subjects</i></p>	<p>Guideline 14: Research involving children</p> <p>Before undertaking research involving children, the investigator must ensure that:</p> <ul style="list-style-type: none"> • the research might not equally well be carried out with adults; • the purpose of the research is to obtain knowledge relevant to the health needs of children; • a parent or legal representative of each child has given permission; • the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and, • a child's refusal to participate or continue in the research will be respected. <p>[....]</p> <p><u>Permission of a parent or guardian.</u> The investigator must obtain the permission of a parent or guardian in accordance with local laws or established procedures. It may be assumed that children over the age of 12 or 13 years are usually capable of understanding what is necessary to give adequately informed consent, but their consent (assent) should normally be complemented by the permission of a parent or guardian, even when local law does not require such permission. Even when the law requires parental permission, however, the assent of the child must be obtained.</p> <p><u>Observation of research by a parent or guardian.</u> A parent or guardian who gives permission for a child to participate in research should be given the opportunity, to a reasonable extent, to observe the research as it proceeds, so as to be able to withdraw the child if the parent or guardian decides it is in the child's best interests to do so.</p>
<p>Council for International Organizations of Medical Sciences</p> <p><i>International Ethical Guidelines for Epidemiological Studies</i></p>	<p>Guideline 14: Research involving children</p> <p>Before undertaking research involving children, the investigator must ensure that:</p> <ul style="list-style-type: none"> – the research might not equally well be carried out with adults; – the purpose of the research is to obtain knowledge relevant to the health needs of children; – a parent or legal representative of each child has given permission; – the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and -- a child's refusal to participate or continue in the research will be respected. <p>Guideline 18: Safeguarding confidentiality</p> <p>A healthcare provider should not submit any identifiable data about a patient to an investigator or to a database unless the patient permits such submission of data or it is authorized or mandated by law. The custodian of a database, and an investigator who receives data for research, must establish secure safeguards for the confidentiality of the data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.</p>
<p>Organisation for Economic Co-Operation and Development</p> <p><i>Guidelines for Human Biobanks and Genetic Research Databases</i></p>	<p>Best Practice 4.8 The operators of HBGRDs involving participants who are minors or with impaired decision-making capacity should have a clearly articulated policy on what steps will be taken, in accordance with applicable law and ethical principles, once such participants become legally competent to consent.</p> <p>Best Practice 4.9 The operators of the HBGRD should have a clearly articulated policy on feedback and the nature of the feedback, if any, that will be provided to participants.</p> <p>Best Practice 5.2 The operators of the HBGRD should have in place protocols and processes to protect participants' personal and medical information, including, but not limited to genetic information.</p> <p>Annotation 30. Research involving vulnerable populations brings to light the need for additional considerations on the part of the operators of HBGRDs and researchers. Examples of vulnerable populations can include minors, individuals with impaired decision-making capacity, military personnel and the elderly. For vulnerable populations, additional considerations should include the well-being of such participants, the type of information that should be communicated to them, and the approach for communicating with these groups. The involvement of vulnerable populations or groups in an HBGRD should be subject to protective conditions in accordance with applicable law and ethical principles.</p> <p>Annotation 31. For minors, especially for very young children, it is common that a substitute decision-maker, usually the parents, make the decision for the minor's participation in the research. The conditions that govern the participation of the minor in research are subject to applicable law and ethical principles and will vary from jurisdiction to jurisdiction. However, in light of the minor's age and autonomy, the HBGRD could consider ways in which the minor can play a more active role. For example, in some jurisdictions, depending on their age, a minor may be able to provide their assent for participating in research.</p> <p>Annotation 32. Where substitute consent has been obtained for a participant lacking capacity (e.g. a minor or individual with impaired decision-making capacity), consideration will need to be given to what will occur once the participant gains or re-gains capacity to consent. In accordance with applicable law and ethical principles, consent may need to be obtained from the participant to continue in the research or to collect further data or human biological materials from them or their withdrawal of consent. For example, particular consideration may be needed in situations where a minor has been recruited as part of family studies.</p>
<p>World Medical Association</p> <p><i>Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects</i></p>	<p>17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.</p> <p>23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.</p>

	<p>27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.</p> <p>28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.</p>
<p>World Medical Association <i>Declaration on Ethical Considerations Regarding Health Databases</i></p>	<p>Patients' consent</p> <ol style="list-style-type: none"> 1. Patients should be informed if their health information is to be stored on a database and of the purposes for which their information may be used. 2. Patients' consent is needed if the inclusion of their information on a database involves disclosure to a third party or would permit access by people other than those involved in the patients' care, unless there are exceptional circumstances as described in paragraph 11. 3. Under certain conditions, personal health information may be included on a database without consent, for example where this conforms with applicable national law that conforms to the requirements of this statement, or where ethical approval has been given by a specially appointed ethical review committee. In these exceptional cases, patients should be informed about the potential uses of their information, even if they have no right to object. 4. If patients object to their information being passed to others, their objections must be respected unless exceptional circumstances apply, for example where this is required by applicable national law that conforms to the requirements of this statement or necessary to prevent a risk of death or serious harm. 5. Authorization from the guardian of the health database is needed before information held on databases may be accessed by third parties. Procedures for granting authorization must comply with recognised codes of confidentiality. 6. Approval from a specially appointed ethical review committee must be obtained for all research using patient data, including for new research not envisaged at the time the data were collected. An important consideration for the committee in such cases will be whether patients should be contacted to obtain consent, or whether it is acceptable to use the information for the new purpose without returning to the patient for further consent. The committee's decisions must be in accordance with applicable national law and conform to the requirements of this statement. 7. Data accessed must be used only for the purposes for which authorization has been given. 8. People who collect, use, disclose or access health information must be subject to an enforceable duty to keep the information secure. <p>De-identified data</p> <ol style="list-style-type: none"> 1. Wherever possible, data for secondary purposes should be de-identified. If this is not possible, however, the use of data where the patient's identity is protected by an alias or code should be used in preference to readily identifiable data. 2. The use of de-identified data does not usually raise issues of confidentiality. Data about people as individuals, in which they retain a legitimate interest, for example a case history or photograph, require protection.
<p>World Health Organization <i>Genetic Databases: Assessing the benefits and the Impact on human and patient rights</i></p>	<p>Recommendation 11: Research using samples or genetic information taken from vulnerable subjects, such as incapacitated adults or children, must be carried out in full conformity with internationally agreed principles and guidelines. Research must be shown to hold the reasonable prospect of benefiting the class of persons to which the particular subject belongs, either in the immediate or the foreseeable future.</p> <p>Recommendation 12: The taking of samples or generation of genetic information for research purposes must respect the child's confidentiality and must only be undertaken with the explicit approval of a competent research ethics committee. It is acknowledged that some research will require the linking of clinical and genetic data in order to proceed and that the main beneficiaries of this research may be future children rather than the child who provides the sample. In such cases data should be coded to prevent identifiable links being made with access to the key to the code being restricted and subject to separate permission on each occasion. Such permission would only normally be granted in the event of a direct clinical benefit to the child. Where a child is able to consent or refuse to participate this must be respected.</p> <p>Recommendation 15: The gathering and storage of genetic samples and information must be subject to rigorous privacy protection measures and in conformity with international and national data protection laws. These privacy measures must be transparent and subject to ethical approval by a suitable body.</p>
<p>Human Genome Organization <i>Statement on DNA Sampling: Control and Access</i></p>	<p>Research samples obtained with consent and stored may be used for other research if; there is general notification of such a policy, the participant has not yet objected, and the sample to be used by the researcher has been coded or anonymized. For the use of research samples obtained before notification of a policy, these samples may be used for other research if the sample has been coded or anonymized prior to use.</p> <p>Security mechanisms must be put into place to ensure the respect of the choices made and of the desired level of confidentiality.</p> <p>Special considerations should be made for access by immediate relatives. Where there is a high risk of having or transmitting a serious disorder and prevention or treatment is available, immediate relatives should have access to stored DNA for the purpose of learning their own status. These exceptional circumstances should be made generally known at both the institutional level and in the research relationship.</p> <p>In the absence of need for access by immediate relatives, stored samples may be destroyed at the specific request of the person. Such destruction is not possible for samples already provided to other researchers or if already entered into a research protocol or used for diagnostic purposes. By their very nature, anonymized samples cannot be withdrawn or destroyed.</p> <p>Unless authorized by law, there should be no disclosure to institutional third parties of participation in research, nor of research results identifying individuals or families. Like other medical information, there should be no disclosure of genetic information without appropriate consent.</p>

<p>European Union</p> <p><i>Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use</i></p>	<p>Article 4: In addition to any other relevant restriction, a clinical trial on minors may be undertaken only if:</p> <p>(a) the informed consent of the parents or legal representative has been obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor;</p> <p>(b) the minor has received information according to its capacity of understanding, from staff with experience with minors, regarding the trial, the risks and the benefits;</p> <p>(c) the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to be withdrawn from the clinical trial at any time is considered by the investigator or where appropriate the principal investigator;</p> <p>(d) no incentives or financial inducements are given except compensation;</p> <p>(e) some direct benefit for the group of patients is obtained from the clinical trial and only where such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods; additionally, such research should either relate directly to a clinical condition from which the minor concerned suffers or be of such a nature that it can only be carried out on minors;</p> <p>(f) the corresponding scientific guidelines of the Agency have been followed;</p> <p>(g) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress have to be specially defined and constantly monitored;</p> <p>(h) the Ethics Committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol; and</p> <p>(i) the interests of the patient always prevail over those of science and society.</p>
<p>European Union</p> <p><i>Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products</i></p>	<p>Article 2:</p> <ol style="list-style-type: none"> The rights, safety and well being of the trial subjects shall prevail over the interests of science and society. Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects. The necessary procedures to secure the quality of every aspect of the trials shall be complied with. <p>Article 5:</p> <p>All clinical trial information shall be recorded, handled, and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.</p>
<p>European Medicines Agency</p> <p><i>Ethical Considerations for Clinical Trials Performed in Children</i></p>	<p>18. Individual Data Protection</p> <p>The specificity of data protection in children relates to future (unknown) use of data obtained in children. Biobank samples retention and the need for consenting to such use should be discussed in the protocol. The trial documents should be archived for a duration that takes into consideration the potential need for long-term review of trials performed in children (long-term safety).</p> <p>Children are less likely to challenge records about themselves. Therefore there is additional duty from researchers to protect confidentiality and access to data.</p> <p>Protocols should specify the level of protection of educational records when studies are performed in schools (access, amendments and disclosure), and the information given to parents or legal representative. This is particularly important when trials include adolescents and address issues of sexuality, illicit drug use or violence.</p> <p>Where personal information on a child is collected, stored, accessed, used, or disposed of, a researcher should ensure that the privacy, confidentiality and cultural sensitivities of the subject and/or the collectivity are respected.</p>
<p>Council of Europe</p> <p><i>Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To the Application of Biology and Medicine: Convention on Human Rights and Biomedicine</i></p>	<p>Article 6 – Protection of persons not able to consent</p> <ol style="list-style-type: none"> Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. ... The authorisation referred to in paragraphs 2...above may be withdrawn at any time in the best interests of the person concerned. <p>Article 10 – Private life and right to information</p> <ol style="list-style-type: none"> Everyone has the right to respect for private life in relation to information about his or her health. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient. <p>Article 16 – Protection of persons undergoing research</p> <p>Research on a person may only be undertaken if all the following conditions are met:</p> <ol style="list-style-type: none"> there is no alternative of comparable effectiveness to research on humans; the risks which may be incurred by that person are not disproportionate to the potential benefits of the research; the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;

	<p>iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;</p> <p>v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.</p> <p>Article 17 – Protection of persons not able to consent to research</p> <p>1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:</p> <ol style="list-style-type: none"> the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled; the results of the research have the potential to produce real and direct benefit to his or her health; research of comparable effectiveness cannot be carried out on individuals capable of giving consent; the necessary authorisation provided for under Article 6 has been given specifically and in writing; and the person concerned does not object. <p>2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:</p> <ol style="list-style-type: none"> the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition; the research entails only minimal risk and minimal burden for the individual concerned.
<p>Council of Europe</p> <p><i>Recommendation Rec(2006)4 of the Committee of Ministers To Member States on Research on Biological Materials of Human Origin</i></p>	<p>Article 14 – Principles applicable to all collections of biological materials</p> <ol style="list-style-type: none"> The person and/or institution responsible for the collection should be designated. The purpose(s) of a collection should be specified. The principles of transparency and accountability should govern its management, including access to and use and transfer of its biological materials and disclosure of information. Each sample of biological material in the collection should be appropriately documented, including information on any relevant consent or authorisation. Clear conditions governing access to, and use of, the samples should be established. Quality assurance measures should be in place, including conditions to ensure security and confidentiality during storage and handling of the biological materials. <p>Article 15 – Right to change the scope of, or to withdraw, consent or authorisation</p> <p>1. When a person has provided consent to storage of identifiable biological materials for research purposes, the person should retain the right to withdraw or alter the scope of that consent. The withdrawal or alteration of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.</p> <p>When identifiable biological materials are stored for research purposes only, the person who has withdrawn consent should have the right to have, in the manner foreseen by national law, the materials either destroyed or rendered unlinked anonymised.</p> <p>2. Where authorisation has been given on behalf of a person not able to consent, the representative, authority, person or body provided for by law should have the rights referred to in paragraph 1 above.</p> <p>3. Where a person on whose behalf authorisation has been given attains the capacity to give consent, that person should have the rights referred to in paragraph 1 above.</p> <p>Article 16 – Transborder flows</p> <p>Biological materials and associated personal data should only be transferred to another state if that state ensures an adequate level of protection.</p> <p>Article 19 – Oversight of population biobanks</p> <ol style="list-style-type: none"> Each population biobank should be subject to independent oversight, in particular to safeguard the interests and rights of the persons concerned in the context of the activities of the biobank. Regular audits should be conducted of the implementation of procedures on access to, and use of, samples. Procedures should be developed for the transfer and for the closure of a population biobank. Population biobanks should publish reports on their past and planned activities at least annually, or more frequently if appropriate. <p>Article 20 – Access to population biobanks</p> <ol style="list-style-type: none"> Member states should take appropriate measures to facilitate access by researchers to biological materials and associated data stored in population biobanks. Such access should be subject to the conditions laid down in this recommendation; it may also be subject to other appropriate conditions. <p>Article 22 – Identifiable biological materials</p> <ol style="list-style-type: none"> If the proposed use of identifiable biological materials in a research project is not within the scope of prior consent, if any, given by the person concerned, reasonable efforts should be made to contact the person in order to obtain consent to the proposed use. If contacting the person concerned is not possible with reasonable efforts, these biological materials should only be used in the research project subject to independent evaluation of the fulfilment of the following conditions: <ol style="list-style-type: none"> the research addresses an important scientific interest; the aims of the research could not reasonably be achieved using biological materials for which consent can be obtained; and there is no evidence that the person concerned has expressly opposed such research use. The person concerned may freely refuse consent for the use in a research project of his or her identifiable biological materials, or withdraw consent, at any time. Refusal to give consent or the withdrawal of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

Article 23 – Unlinked anonymised biological materials

1. Unlinked anonymised biological materials may be used in research provided that such use does not violate any restrictions placed by the person concerned prior to the anonymisation of the materials.
2. Anonymisation should be verified by an appropriate review procedure.

- ¹ Lillian R BeVier, "Information About Individuals in the Hands of Government: Some Reflections on Mechanisms for Privacy Protection" (1995) 4 Wm & Mary Bill Rts J 455 at 458.
- ² Tom Gerety, "Redefining Privacy" (1977) 12 Harv CR-CLL Rev 233 at 234.
- ³ *Ettore v Philco Television Broadcasting Co.*, 229 F (2d) 481 at para 10 (3d Cir 1956).
- ⁴ *R v Wise*, [1992] 1 SCR 527 at para 67, LaForest J, dissenting.
- ⁵ Graeme Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University Press, 2002).
- ⁶ Daniel J Solove, *Understanding Privacy* (Cambridge: Harvard University Press, 2008) at 100.
- ⁷ Anita L Allen, "Genetic Privacy: Emerging Concepts and Values" in Mark A Rothstein, ed, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997) 31 at 33.
- ⁸ See e.g. Emmanuelle Lévesque and Bartha M Knoppers, « Principes assurant la protection des enfants participant à des biobanques : du stade prénatal jusqu'aux adolescents » McGill JL & Health [forthcoming in 2012].
- ⁹ *The Constitution Act, 1867* (UK), 30 & 31 Victoria, c 3, s 92(7), (13).
- ¹⁰ *Ibid*, s 91(27).
- ¹¹ *Reference re Assisted Human Reproduction Act*, [2010] 3 SCR 457.
- ¹² Michael Yeo, "Biobank Research: The Conflict Between Privacy and Access Made Explicit" (Analytic paper commissioned by the Canadian Advisory Council on Biotechnology, 2004).
- ¹³ HumGen, online: <http://www.humgen.org/int/>.
- ¹⁴ Canadian Institutes of Health Research, Adam Kardash & Antonella Penta, eds, *A Compendium of Canadian Legislation Respecting the Protection of Personal Information in Health Research* (Ottawa: Public Works and Government Services Canada, 2005), online: <http://www.cihr-irsc.gc.ca/e/31075.html>.
- ¹⁵ Lorraine Sheremeta, "Population Biobanking in Canada: Ethical, Legal and Social Issues" (Analytic paper commissioned by the Canadian Advisory Council on Biotechnology, 2003) at 9.
- ¹⁶ Jasper A Bovenberg, *Property Rights in Blood, Genes & Data, Naturally Yours?* (Leiden: Brill-Martinus Nijhoff Publishers, 2006) at 117-118.
- ¹⁷ Anne Cambon-Thomsen, Emmanuelle Rial-Sebbag & Bartha M Knoppers, "Trends in Ethical and Legal Frameworks for the Use of Human Biobanks" (2007) 30:6 European Respiratory Journal 373 at 375.
- ¹⁸ *DNA Identification Act*, SC 1998, c 37.
- ¹⁹ *Privacy and Safeguards*, online: National DNA Data Bank http://www.nddb-bndg.org/pri_secu_e.htm. The National DNA Data Bank is overseen by the National DNA Data Bank Advisory Committee. A representative of the Office of the Privacy Commissioner of Canada sits on the DNA Data Bank Advisory Committee to ensure that the Data Bank has available expert advice in the field of individual privacy. The DNA Data Bank is also subject to auditing by the Office of the Privacy Commissioner at any time.
- ²⁰ The age of majority is 18 years of age in Alberta (*Age of Majority Act*, RSA 2000, c A-6, s 1), Manitoba (*The Age of Majority Act*, CCSM, c A7, s 1), Ontario (*Age of Majority and Accountability Act*, RSO 1990, c A7, s 1), Québec (art 153 CCQ), Prince Edward Island (*Age of Majority Act*, RSPEI 1988, c A-8, s 1) and Saskatchewan (*The Age of Majority Act*, RSS 1978, c A-6, s 2). The age of majority is 19 years of age in British Columbia (*Age of Majority Act*, RSBC 1996, c 7, s 1), New Brunswick (*Age of Majority Act*, RSNB 1973, c A-4, s 1(1)), Newfoundland and Labrador (*Age of Majority Act*, SNL 1995, c A-4.2, s 2), the Northwest Territories (*Age Of Majority Act*, RSNWT 1988, c A-2, s 2), Nova Scotia (*Age of Majority Act*, RSNS 1989, c 4, s 2(1)), Nunavut (*Age Of Majority Act*, RSNWT (Nu) 1988, c A-2, s 2) and the Yukon (*Age of Majority Act*, RSY 2002, c 2, s 1(1)).
- ²¹ See e.g. Karine Sénécal, Julie Samuël & Denise Avard, "Research and the Assent of the Child: Towards Harmonization?" in Denise Avard, Julie Samuël & Bartha M. Knoppers, *Paediatric Research in Canada* (Montreal: Les Éditions Thémis) 33.
- ²² Interagency Advisory Panel on Research Ethics, *2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Her Majesty the Queen in Right of Canada, 2010) [TCPS].
- ²³ "Government of Canada boosts efforts to find treatments for pediatric cancers and rare genetic diseases" (22 February 2011), online: <http://www.cpgdsconsortium.com/>.

- ²⁴ University of Minnesota, Department of Pediatrics, “Gopher Kids Study”, online: <http://www.peds.umn.edu/gopherkids/>.
- ²⁵ Wellcome Trust, Avon Longitudinal Study of Parents and Children, online: <http://www.wellcome.ac.uk/Funding/Biomedical-science/Funded-projects/Major-initiatives/ALSPAC/index.htm>.
- ²⁶ ALSPAC, “New Data Collection Plan”, online: <http://www.bristol.ac.uk/alspac/documents/new-data-collection-plan2011-2013.pdf>. See also ALSPAC, “New Data Collection”, online: <http://www.bristol.ac.uk/alspac/documents/new-data-collection-2009-16.pdf>.
- ²⁷ It is specified on the website that the COPSAC₂₀₁₀ cohort must sign approved consent forms prior to any study-related procedure, but it is not specified whether the COPSAC₂₀₀₀ cohort was provided a consent form. The website states that the study is conducted in accordance with the *Declaration of Helsinki* and was approved by the Copenhagen Ethics Committee and the Danish Data Protection Agency. One can infer that these oversight bodies imposed privacy protection measures for both the mother and child, as discussed below. The website also states that the COPSAC₂₀₁₀ cohort study is conducted and monitored in accordance with the requirements of Good Clinical Practice (“GCP”), as defined in Guidelines, EU Clinical Trials Directive (2001/20/EC) and the EU GCP Directive (2005/28/EC). Participant confidentiality is protected in accordance with the GCP Guidelines.
- ²⁸ See e.g. *Universal Declaration of Human Rights*, GA Res 217(III), UNGAOR, 3d Sess, Supp No 13, UN Doc A/810 (1948) 71 at art 12 (“No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks”); *International Covenant on Civil and Political Rights*, GA Res 2200A (XXI), UNGAOR, 1966, Supp No 16, UN Doc A/6316 at art 17 (“No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation”); OECD, *OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (1980) at art 19 [OECD 1980 Guidelines].
- ²⁹ *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [*Canadian Charter*].
- ³⁰ *Bigstone v St. Pierre*, [2011] SJ No 167 (Sask CA) at para 20. See also *R v Tessling*, [2004] 3 SCR 432.
- ³¹ *Ontario AIDS Society v Ontario* (1995), 25 OR (3d) 388 (Ont Gen Div); appeal dismissed, (1996), 31 OR (3d) 798 (Ont CA); leave to appeal to the Supreme Court of Canada denied, [1997] SCCA No 33. See also *Ruby v Canada* (2000), 187 DLR. (4th) 675 (FCA), Létourneau and Robertson JJA (“...[T]here is an emerging view that an individual’s right to privacy is also enshrined in one’s liberty interest set out in section 7. This is so because the protection of private life is considered to be at the heart of liberty in a democratic society” at para 165).
- ³² *R v Colarusso*, [1994] 1 SCR 20 at 60. See also *Hunter v Southam*, [1984] 2 SCR 145 at 159; *R. v Dymont*, [1988] 2 SCR 417 at 429; *R. v Plant*, [1993] 3 SCR 281 at 293.
- ³³ *Canadian Charter*, *supra* note 29, s 52(1).
- ³⁴ *Ibid*, s 32(1).
- ³⁵ *Charter of human rights and freedoms*, RSQ, c C-12 [*Québec Charter*].
- ³⁶ *Canadian Human Rights Act*, R.S., 1985, c. H-6.
- ³⁷ In Québec, art 5 of the *Québec Charter* and arts 35 and 1457 CCQ can probably be interpreted as equivalent to a statutory tort.
- ³⁸ *Privacy Act*, RSC 1985, c P-21.
- ³⁹ *Personal Information Protection and Electronic Documents Act*, 2000, c. 5 [*PIPEDA*].
- ⁴⁰ *Personal Information Protection Act*, SBC 2003, c 63 [*BC PIPA*].
- ⁴¹ *Freedom of Information and Protection of Privacy Act*, RSBC 1996, c 165 [*BC FIPPA*].
- ⁴² *Privacy Act*, RSBC 1996, c 373.
- ⁴³ *E-Health (Personal Health Information Access and Protection Act of Privacy) Act* SBC 2008, c 38 [*E-Health Act*].
- ⁴⁴ *Personal Information Protection Act*, SA 2003, c P-6.5 [*Alberta PIPA*].
- ⁴⁵ *Freedom of Information and Protection of Privacy Act*, RSA 2000, c F-25 [*Alberta FIPPA*].
- ⁴⁶ *Health Information Act*, RSA 2000, c H-5 [*Alberta Health Information Act*].
- ⁴⁷ *Freedom of Information and Protection of Privacy Act*, SS 1990-91, c F-22.01 [*Sask FIPPA*].
- ⁴⁸ *The Health Information Protection Act*, SS 1999, c H-0.021 [*Sask HIPA*].

- ⁴⁹ *The Local Authority Freedom of Information and Protection of Privacy Act*, SS 1990-91, c L-27.1.
- ⁵⁰ *The Privacy Act*, RSS 1978, c P-24.
- ⁵¹ *Freedom of Information and Protection of Privacy Act*, CCSM, c F-175 [*Man FIPPA*].
- ⁵² *The Personal Health Information Act* CCSM, c P-33.5 [*Man Health Information Act*].
- ⁵³ *The Privacy Act*, CCSM c P125.
- ⁵⁴ *Freedom of Information and Protection of Privacy Act*, RSO 1990, c F-31 [*Ont FIPPA*].
- ⁵⁵ *Personal Health Information Protection Act*, 2004, SO 2004, c 3, Sch A [*OPHIPA*].
- ⁵⁶ *Municipal Freedom of Information and Protection of Privacy Act*, RSO 1990, c M.56.
- ⁵⁷ *An Act respecting Access to documents held by public bodies and the Protection of personal information*, RSQ, c A-2.1 [*Québec public sector privacy act*].
- ⁵⁸ *An Act respecting the protection of personal information in the private sector*, RSQ, c P-39.1 [*Québec private sector privacy act*].
- ⁵⁹ *An Act respecting health services and social services*, RSQ, c S-4.2.
- ⁶⁰ *Civil Code of Québec*, LRQ, c C-1991.
- ⁶¹ *Québec Charter*, *supra* note 35.
- ⁶² *Right to Information and Protection of Privacy Act*, SNB 2009, c R-10.6 [*NB Privacy Act*].
- ⁶³ *Personal Health Information Privacy and Access Act*, SNB 2009, c P-7.05 [*NB PHIPA*].
- ⁶⁴ *Freedom of Information and Protection of Privacy Act*, SNS 1993, C 5 [*NS FIPPA*].
- ⁶⁵ *Municipal Government Act*, SNS 1998, c 18.
- ⁶⁶ *Personal Information International Disclosure Protection Act*, SNS 2006, c 3.
- ⁶⁷ *Freedom of Information and Protection of Privacy Act*, RSPEI, c F-15.01 [*PEI FIPPA*].
- ⁶⁸ *Access to Information and Protection of Privacy Act*, SNL 2002, c A-1.1.
- ⁶⁹ *Personal Health Information Act*, SNL 2008, c P-7.01 [*Newfoundland PHIPA*].
- ⁷⁰ *Privacy Act*, RSNL 1990, c P-22.
- ⁷¹ *Access to Information and Protection of Privacy Act*, RSY 2002, c 1.
- ⁷² *Access to Information and Protection of Privacy Act*, SNWT 1994, c 20 [*Northwest Territories Privacy Act*].
- ⁷³ *Access to Information and Protection of Privacy Act*, SNWT (Nu) 1994, c 20 [*Nunavut Privacy Act*].
- ⁷⁴ OECD, *OECD Guidelines for Human Biobanks and Genetic Research Databases* (2009) [*OECD HBGRD Guidelines*].
- ⁷⁵ Sheremeta, *supra* note 15 at 56.
- ⁷⁶ Paul N. Schofield et al, "Sustaining the Data and Bioresource Commons" (2010) 330 *Science* 592.
- ⁷⁷ *OECD HBGRD Guidelines*, *supra* note 75 at para 2.
- ⁷⁸ *PIPEDA*, *supra* note 40, s 30(2.1).
- ⁷⁹ However, the applicability of privacy legislation to the contents of a biobank should be discussed as well. Privacy legislation generally defines "personal information" or "health information" as "recorded information about an identifiable individual" or "identifying information about an individual in oral or recorded form." *A contrario*, information about non-identifiable individuals, e.g. anonymous or anonymized information, does not fall under the purview of the legislation. Further, a plain and ordinary meaning of information demonstrates that biological samples are not recorded information – only information extracted from those biological samples can be interpreted as recorded information (assuming it is documented in paper or electronic format and linked to an identifiable individual). Thus, most privacy statutes will not prima facie apply to genetic material or other biological samples collected for a biobank, though given DNA can be digitalized, a broad interpretation could apply. The current bi-modal legislative framework (i.e. "identifiable" information affords legal protection, "non-identifiable" information does not) affords clarity but little justification; identifiability, especially in a biospecimen context, exists on a continuum, and ever-evolving de-identification techniques will continue to challenge and undermine the bi-modal model.
- ⁸⁰ Canadian Institutes of Health Research, *Personal Information Protection and Electronic Documents Act: Questions and Answers for Health Researchers* (Ottawa: Public Works and Government Services Canada, 2001) at 8 (emphasis added).
- ⁸¹ "Co-Funding", online: Genome Canada <http://www.genomecanada.ca/en/portfolio/co-funding.aspx>.

- ⁸² *Personal Health Information Protection Act, 2004*, O Reg 329/04, s 13(1).
- ⁸³ Halyna Perun, Michael Orr & Fannie Dimitriadis, *Guide to the Ontario Personal Health Information Protection Act* (Toronto: Irwin Law, 2005) at 362.
- ⁸⁴ Interview with Monique Albert, Manager, Ontario Tumour Bank (May 5, 2011).
- ⁸⁵ With the coming into effect on July 1, 2011, of Bill 130, the Fonds de la recherche en santé du Québec officially became the Fonds de recherche du Québec – Santé.
- ⁸⁶ Fonds de la Recherche en Santé du Québec, *Final Report Advisory Group on a Governance Framework for Data Banks and Biobanks Used for Health Research* (Québec: Fonds de la recherche en santé du Québec, 2006) [FRSQ Biobank Report].
- ⁸⁷ *Universal Declaration on the Human Genome and Human Rights*, GA Res A/RES/53/152, UNGAOR, 1998, 53d Sess, art 18 [Declaration on the Human Genome]; *TCPS*, *supra* note 22, ch 12B.
- ⁸⁸ Canadian Institutes of Health Research, *CIHR Best Practices for Protecting Privacy in Health Research* (Ottawa: Public Works and Government Services Canada, 2005), element 8 [CIHR Privacy Best Practices].
- ⁸⁹ *TCPS*, *supra* note 22, art 12.1(b).
- ⁹⁰ *Ibid*, s 5D, 12B.
- ⁹¹ FRSQ Biobank Report, *supra* note 86, ss 9.2, 11.1.
- ⁹² *TCPS*, *supra* note 22, art 12.5.
- ⁹³ Canadian Institutes of Health Research, National Council on Ethics in Human Research, Maternal, Infant, Child and Youth Research Network, Centre of Genomics and Policy, *Best Practices for Health Research Involving Children and Adolescents: Genetic, Pharmaceutical, Longitudinal Studies and Palliative Care Research* (2011) [BPHR], s 7.2, online: <http://www.pediagen.org/>.
- ⁹⁴ *Ibid*.
- ⁹⁵ *OECD HBGRD Guidelines*, *supra* note 74, art 7.
- ⁹⁶ See generally Kristien Hens, Jeans-Jacques Cassiman, Herman Nys & Kris Dierickx, “Children, Biobanks and the Scope of Parental Consent” (2011) 19 *European Journal of Human Genetics* 735.
- ⁹⁷ David Gurwitz et al, “Children and Population Biobanks” (2009) 325 *Science* 819.
- ⁹⁸ *Ibid*.
- ⁹⁹ Kyle Brothers and Ellen Wright Clayton, “Biobanks: Too Long to Wait for Consent” (2009) 326 *Science* 798; Kristen Hens, John Wright & Kris Dierickx, “Biobanks: Oversight Offers Protection” (2009) 326 *Science* 798.
- ¹⁰⁰ David Gurwitz et al, “Response” (2009) 326 *Science* 799.
- ¹⁰¹ Nils Homer et al, “Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays” (2008) 4:8 *PLoS Genetics* 1; P3G Consortium et al, “Public Access to Genome-Wide Data: Five Views on Balancing Research with Privacy and Protection” (2009) 5:10 *PLoS Genetics* 1.
- ¹⁰² *PIPEDA*, *supra* note 39, s 5(3).
- ¹⁰³ *Privacy Act*, RSC 1985, c P-21, s 8(2)(a).
- ¹⁰⁴ Fair information practices/principles generally revolve around eight core principles, as espoused in OECD 1980 Guidelines, *supra* note 28: collection limitation; data quality; purpose specification; use limitation; security safeguards; openness; individual participation; and accountability. The fair information practices included in Schedule 1 of *PIPEDA*, *supra* note 39, which are enunciated in the Canadian Standards Association Model Code for the Protection of Personal Information, are somewhat broader: accountability; identifying purposes; consent; limited collection; limiting use, disclosure and retention; accuracy; safeguards; openness; individual access; and challenging compliance. The United States’ *Code of Fair Information Principles* (Washington, DC: US Department of Health, Education and Welfare, 1973) first elaborated some of these principles out of concerns related to computerization.
- ¹⁰⁵ See generally Trudo Lemmens and Lisa M Austin, “The End of Individual Control Over Health Information: Governing Biobanks and Promoting Fair Information Practices” (2009) Social Science Research Network, online: <http://ssrn.com/abstract=1337695>.

- ¹⁰⁶ *E-Health Act*, *supra* note 43, ss 4-5, 14-15; *Alberta Health Information Act*, *supra* note 46, ss 49-54; *OPHIPA*, *supra* note 55, s 44.
- ¹⁰⁷ Vancouver CHILD Study Information and Consent Form at 7, online: http://www.canadianchildstudy.ca/documents/vancouver_consent_jan_2011.pdf#8 Jan19 2011.pdf [Vancouver CHILD Form]; Edmonton CHILD Study Information and Consent Form at 11, online: http://www.canadianchildstudy.ca/documents/edmonton_consent.pdf [Edmonton CHILD Form]; Winnipeg CHILD Study Information and Consent Form at 7, online: http://www.canadianchildstudy.ca/documents/Winnipeg_consent_nov_2010.pdf [Winnipeg CHILD Form]; Toronto CHILD Study Information and Consent Form at 2, online: http://www.canadianchildstudy.ca/documents/MSH_HSC%20CHILD%20Informed%20Consent_May%202022%20Optimized.pdf [Toronto CHILD Form].
- ¹⁰⁸ FORGE Canada, “Children/Minors: Information and Consent Form” at 2; FORGE Canada, “Affected/Unaffected/Incompetent Adults: Information and Consent Form” at 2, on file with authors [FORGE Canada consent forms].
- ¹⁰⁹ *Ibid.*
- ¹¹⁰ *Ibid.*
- ¹¹¹ IRNPQEO, “Databank and Bank of Biological Material Management Policy”, at 20-21, on file with authors.
- ¹¹² *Ibid* at 21.
- ¹¹³ National Children’s Study, “Informed Consent Form – Child” (OMB Control Number: 0925-0593, v20101109) at 9, on file with authors.
- ¹¹⁴ *Ibid.*
- ¹¹⁵ National Children’s Study, “DACC Policy Manual and Data Use Agreements”, online: <http://www.nationalchildrensstudy.gov/about/organization/dacc/Pages/PolicyManualandDataUseAgreements.aspx>.
- ¹¹⁶ *Protection of Human Subjects*, 45 CFR 46 (2009).
- ¹¹⁷ University of Minnesota, Department of Pediatrics, Gopher Kids Study, “Consent Form” at 2, online: http://www.peds.umn.edu/prod/groups/ahc/@pub/@ahc/documents/content/ahc_content_200438.pdf [Gopher Kids Consent Form].
- ¹¹⁸ The Avon Longitudinal Study of Parents and Children (ALSPAC) Management and Policy, online: <http://www.bristol.ac.uk/alspac/documents/alspac-policy.pdf>.
- ¹¹⁹ ALSPAC Data Transfer Agreement, online: <http://www.bristol.ac.uk/alspac/documents/appendix4-dta-2008-08.pdf>. This includes requirements that: (a) data must be stored in a secure location on its premises and researchers must not permit it to come into the possession or control of any non-authorized persons; (b) no third party data transfers without the relevant third party entering into a separate DTA with ALSPAC; (c) data must be used only to carry out the research described in DTA, only for research that has appropriate ethical approval, and not for any commercial purposes; (d) all reasonable endeavours should be taken to ensure that the data be returned or destroyed upon, *inter alia*, withdrawal of consent of the relevant study participant; and (e) data must be kept confidential and researchers may not try to identify study participants.
- ¹²⁰ Danish Data Protection Agency, “Research biobanks”, online: <http://www.datatilsynet.dk/english/health-research-and-statistics-projects/research-biobanks/>.
- ¹²¹ *Ibid.*
- ¹²² *Ibid.*
- ¹²³ *Ibid.*
- ¹²⁴ *Ibid.*
- ¹²⁵ *Declaration on the Human Genome*, *supra* note 88, art 5(b); Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS, 2002), guideline 18 [CIOMS 2002 Guidelines]; *TCPS*, *supra* note 22, art 13.7.
- ¹²⁶ *International Declaration on Human Genetic Data*, UNESCO, 33d Sess (2003), Art 14 [*Declaration on Human Genetic Data*].
- ¹²⁷ *OECD HBGRD Guidelines*, *supra* note 74 at para 1.D.
- ¹²⁸ *Ibid* at para 6.5, 6.7.
- ¹²⁹ National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellor’s Committee, *National Statement on Ethical Conduct in Human Research* (Canberra: Australian Government, 2007), Guideline 3.2.5.

¹³⁰ *CIHR Privacy Best Practices*, *supra* note 88.

¹³¹ *Ibid*, element 7.

¹³² *BPHR*, *supra* note 93.

¹³³ *Ibid*, s 5A.

¹³⁴ *Ibid*.

¹³⁵ *Ibid*, Art 5.1.

¹³⁶ *Ibid*, Art 5.3.

¹³⁷ *Ibid*, Art 5.4.

¹³⁸ *Ibid*, Art 12.5.

¹³⁹ *BPHR*, *supra* note 93, s 7.2.

¹⁴⁰ *Ibid*.

¹⁴¹ *NB PHIPA*, *supra* note 63, s 1. Other provincial personal health information statutes are substantially similar to New Brunswick's statute with respect to third party access. However, only Alberta's statute, like New Brunswick's, allows custodians to disclose de-identified personal health information for any purpose. See *Alberta Health Information Act*, *supra* note 47, s 32.

¹⁴² *NB PHIPA*, *supra* note 63, s 36.

¹⁴³ *BPHR*, *supra* note 93, s 2.3.1.

¹⁴⁴ In the United States, see NJ Stat § 10:5-49 (2009). In Sweden, see *The Genetic Integrity Act*, SFS 2006:351, ch 8.

¹⁴⁵ See e.g. *E-Health Act*, *supra* note 43, s 1 ("personal health information" means recorded information about an identifiable individual that is related to the individual's health or the provision of health services to the individual"). It is our understanding that Health Canada Legal Services has advised Health Canada and the Public Health Agency of Canada that human biological materials are considered personal information for the purposes of the *Privacy Act*.

¹⁴⁶ See e.g. *OPHIPA*, *supra* note 55, ss 65(1)-(2).

¹⁴⁷ *Ibid*, s 65(3).

¹⁴⁸ *Ibid*, s 72(1)(a).

¹⁴⁹ *Genetic Information Nondiscrimination Act of 2008*, Pub L 110-233, 122 Stat 881 [*GINA*].

¹⁵⁰ "Genetic Information Nondiscrimination Act ('GINA') Becomes the Law" (22 May 2008), online: Troutman Sanders <http://www.troutmansanders.com/firm/media/mediadetail.aspx?media=853>.

¹⁵¹ FORGE Canada consent forms, *supra* note 108 at 2.

¹⁵² *Ibid*.

¹⁵³ National Children's Study, "Informed Consent Form – Pregnant Women" (OMB Control Number: 0925-0593, v20101109) at 9, on file with authors.

¹⁵⁴ University of Minnesota, Department of Pediatrics, Gopher Kids Study, "Consent Form", online: http://www.peds.umn.edu/prod/groups/ahc/@pub/@ahc/documents/content/ahc_content_200438.pdf [Gopher Kids Consent Form].

¹⁵⁵ *Ibid*.

¹⁵⁶ *TCPS*, *supra* note 22, art 4.4; World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (Seoul: WMA, 2008), s 17; *Declaration on the Human Genome*, *supra* note 88, art 5(e); *Universal Declaration on Bioethics and Human Rights*, UNESCO, 2005, s 7(b) [*Declaration on Bioethics*].

¹⁵⁷ See e.g. *TCPS*, *supra* note 22, art 3.3; Art 21 CCQ; *PIPEDA*, *supra* note 39, Principle 4.3 of Schedule 1; *OPHIPA*, *supra* note 55, s 23(1)(2).

¹⁵⁸ Mireille Lacroix et al, "Should Physicians Warn Patients' Relatives of Genetic Risks?" (2008) 178:5 *Can Med Assoc J* 593; Benjamin S Wilfond & Katherine J Carpenter, "Incidental Findings in Pediatric Research" (2008) 36:2 *JL Med & Ethics* 332.

¹⁵⁹ Kristien Hens et al, "Biological Sample Collections from Minors for Genetic Research: A Systematic Review of Guidelines and Position Papers" (2009) 17 *European Journal of Human Genetics* 979; Emma Williamson et al, "Children's Participation in Genetic Epidemiology: Consent and Control", in Richard Tutton & Oonagh Corrigan (eds), *Genetic Databases: Socio-Ethical Issues in the*

Collection and Use of DNA (London: Routledge, 2004) 139. See also Roberta L Woodgate & Marie Edwards, "Children in Health Research: A Matter of Trust" (2010) 36:4 *Journal of Medical Ethics* 211.

¹⁶⁰ *Convention on the Rights of the Child*, GA Res 44/25, UNGAOR, 44th Sess, UN Doc A/RES/44/25 (1989), art 13(1).

¹⁶¹ *Ibid*, art 24(1).

¹⁶² *Ibid*, art 12(1).

¹⁶³ *Ibid*, art 18(1).

¹⁶⁴ *Declaration on Human Genetic Data*, *supra* note 126, art 13. See also Council of Europe, *Convention on Human Rights and Biomedicine*, s 10; Council of Europe, ETS, *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, no 164, Oviedo, 1997, s 26(1).

¹⁶⁵ Working Group of the International Bioethics Committee on Confidentiality and Genetic Data, *Report on Confidentiality and Genetic Data* (Paris: UNESCO, 2000), para 51.

¹⁶⁶ *TCPS*, *supra* note 22, art 3.4, 13.2, 13.3; OECD HBGRD Guidelines, *supra* note 74, para 7.2, 7.8.

¹⁶⁷ European Medicines Agency (EMA), *Ethical Considerations for Clinical Trials Performed in Children (Recommendations of the Ad hoc Group for the Development of Implementing Guidelines for Directive 2001/20/EC Relating to Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use)*, 2008, s 18.

¹⁶⁸ *BPHR*, *supra* note 93, s 8.2.

¹⁶⁹ *Ibid*.

¹⁷⁰ Kristien Hens et al, "The Return of Individual Research Findings in Paediatric Genetic Research" (2010) 37 *Journal of Medical Ethics* 179.

¹⁷¹ *Ibid*. See also Kristien Hens et al, "Genetic Research on Stored Tissue Samples from Minors: A Systematic Review of the Ethical Literature" (2009) 149A *American Journal of Medical Ethics Part A* 2346 at 2349.

¹⁷² *Ibid*. See also Kristien Hens, Emmanuelle Lévesque & Kris Dierickx, "Children and Biobanks: A Review of the Ethical and Legal Discussion" (2011) *Human Genetics* at 8, online: <http://www.springerlink.com/content/37m67n528658x033/>.

¹⁷³ Faye Mishna, Beverley J Antle & Cheryl Regehr, "Tapping the Perspectives of Children: Emerging Ethical Issues in Qualitative Research" (2004) 3 *Qualitative Social Work* 449.

¹⁷⁴ *BPHR*, *supra* note 93, s 7.3.3.

¹⁷⁵ *Ibid*, s 2.1.3.

¹⁷⁶ See e.g. *PIPEDA*, *supra* note 39, Principle 4.3 of Schedule 1.

¹⁷⁷ *Alberta Health Information Act*, *supra* note 46, s 104(1)(b)-(c); *Man Health Information Act*, *supra* note 52, s 60(1)(e); *Sask HIPA*, *supra* note 48, s 56(c)-(d); *Newfoundland PHIPA*, *supra* note 69 (a right or power of an individual under the Act may be exercised "by the parent or guardian of a minor where, in the opinion of the custodian, the minor does not understand the nature of the right or power and the consequences of exercising the right or power" s 7(d)). *NB PHIPA*, *supra* note 63 (the province's *Medical Consent of Minors Act* applies for the purpose of providing the consent of the person to the collection, use or disclosure of personal health information or for the refusal or withdrawal of the person's consent, s 5). The applicability of this Act to a paediatric biobank is questionable since the biobank may not qualify as "medical treatment". But see *Medical Consent of Minors Act*, SNB 1976, c M-6.1 (definition of "medical treatment" includes "any procedure undertaken for the purpose of preventing any disease or ailment" s 1). See also arts 19, 21, 22, 24, 25, 35 CCQ (whereby Québec also contemplates that a person's privacy may only be invaded upon consent or authorization by law, and such consent, in a paediatric biobank context, may be given by the parent).

¹⁷⁸ *OPHIPA*, *supra* note 55, ss 23(1)(2), 24. A substitute may be a "parent of the child or a children's aid society or other person who is lawfully entitled to give or refuse consent in the place of the parent can consent" on behalf of an individual less than 16 years of age. The Act also stipulates certain factors that the substitute decision-maker must take into consideration before providing or refusing consent, withdrawing consent, or providing an express instruction: the wishes, values and beliefs of the individual as related to his or her personal health information; whether the benefits expected from the collection, use or disclosure of the information outweigh the risks; whether the purpose for which the collection, use or disclosure is sought can be accomplished without collection, use or disclosure; and whether the collection, use or disclosure is necessary to satisfy any legal obligation.

- ¹⁷⁹ A mature minor has been defined as “a child who is capable of giving consent to or refusing treatment and is able to appreciate the nature and consequences of the consent or refusal”. See Eric Nelson, Kathrina Haymond & Mona Sidarous, “Selected Legal and Ethical Issues Relevant to Pediatric Genetics” (1998) 6 Health Law Journal 83 at 91.
- ¹⁸⁰ Art 21 CCQ.
- ¹⁸¹ Art 14 CCQ.
- ¹⁸² *OPHIPA*, *supra* note 55, s 23(2)(i); arts 14, 17, 18, 21 CCQ. Other statutes, including *Newfoundland PHIPA*, *supra* note 69, and *NB PHIPA*, *supra* note 63, do not distinguish between research and clinical consent.
- ¹⁸³ *OPHIPA*, *supra* note 55, s 23(1)(1).
- ¹⁸⁴ *Ibid*, s 23(1)(2).
- ¹⁸⁵ Lucinda Ferguson, “The End of an Age: Beyond Age Restrictions for Minors’ Medical Treatment Decisions” (Research paper prepared for Law Commission of Canada, 2004) at 1.
- ¹⁸⁶ Paul A Klaczynski, James P Byrnes & Janis E Jacobs, “Introduction to the Special Issue: The Development of Decision-Making” (2001) 22 Applied Developmental Psychology 225 at 232.
- ¹⁸⁷ See e.g. Benjamin Shmueli & Ayelet Blecher, “Privacy for Children” 42:3 Colum HRL Rev [forthcoming in 2011].
- ¹⁸⁸ Christine A Readdick, “Solitary Pursuits: Supporting Children’s Privacy Needs” (1993) 49 Young Children 60.
- ¹⁸⁹ See e.g. Bruce Hafen, “Children’s Liberation and the New Egalitarianism: Some Reservations about Abandoning Children to Their ‘Rights’” (1976) BYUL Rev 605; Angela Campbell, “Stretching the Limits of ‘Rights Talk’: Securing Health Care Entitlements for Children” (2003) 27 Vt L Rev 399; Emily Buss, “Allocating Developmental Control Among Parent, Child and the State” (2004) U Chicago Legal F 27.
- ¹⁹⁰ Lemmens and Austin, *supra* note 105 at 32.
- ¹⁹¹ *Ibid* at 32.
- ¹⁹² Lisa M Austin & Trudo Lemmens, “Privacy, Consent, and Governance”, in Kris Dierickx & Pascal Borry, eds, *New Challenges for Biobanks: Ethics, Law and Governance* (Antwerpen: Intersentia, 2009) 111 at 116.
- ¹⁹³ Michael Yeo, “Looking Out from Inside the Panopticon: A Privacy Perspective on Biobanking” (Analytic paper commissioned by the Office of the Privacy Commissioner of Canada for 29th International Conference of Data Protection and Privacy Commissioners, 2007) at 33.
- ¹⁹⁴ See e.g. *TCPS*, *supra* note 22, Art 3.10; *Declaration of Helsinki*, *supra* note 156, note 2, at 27, 28; *Declaration on Bioethics*, *supra* note 156, s 7(a); *Declaration on Human Genetic Data*, *supra* note 126, 8(b)-(c); Art 21 CCQ; Fonds de la recherche en santé du Québec, *FRSQ Standards on Human Health Research Ethics and Scientific Integrity* (Québec: FRSQ, 2009), ss 19, 21.
- ¹⁹⁵ Nola M Ries, “Growing Up As a Research Subject: Ethical and Legal Issues in Birth Cohort Studies Involving Genetic Research” (2007) 15 Health LJ 1 at 17; Sénécal et al, *supra* note 21 at 57-58; Tessa John et al, “Children’s Consent and Paediatric Research: Is It Appropriate for Healthy Children to be the Decision-Makers in Clinical Research?” (2008) 93 Archives of Disease in Childhood 379; Ole D. Wolthers, “A Questionnaire on Factors Influencing Children’s Assent and Dissent to Non-Therapeutic Research” (2006) 32 Journal of Medical Ethics 292; Bernie Carter, “Researching Children and Young People: Exploring the Ethical Territory” in Gosia Brykczynska and Joan Simons (eds), *Ethical and Philosophical Aspects of Nursing Children and Young People* (Oxford: Blackwell Publishing Ltd, 2011) 201. See also Richard Ashcroft et al, “Children’s Consent to Research Participation: Social Context and Personal Experience Invalidate Fixed Cutoff Rules” (2003) 3:4 American Journal of Bioethics 16.
- ¹⁹⁶ FORGE Canada, “Children/Minors: Information and Consent Form” at 4, on file with authors.
- ¹⁹⁷ Interview of Karen Birmingham, ALSPAC Research Ethics Manager (21 July 2011).
- ¹⁹⁸ *Ibid*.
- ¹⁹⁹ National Children’s Study, “The National Children’s Study: An Evolving System: Concept of Operations” (2011) at 20, online: http://www.nationalchildrensstudy.gov/about/overview/Pages/NCS_concept_of_operations_04_28_11.pdf.
- ²⁰⁰ National Children’s Study, Informed Consent Form – Pregnant Women (OMB Control Number: 0925-0593, v20101109) at 12, on file with authors.

- ²⁰¹ Søren Holm, “Informed Consent and the Bio-banking of Material from Children” (2005) 1:1 *Genomics, Society and Policy* 16 at 22-23; Ries, *supra* note 195 at 27.
- ²⁰² ALSPAC, “Withdrawal of Consent Policy”, online: <http://www.bristol.ac.uk/alspac/documents/ethics-full-withdrawal-of-consent-policy-07022011.pdf>.
- ²⁰³ See e.g. *Declaration of Helsinki*, *supra* note 156, ss 9, 24, 28; *CIOMS 2002 Guidelines*, *supra* note 125, guideline 14.
- ²⁰⁴ National Children’s Study, “Informed Consent Form – Child” (OMB Control Number: 0925-0593, v20101109) at 10, on file with authors.
- ²⁰⁵ *BPHR*, *supra* note 93, s. 4.1.2.
- ²⁰⁶ Allen, *supra* note 7.
- ²⁰⁷ Gert Helgesson, “Children, Longitudinal Studies, and Informed Consent” (2005) 8:3 *Medicine, Health Care and Philosophy* 307; Kristien Hens et al, “Risks, Benefits, Solidarity: A Framework for the Participation of Children in Genetic Biobank Research” (2011) 158:5 *Journal of Pediatrics* 842.
- ²⁰⁸ Bartha M Knoppers & Ruth Chadwick, “Human Genetic Research: Emerging Trends in Ethics” (2005) 6 *Nature Review Genetics* 75.
- ²⁰⁹ See e.g. Natural Sciences and Engineering Research Council of Canada, “Memorandum of Understanding, Schedule 8: Investigation and Resolution of Breaches of Agency Policies,” available online: http://www.nserc-crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/MOURoles-ProtocolRoles/8-Breaches-Inobservation_eng.asp.
- ²¹⁰ See e.g. Colo Rev Stat § 10-3-1104.6 (2010); Fla Stat §760.40 (2010); *GINA*, *supra* note 148.
- ²¹¹ See EC, *Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: A comprehensive approach on personal data protection in the European Union*, COM (2010) 609 final, online: http://ec.europa.eu/health/data_collection/docs/com_2010_0609_en.pdf.
- ²¹² *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402 (HL).
- ²¹³ Fern M Brunger, “Social Science and Educational Research Involving Children” in Avard et al, *Paediatric Research in Canada*, *supra* note 22. See also Bonnie Leadbeater and Kathleen Glass, “Including Vulnerable Populations in Community-Based Research: New Directions for Ethics Guidelines and Ethics Research” in Bonnie Leadbeater, ed, *Ethical Issues in Community-Based Research with Children and Youth* (Toronto: University of Toronto Press, 2006).
- ²¹⁴ *TCPS*, *supra* note 22, art 3.10.
- ²¹⁵ Office of the Privacy Commissioner (New South Wales), *Submission G118* (18 March 2002), in Australia Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report 96 (Sydney: Commonwealth of Australia, 2003) at 245-246 [*Essentially Yours*].
- ²¹⁶ US Government Accountability Office, *Medical Records Privacy: Uses and Oversight of Patient Information in Research* (Washington, DC: GAO, 1999), online: <http://www.gao.gov/archive/1999/he99070t.pdf>. See also US Government Accountability Office, *Medical Records Privacy: Access Needed for Health Research, but Oversight of Privacy Protections Is Limited* (Washington, DC: GAO, 1999), online: <http://www.gao.gov/archive/1999/he99055.pdf>.
- ²¹⁷ *DNA Identification Act*, *supra* note 18.
- ²¹⁸ Bartha M Knoppers & Madelaine Saginur, “The Babel of Genetic Data Terminology” (2005) 23:8 *Nature Biotechnology* 925; See also International Conference on Harmonization, *Definitions for Genomic Biomarkers. Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories* (2007), online: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E15/Step4/E15_Guideline.pdf. This guideline sets forth standardized definitions of “coded”, “anonymous” and “anonymized”.
- ²¹⁹ *Ibid.*
- ²²⁰ Adapted from *Essentially Yours*, *supra* note 215 at 255.
- ²²¹ Adapted from *Essentially Yours*, *supra* note 215 at 287.

²²² See e.g. “Fines needed to help stem growing data breaches, Privacy Commissioner says” (May 4, 2011), online: Office of the Privacy Commissioner of Canada http://www.priv.gc.ca/media/nr-c/2011/nr-c_110504_e.cfm.

²²³ World Health Organization, International Clinical Trials Research Platform Search Portal, online: <http://apps.who.int/trialsearch/>.

²²⁴ National Institutes of Health, ClinicalTrials.gov, online: <http://www.clinicaltrials.gov/>.